

CHAPTER 61

Department of Health and Environmental Control

61-1. [Repealed].

HISTORY: Former Regulation, titled Medical and Dental Scholarship Fund, repealed by SCSR 44-6 Doc. No. 4898, eff June 26, 2020.

61-3. The Practice of Selling and Fitting Hearing Aids.

(Statutory Authority: Section 40-25-30 et seq of 1976 Code, as amended.)

Definitions and Interpretations

I. Definitions:

For the purpose of these rules and regulations, the following definitions shall apply:

(a) The Act: The "Fitting and Selling of Hearing Aids Act" enacted June 25, 1971. [1976 Code §§ 40-25-10 et seq.]

(b) The Department: The South Carolina Department of Health and Environmental Control.

(c) The Commission: The State Commission for Hearing Aid Dealers and Fitters.

(d) License: A license issued by the Department under this Act to a hearing aid dealer and fitter.

(e) Temporary Permit: A permit issued by the Department under this Act while the applicant is in training to become a licensed hearing aid dealer and fitter.

(f) Hearing Aid: Any acceptable wearable instrument or device designated for or offered for the purpose of aiding or compensating for impaired human hearing and any parts, attachments or accessories, including earmold, but excluding batteries and cords.

(g) Practice of Fitting and Dealing in Hearing Aids: The measurement of human hearing by means of an audiometer or by any other established means for the purpose of making selections, adaptations or sale of hearing aids. The term also includes the making of impressions for earmolds. Counseling and instruction relative to the above.

(h) Sale of Hearing Aids: Any transfer of title or of the right to use by lease, bailment, or any other contract, excluding wholesale transactions with distributors or representatives.

(i) Otolaryngologist: A licensed physician specializing in diseases of the ear, nose and throat.

(j) Audiologist: An individual completing satisfactory graduate work and holding a Certificate of Clinical Competence and who is actually engaged in audiological practice.

(k) Licensee: The individual authorized to engage in the practice of fitting and selling hearing aids and on whom rests the responsibility for complying with the provisions of the Act and these Rules and Regulations promulgated thereunder.

(l) Application: Application means a form which shall contain all of the prescribed information established by the Department as set forth in the Act.

(m) Examination: Examination means the testing of knowledge and proficiency of an applicant required for fitting and selling hearing aids.

(n) Registrant: Registrant shall be synonymous with licensee, holder of a certificate of registration, trainee and temporary permit holder.

II. Interpretations:

(a) License: A license is issued by the Department pursuant to the provisions of the Act and these Rules and Regulations promulgated thereunder. This license shall be posted in a conspicuous place in his office or place of business at all times in full view at the address specified on the license. A

license is not assignable or transferable and is subject to revocation or suspension for a fixed period by the Department for cause as defined within Section 13(2) of the Act [§ 40-25-160(2)].

(b) Term of License:

(1) Each person licensed to fit and sell hearing aids shall annually, on or before January 30, pay to the Department a fee of fifty dollars (\$50.00) for issuance or renewal of license.

(2) A thirty (30) day grace period shall be allowed after January 30, during which time licenses may be renewed on payment of a fee of sixty dollars (\$60.00) to the Department. After expiration of the grace period, the Department may renew such license upon payment of a fee of seventy-five dollars (\$75.00) to the Department. No person who applies for renewal, whose license has expired, shall be required to submit to any examination as a condition to renewal, provided such renewal application is made within a period of two (2) years from the date of such expiration.

(3) A license shall be effective for a twelve (12) month period, beginning January 31 and ending January 30 of the succeeding year.

(c) Temporary Permit: A temporary permit shall be issued to an applicant who fulfills the requirements of the Act but does not meet the experience qualifications and shall entitle applicant to engage in the fitting and selling of hearing aids for a period of one (1) year under the supervision of a licensed hearing aid dealer and fitter.

PART I

CHAPTER I—Management

SECTION 101. Application

(a) No person shall fit, or offer for sale, hearing aids in this State unless such person has complied with the requirements hereof as to registration and licensing.

(b) An individual, in making his first registration hereunder, shall write or cause to be written upon the application blank, so furnished by the Department, his full name, business address, residence address and such other facts for identification of the applicant as may be deemed necessary and shall execute and verify the same before a notary public and shall file the same with the Department.

(c) The Department on or before December 1 of each year, after the first registration, shall mail to each licensee or registrant a blank form of application for registration addressed to the last known business of such person.

(d) The Department shall, in accordance with the Act, issue to any individual who has submitted his application for registration complete with the information as may be deemed applicable by the Department, a license or temporary permit under the seal of the Department for the ensuing year.

(1) Any licensee or temporary permit holder must maintain a progressing level of professional competence by participation during each calendar year in educational programs designed to keep such licensee informed of changes, current practices, and developments pertaining to the fitting of hearing aids and rehabilitation as appropriate to hearing aid use.

(2) The licensee shall annually submit to the Commission proof of having participated in a minimum of eight hours of continuing education during the calendar year. A licensee who is granted a license during a calendar year shall not be required to complete such requirements during that year and such requirement shall begin the second full licensing year. The requirement may be fulfilled by attending and participating in training activities approved by the Commission.

(3) Failure to complete the minimum educational requirements shall result in a license suspension until the requirements are met. The Commission, upon sufficient cause shown by the licensee, may allow the licensee to make up the necessary hours during the next calendar year. The make-up allowance shall not waive the full annual requirements for continued education.

(e) Application for Examination Fee: An application for examination shall be accompanied by a check or money order made payable to the South Carolina Department of Health and Environmental Control in the amount of fifty dollars (\$50.00). It shall be understood by the applicant that the examination fee shall in no instance be refunded, applied as payment for temporary permit, or transferred to the license fee.

(f) Failure to complete all forms and provide all information required by law may be just cause for the application to be rejected by the Department.

(g) Any person furnishing false information or omitting pertinent information in such application shall be denied the right to the examination, or if the applicant has already been licensed before the falseness of such information has been made known to the Department, such license shall be subject to suspension or revocation.

SECTION 102. License

A license under this Act shall confer upon the holder the right to select, fit and sell hearing aids.

(a) Licenses or temporary permits shall not by any manner or means be duplicated by the licensee or other persons.

(b) Any change in status of licensee or temporary permit, such as address or name, shall make the license null and void and shall be returned to the Department for proper disposition.

(c) Persons who hold a license or temporary permit shall notify the Department in writing of his regular address, business address, office address or the place where he engages or intends to engage in the fitting or the sale of hearing aids. Notification of any change of status must be made to the Department within fifteen (15) days subsequent to such change.

SECTION 103. Temporary Permit

An applicant who fulfills the requirements of the Act, and who has not previously applied to take the examination delineated in Section 202 of these Rules and Regulations, may apply to the Department for a temporary permit.

(a) Prior experience or a waiting period shall not be required provided he shall be reasonably supervised and trained for a period of one year by a currently licensed hearing aid dealer.

(b) Annual reports of progress must be maintained on each person with a temporary permit by a licensed dealer verifying adequate personal contact supervision, and training and all such reports shall be kept on file at the Department. The phased training reports shall be submitted quarterly to complete the annual reports of progress.

(c) If any person who holds a temporary permit has not successfully passed the licensing examination within one year from the date of issuance, the temporary permit may, at the discretion of the Department, be renewed or he shall be required to reapply at a date specified by the Department.

SECTION 104. Display of License/Temporary Permit

The license or temporary permit shall be prominently displayed in his office or place of business in full view of any customer or client. The wallet sized identification shall be in the possession of licensed hearing aid dealers and temporary permit holders at all times and shall be displayed upon request by any customer, client, or agent of the Department, or peace officer.

Where there is more than one office or place of business, duplicate licenses shall be issued by the Department.

SECTION 105. Fees

(a) All fees shall be made payable to the South Carolina Department of Health and Environmental Control and are not transferable.

(b) Licensing fee or renewal fee established in the Act is fifty dollars (\$50.00) and duplicate licenses will be issued where more than one office or place of business is in operation.

(c) Temporary permit fee has been established at twenty-five dollars (\$25.00).

(d) Examination fee is set in the amount of fifty dollars (\$50.00) and is not refundable.

SECTION 106. Conduct/Ethics

1. It shall be the responsibility of the licensee or the temporary permit holder, under the Act, to be familiar with and to avoid commission of any acts regarded as unethical conduct including, but not limited to, the following:

(a) The obtaining of any fee or making any sale by fraud or misrepresentation.

(b) Employing directly or indirectly any suspended or unregistered person to perform any work covered by the Act.

(c) Engaging in falsification of name or using an alias with fraudulent intent for the purposes of fitting and selling hearing aids.

(d) Gross incompetence, or negligence shall be considered, in dispensing or selling a hearing aid to a customer, client or person without that person having been given the opportunity of tests utilizing appropriate established procedures and instrumentation to determine the extent or type of hearing impairment: except in cases of selling replacement hearing aids, in which case retesting hearing within 18 months of original purchase except in extenuating circumstances as determined by the Department.

(e) Using or causing or promoting the use of any advertising matter, promotional literature, testimonial, guarantee, warranty, label, brand, insignia, or any other representation, however disseminated or published, which is misleading, deceiving, or untruthful.

(f) Advertising or offering for sale a particular model, type or kind of hearing aid when the offer is not a bonafide effort to sell the product so offered as advertised and at the advertised price. In determining whether there has been a violation of this rule, consideration will be given to actions or practices indicating that the offer was not made in good faith for the purpose of selling the advertised product, but was made for the purpose of contacting prospective purchasers and selling them a product offered.

(g) Violation of any of the provisions of the Act.

2. Actions or procedures which shall be considered for the purpose of determining misrepresentation shall be the following:

(a) The creation, by virtue of the initial offer or advertisement, of a false impression of the product offered in any material respect.

(b) A refusal to show, demonstrate or sell the product offered in accordance with the terms of offer.

(c) To vilify by actions or words, the product offered, credit terms, availability of service, repairs or parts in connection with the offer or advertisement.

(d) To delay, in the event of sale, the delivery of such product or the service of such product offered within a reasonable time thereafter.

(e) Representing, advertising or implying that the hearing aid or repair is guaranteed without complete disclosure of the nature and extent of the guarantee and any conditions or limitations thereof.

3. Representing that the professional services or advice of a physician will be used or made available in the selling or fitting, adjustment, maintenance or repair of hearing aids when that is not true, or using the words "doctor", "clinic", "audiologist", or any similar words, abbreviations, or symbols which tend to connote the audiological or medical profession when such is not the case.

4. Permitting another the use of license or temporary permit.

5. The indulgence in excessive consumption of beverages or drugs for purposes of intoxication shall constitute habitual intemperance.

6. Offering for sale, rent, or lease, by advertisement, a manufacturer's product or using a manufacturer's name or trademark which implies a relationship with the manufacturer(s) that does not exist.

7. Directly or indirectly giving or offering to give, permitting or causing the exchange of anything of value, whether it be money or otherwise, to any person who advises another as an inducement to influence him or others to purchase or contract for purchase products sold or offered for sale by a hearing aid dealer or fitter.

8. Making any statement or implying that the use of any hearing aid will restore or preserve hearing, prevent or regress hearing impairment.

9. To conduct business during any affliction thereby causing to be spread any contagious or infectious disease which may constitute a hazard to the well-being of any client.

10. Committing or contributing to any of the above actions or deeds shall be construed a violation of the Act.

SECTION 107. Corporation or Like Organizations

Nothing in this Law shall prohibit a corporation, partnership, trust, association or other like organizations from engaging in the business of fitting and selling or offering for sale hearing aids at retail without a license, if it employs licensed persons in the direct sale and fitting of such products. Such corporations, partnerships, trusts, associations, or other like organizations shall also file annually with the Department and Commission a list of all licensed hearing aid dealers, fitters, and holders of temporary permits directly or indirectly employed by it. Corporate officers or agents of such organizations shall file with the Department by affixing their signature(s) to the application and thereby submit themselves to the Rules and Regulations and the provisions of this Act which the Department may deem applicable.

PART II

CHAPTER II—Procedures

SECTION 201. Procedures/Equipment

1. The following procedure shall be used in the fitting and selling of hearing aids where applicable:

(a) Pure tone audiometric testing by air and bone conduction to determine the level of hearing impairment.

(b) Speech reception threshold, speech discrimination, sound pressure measurement of the speech frequency range for the purpose of determining the best ear(s) for maximal hearing aid benefit and comfort. Selection of the best instrument to compensate for degree of loss.

(c) Only when the above procedures are clearly impractical, then the selection of the best instrument to compensate the loss may be made by trial of several instruments.

The following minimal equipment shall be used in the fitting and selling of hearing aids:

(a) Pure tone audiometer which shall meet with the latest specification standards as determined by the Department.

(b) Speech audiometer or a master hearing aid in order to determine the most comfortable listening level and speech discrimination.

(c) Ear light or an otoscope, for revealing any obstruction of the auditory canal, shall be free of cerumen and maintained in an aseptic manner at all times.

(d) Audiometers shall be checked for proper calibration as often as deemed necessary but not less than once each year. Evidence of calibration shall be furnished with the license renewal application and a copy maintained on file in the office.

1. Calibration shall be conducted by person, or an institution of higher learning equipped with proper instruments for calibrating as determined by the Department.

(e) Maintain or have access to facilities for making ear molds.

(f) A hearing aid office or place of business must have available or access to a selection of hearing aids and supplies and offer services complete enough to accommodate within reasonable limits the various needs of the clientele.

(g) The testing room shall be sufficient in dimensions to accommodate all equipment necessary for the proper testing and evaluation of the client.

(h) Every person who fits and sells hearing aids shall transmit to each person supplied with a hearing aid a receipt which shall contain the licensee's signature, show his business address and the license or temporary permit number together with the make, model and serial number of the hearing aid furnished and full terms of the sale clearly stated thereon. In the event of a used or rebuilt, reconditioned hearing aid, it shall be so specified on said receipt and shall indicate the length of time of the guarantee and by whom guaranteed.

1. The licensee shall advise the purchaser prior to any sale, testing or evaluation by the hearing aid dealer that any examination or representation is not to be construed as a diagnosis, a

medical opinion or that such examination imparts to the purchaser a prescription by a person licensed to practice medicine in this State.

2. Any person engaging in the fitting and sale of hearing aids will, when dealing with a child twelve years of age or under, ascertain whether the child has been examined by an otolaryngologist for his recommendation within ninety days prior to the fitting. If such not be the case, a recommendation to do so must be made and this fact noted on the receipt.

SECTION 202. Examination

1. An applicant for license, or holder of a temporary permit who meets all the requirements of the Act, shall appear at a time, place, and before such persons as prescribed by the Department to be examined by written and practical testing. The examination shall be such that it will establish knowledge and proficiency in each of the following categories:

- (a) Basic physics of sound.
- (b) Anatomy and physiology of the ear.
- (c) Basic structure and functions of hearing aids.
- (d) Pure tone audiometry, air and bone conduction.
- (e) Live voice or recorded speech, speech audiometry including speech reception threshold testing and speech discrimination testing.
- (f) Masking (when indicated).
- (g) Recording and evaluation of audiograms.
- (h) Speech audiometry.
- (i) Taking earmold impressions.

2. Examination and Fee:

- (a) A fee of fifty dollars (\$50.00) has been established for the examination and is not transferable or refundable.
- (b) Receipt shall be transmitted to applicant.
- (c) Application for examination shall be kept on file by the Department.
- (d) Applicant shall be notified within a reasonable time of the results of the prescribed tests.
- (e) Examinations for applicants shall be given not less than once each year.

3. The examination shall not constitute criteria or standards nor be conducted in a manner requiring college training in order to pass, or imply that the applicant possess a degree of competence normally expected of physicians or audiologists.

SECTION 203. Inspections

Inspection(s) shall be conducted periodically by the Department; such inspection(s) shall include but not be limited to the following:

1. Calibration check of audiometric equipment: evidence of calibration check shall be furnished upon request or shall be affixed to audiometer and shall have date and name of person(s) calibrating such equipment.

(a) Calibration shall be conducted on each audiometer as often as deemed necessary but not less than once each year.

(b) Calibration shall be accomplished by the manufacturer or properly trained person or an institution of higher learning equipped with proper instruments for calibrating audiometer as determined by the Department.

(c) Calibration of audiometers and earphones shall be in accordance with the American National Standards and Specification of Audiometers recent edition.

2. Records or receipt applicable to the sale of hearing aid:

(a) Such records or receipts shall contain the signature or initials of licensee, the business address, make, model and serial number of the hearing aid offered.

(b) Full disclosure of the terms of the sale.

(c) The warranty or guarantee and by whom.

(d) Any person engaging in the fitting and sale of hearing aids will, when dealing with a child twelve years of age or under, ascertain whether the child has been examined by an otolaryngologist for his recommendations within ninety days prior to the fitting. If such not be the case, a recommendation to do so must be made and this fact noted on the receipt.

(e) These records and receipts shall be retained, by the licensee or dealer, for a period of time not less than ten (10) years in keeping with good practice.

(f) Suggest all employees be required to check in to the owner of the business all pertinent records on termination of association with said owner of business.

3. The facility and individuals who work with, or handle, the equipment shall be clean at all times and all necessary precautions shall be taken to prevent the spread of any communicable disease.

4. Audiograms shall be recorded when applicable, and shall transmit the following information:

(a) Date of evaluation.

(b) Name of customer or client.

(c) Address of customer or client.

(d) Sex.

(e) Age.

(f) Signature of individual conducting test.

(g) Audiogram shall be filed by the dealer, licensee or permit holder at his place of business for a period of ten (10) years or until such time as good practice may dictate.

5. An otoscope or ear light shall be operational and maintained in a clean manner and free of any debris or cerumen at all times.

SECTION 204. General

Conditions arising which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the South Carolina Department of Health and Environmental Control.

SECTION 205. Continuing Education Programs—Approval

Any person or organization desiring to conduct continuing education training programs must submit such programs to the Commission for approval.

a. Courses which have been approved by the National Institute of Hearing Instruments Studies (NIHIS) of the National Hearing Aid Society will be approved by the Commission under the following conditions:

(1) The organization offering the program furnishes to the Department, not later than thirty days prior to its presentation, an outline which identifies the course content and NIHIS approved hours;

(2) The course is publicized and available to all South Carolina licensed hearing aid dealers; and

(3) The organization offering the courses furnishes the Department the names of such dealers who attended the program and the courses and hours creditable to each one.

b. Courses which do not meet the requirements outlined in "a", above, may be approved by the Commission under the following conditions:

(1) The organization offering the program furnishes to the Department, not later than sixty days prior to its presentation, an outline which includes:

(a) date and location;

(b) a description of each course;

(c) hours of each course; and

(d) biographical data of the instructors.

(2) The course is publicized and available to all South Carolina licensed hearing aid dealers; and

(3) The organization offering the courses furnishes the Department the names of such dealers who attended the program and the courses and hours creditable to each one.

c. The Department will secure Commission approval as appropriate and notify the training organization of the hours approved.

61-4. CONTROLLED SUBSTANCES.

(Statutory Authority: S.C. Code § 44-53-280(a))

Editor's Note

Unless otherwise noted, the following constitutes the history for 61-4.

HISTORY: Amended by State Register Volume 21, Issue No. 6, Part 2, eff June 27, 1997; State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

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PART 100

PURPOSE AND SCOPE; DEFINITIONS, INFORMATION, PAYMENT OF FEES, CERTAIN EXEMPTIONS, SEPARATE REGISTRATIONS, OUT-OF-STATE DISPENSING OF PRESCRIPTIONS.

101. Purpose and Scope.

This regulation implements the provisions of Section 44-53-10, et seq., of the S.C. Code of Laws, 1976, as amended. It establishes the requirements necessary to ensure the appropriate security, authority and accountability with regard to the possession, manufacture, dispensing, administering, use and distribution of controlled substances in South Carolina.

HISTORY: Added by State Register Volume 37, Issue No. 6, eff June 28, 2013.

102. Definitions.

As used in this regulation, the following terms shall have the meaning specified:

- (a) Act. Article 3 of Chapter 53 of Title 44 of the 1976 S.C. Code of Laws, including all amendments thereto.
- (b) Administration and the Abbreviation DEA. Refer to Drug Enforcement Administration, United States Department of Justice, the successor agency to the Bureau of Narcotics and Dangerous Drugs as defined in the Act.
- (c) Automated Storage Machine. A mechanical system that performs operations, other than compounding or administration, that allow medications to be provided to the patient and stored near the point of care while controlling and tracking drug distribution under the control of a licensed pharmacist.
- (d) Bureau Director. The Director of the Bureau of Drug Control, DHEC.
- (e) Code. The Code of Laws of South Carolina, 1976, including all amendments thereto.
- (f) Commercial Container. Any bottle, jar, tube, ampoule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and, in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "commercial container" does not include any package liner, package insert, or other material kept with or within a

commercial container, nor any carton, crate, box, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(g) **Compounder.** Any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages, or changes the dosage forms of a narcotic drug listed in Schedules II, III, IV, or V for use in maintenance or detoxification treatment by another narcotic treatment program. The term “compounder” as the content requires, includes any lawfully authorized person who changes the dosage forms, mixes, or prepares any controlled substance for use by the ultimate user pursuant to the legitimate and lawful order of a practitioner acting in the regular course of professional practice or by the practitioner personally, if authorized by law to compound and dispense controlled substances.

(h) **Controlled Premises:**

(1) Places where original or other records or documents required under the Act are required to be kept, and

(2) Places, including factories, warehouses, or other establishments, and conveyances, where persons registered under the Act or exempted from registration under the Act may lawfully hold, manufacture, dispense, distribute, administer, or otherwise dispose of controlled substances.

(i) **Controlled Substance.** A drug, substance, or immediate precursor in Schedules I through V as described in S.C. Code Sections 44-53-190, 44-53-210, 44-53-230, 44-53-250, and 44-53-270.

(j) **DHEC.** The South Carolina Department of Health and Environmental Control.

(k) **Director.** Unless otherwise specified, the Director of the Department of Health and Environmental Control.

(l) **Dispenser.** An individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

(m) **Detoxification Treatment.** The dispensing for a period not in excess of twenty-one days, of a narcotic or narcotics drugs in decreasing dosages to an individual in order to alleviate adverse physiological or psychological effects incidental to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time. SEE ALSO §§ 1007 through 1011 inclusive.

(n) **Emergency Situation.** For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Act, the term “emergency situation” means those situations in which the prescribing practitioner determines:

(1) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(2) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act; and

(3) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

(o) **Hearing.** Any hearing held pursuant to the provisions of the Act or of this regulation, including, but not limited to, hearings for the granting, denial, revocation, or suspension of a registration pursuant to the Act.

(p) **Home Infusion Pharmacy.** A pharmacy which compounds solutions for direct administration to a patient in a private residence, Long Term Care Facility or hospice setting by means of parenteral, intravenous, intra-muscular, subcutaneous or intra-spinal infusion.

(q) **Individual Practitioner.** A physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the State of South Carolina, or by other jurisdiction, or otherwise permitted by the United States or the State of South Carolina, or by any other jurisdiction in which he practices to dispense a controlled substance in the regular course of professional practice, but does not include a pharmacist, a pharmacy, or any institutional practitioner.

(r) **Inspector or Drug Inspector.** An officer or employee of the Bureau of Drug Control authorized by the Bureau Director to make inspections under the Act, and to conduct audit procedures in relation to controlled substances, and includes the Director of the Bureau of Drug Control.

(s) **Institutional Practitioner.** A hospital or other person (other than an individual) licensed, registered, or otherwise permitted by the United States, the State of South Carolina, or other

jurisdiction in which it practices, to dispense a controlled substance in the regular course of professional practice, but does not include a pharmacy.

(t) Interested Person. Any person adversely affected or aggrieved by any rule or proposed rule issued or issuable pursuant to the Act.

(u) Long Term Care Facility (LTCF). Nursing home, intermediate care, mental care, or other facility or institution which provides extended health care to resident patients and is licensed as such by DHEC or other appropriate State agency, which may further define the term for licensing and certification purposes.

(v) Name. The official name, common or usual name, chemical name, or brand name of a substance.

(w) Person. Includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(x) Pharmacist. Any pharmacist licensed by a state to dispense controlled substances, and shall include any person (e.g., pharmacy intern) authorized by the State to dispense controlled substances under the supervision of a pharmacist licensed by the State.

(y) Prescription. An order for medication which is dispensed to or for an ultimate user, but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

(z) Proceeding. All actions taken for the issuance, amendment, or repeal of any rules and regulations issued pursuant to the Act, commencing with the publication by the Bureau Director of the proposed rule, amended rule, or appeal.

(aa) Readily Retrievable. Certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, red-lined, or in some other manner visually identifiable apart from other items appearing on the records; when the term is not applicable to data processing systems, the term also means that a registrant is able to produce controlled substances records in a timely manner (usually within one hour) and that such records are segregated, sorted, or filed in such a manner that the controlled substances information may be derived from the material within a reasonable time (usually with a few hours) by an inspector.

(bb) Register and Registration. Refer only to registration required and permitted by the Act;

(cc) Registrant. Any person who is registered pursuant to the Act.

(dd) Scheduling of a Controlled Substance. Controlled substances are scheduled in accordance with provisions set forth in state law. Changes in the schedule of a controlled substance are made as set forth in S.C. Code Ann. § 44-53-160.

(ee) Any term not defined in this section shall have the definition set forth in the Act, or amendments thereto.

HISTORY: Formerly R. 61-4.101. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

103. Information; Special Instructions.

Information regarding procedures under these rules and special instructions supplementing these rules will be furnished upon request by writing to the Bureau of Drug Control DHEC, 2600 Bull Street, Columbia, SC 29201.

HISTORY: Formerly R 61-4.102. Renumbered by State Register Volume 37, Issue no. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.103 was titled "Free amounts".

104. Time and Method of Payment of Fees; Refund.

Registration and re-registration fees shall be paid at the time when the application for registration is submitted for filing. Payment shall be made in the form of a personal, certified or cashier's check, money order, credit card or online electronic payment, made payable to DHEC. Payments made in

the form of stamps, foreign currency, or third party endorsed checks will not be accepted. In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant.

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

105. Registrants Exempt from Fee.

(a) Any federal agency, installation or official authorized by law to procure or purchase controlled substances for official use shall be exempt from payment of a fee for registration or re-registration.

(b) In order to claim exemption from the payment of fees for registration or re-registration, the registrant shall have completed the certification on the appropriate application form, wherein the applicant's superior or the agency head certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess or handle controlled substances.

(c) Exemption from payment of a registration fee does not relieve the registrant of any other requirements or duties prescribed by law.

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

106. Persons Required to Register.

Every person who manufactures, distributes, prescribes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance shall obtain annually a registration unless exempted by law. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

107. Separate Registration for Independent Activities.

(a) The following groups of activities are deemed to be independent of each other:

- (1) Manufacturing controlled substances;
- (2) Distributing controlled substances;
- (3) Dispensing controlled substances listed in schedules II through V;
- (4) Conducting research (other than research described in paragraph (a) (6) of this section) with controlled substances listed in schedules II through V;
- (5) Conducting instructional activities with controlled substances listed in schedule II through V;
- (6) Conducting a narcotic treatment program using any drug listed in Schedules II through V: however, pursuant to §109, employees, agents or affiliated practitioners, in programs, need not register separately. Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed shall be separately registered and obtain narcotic drugs by use of order forms pursuant to §§ 901 and 902;
- (7) Conducting research and instructional activities with controlled substances listed in schedule I;
- (8) Conducting chemical analysis with controlled substances listed in any schedules;
- (9) Importing controlled substances;
- (10) Exporting controlled substances listed in schedules I through IV;
- (11) A compounder as defined by § 102(g); and
- (12) Automated storage machines at long term care facilities.

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

(1) A person registered to manufacture or import any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture or import;

(2) A person registered to manufacture any controlled substance listed in schedules II through V shall be authorized to conduct chemical analysis and pre-clinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in schedule I shall be authorized to manufacture or import such class if and to the extent that such manufacture and importation is set forth in the research protocol filed with the application for registration which shall conform with the provisions of 21 CFR § 1301.33, and to distribute such class to other persons registered or authorized to conduct research with such class, or registered or authorized to conduct chemical analysis with controlled substances;

(4) A person registered to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons registered to conduct chemical analysis or instructional activities and to persons exempted from registration pursuant to § 111, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances;

(5) A person registered or authorized to conduct research (other than research described in paragraph (a)(6) of this section) with controlled substances listed in those schedules in which he or she is authorized to conduct research, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, to import such substances for research purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 111, and to conduct instructional activities with controlled substances; and

(6) A person registered to dispense controlled substances listed in Schedules II through V may conduct research (other than research described in paragraph (a) (6) of this section) in conformity with the provisions of S.C. Code Ann. § 44-53-300(c) and conduct instructional activities with those substances.

(c) A single registration to engage in any group of independent activities may include one or more substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substance listed in Schedule I for which he or she has filed and had approved a research protocol.

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

108. Separate Registrations for Separate Locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registrants other than the registered person or to persons not required to register by the Act;

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances for display purposes or lawful distribution as samples only nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the

professional practice of the practitioner at such office and where no supplies of controlled substances are maintained.

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

109. Exemption of Agents and Employees; Affiliated Practitioners.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment. (For example, a pharmacist employed by a pharmacy need not be individually registered to conduct lawful business activity in preparing and dispensing of controlled substances if the pharmacy in which he or she is employed is properly registered under the Act; a manufacturer's sales representative may lawfully distribute samples of controlled substances manufactured by his or her employer, provided the manufacturer-employer is lawfully registered and the distribution is made to a registrant authorized to possess controlled substances and not to a non-registrant employee of the recipient of the sample.)

(b) An individual practitioner who is affiliated with one or more other individual practitioners in any legitimate and lawful form of business arrangement (i.e., partnership, professional association, etc.) shall be registered individually with DHEC prior to engaging in any form of controlled substances activity, pursuant to the provisions of S.C. Code Ann. §§ 44-53-290 and 44-53-370(a)(1). With the written Power of Attorney of another affiliated practitioner within the group, any other affiliate individual practitioner may administer or dispense (other than by prescribing) controlled substances within the regular course of professional practice if and to the extent the practitioner granting the power of attorney has authorized. (For example, Dr. X and Dr. Y are partners; they shall be individually registered in order to utilize controlled substances in their practice; if Dr. X desired, he or she could issue Dr. Y a power of attorney to utilize Dr. X's office stock of controlled substances to administer an injection of product CRx to Dr. Y's Patient, Mrs. A. while she is in the office. Dr. Y may not, however, sign Dr. X's name to prescriptions, nor may Dr. Y use Dr. X's registration number to obtain stocks of controlled substances for himself or herself or his or her own office stock.) Any power of attorney, once granted, may be revoked by the grantor in writing. Nothing in this Section shall be construed to relieve the grantor of any power of attorney of any responsibility for the proper storage, record keeping, handling, or legitimate use of any controlled substances acquired by the grantor; nor shall anything be construed as relieving the grantee practitioner from full and complete responsibility for his or her actions conducted pursuant to the power of attorney or for controlled substances acquired or utilized pursuant to this paragraph.

(c) Pharmacists listed with the S.C. Board of Pharmacy as the "pharmacist-in-charge" of a pharmacy holding a permit issued by that Board to operate as a retail pharmacy, shall be considered as a "registrant" within the meaning of the Act and this Regulation, and shall be primarily responsible for the controlled substances activity at the registered location of the pharmacy. Nothing in this paragraph shall be construed as relieving an owner, partner, corporate officer, or any other person who may be a registrant-in-fact (due to his or her position within the business entity) from any direct or vicarious liability which may be incurred due to unlawful or ultra vires activity, nor shall it be construed to relieve any employee of the business entity from direct responsibility for his or her own unlawful acts.

(d) Individual practitioners permitted under the provisions of Federal Regulation 21 CFR § 1301.24 to dispense, administer, or prescribe controlled substances under the registration of a hospital or other institution which is registered, in lieu of personal registration, are prohibited from this practice by the provisions of S.C. Code Ann. §§ 44-53-290 and 44-53-370(a)(1). No prescriptions issued within this State shall be dispensed by any person registered with DHEC unless the individual practitioner issuing the prescription holds a valid individual practitioner registration with DEA. Nothing shall prevent the dispensing of such prescriptions if they are co-signed by an individual practitioner holding a valid individual registration with the DEA and DHEC, providing that the co-signing practitioner has established a valid practitioner-patient relationship as set forth by §§ 1103 and 1204 of this Regulation prior to the dispensing of the controlled substance. Nothing in this paragraph shall preclude any pharmacy or dispensary operated by the Federal government on any property or enclave not subject to

State jurisdiction from any act permitted under Federal law or regulation, nor shall it preclude the dispensing of out-of-state prescriptions as permitted by § 114 of this Regulation.

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

110. Exemption of Certain Military and Other Personnel.

(a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service or Bureau of Prisons who is authorized to prescribe, dispense or administer, but not procure or purchase controlled substances in the course of his or her official duties, provided such prescribing, dispensing, and administering of controlled substances takes place upon a military reservation or other Federal enclave. Practitioners who issue prescriptions for controlled substances which are to be dispensed from governmental stocks shall be exempt from registration. Any practitioner who issues prescriptions for controlled substances which are to be dispensed from non-governmental pharmacies or dispensaries shall register with DHEC prior to issuing such prescriptions.

(b) Practitioners who issue prescriptions for controlled substances which are dispensed from non-governmental pharmacies or dispensaries must complete a controlled substances registration application annually;

(c) Practitioners who register annually with DHEC are granted an exemption to the fee requirement pursuant to Section 1303 of this regulation, provided that the request for exemption to the fee requirement is filed in writing with the Bureau Director. The written request must contain a military picture ID of the requestor, as well as documentation of the name and location of the military installation or hospital facility where the practitioner is located.

(d) This registration requirement and fee exemption applies only to practitioners and officials of the United States military service organizations, including the Army, Navy, Marine Corp, Air Force, and Coast Guard, and the Public Health Service, Bureau of Prisons, and Veteran's Administration, who are based on military installations or other Federal hospital facilities, providing healthcare on behalf of the Federal government.

(e) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities.

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

111. Exemption of Law Enforcement Officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any official or employee of the DEA, U.S. Department of Justice, any officer of the U.S. Bureau of Customs, any officer or employee of the United States Food and Drug Administration, and any other federal officer who is lawfully engaged in the law enforcement of any federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his or her official duties; and

(2) Any officer or employee of any state, or any political subdivision or agency thereof, who is engaged in the enforcement of any state or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his or her official duties.

(b) Any official exempted by this section may when acting in the course of his or her official duties, possess any controlled substances and distribute any such substance to any other official who is also exempted by this section and acting in the course of his or her official duties.

(c) Any official exempted by this section may procure any controlled substance in the course of an inspection, in accordance with the Act or in the course of any criminal investigation involving the person from whom the substance was procured.

(d) In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use in chemical analysis, such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials

exempted by this section and within the activity described. For purposes of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section.

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

112. Exemption of Civil Defense Officials.

(a) The requirement of registration is waived for any official of a civil defense or disaster relief organization who, in the course of his or her official duties, is authorized to:

(1) Maintain, and distribute for such maintenance, controlled substances held for emergency use; or

(2) Procure controlled substances for the purpose of maintaining supplies for emergency use, provided that all of such procurement is from the U.S. General Services Administration and in accordance with the rules of the U.S. Office of Emergency Preparedness.

(b) The requirement of registration is waived for any official of a civil defense or relief organization during a state of emergency or disaster within his or her jurisdiction proclaimed by the President or by a concurrent resolution of the Congress, which official, in the course of his or her official duties, during such emergency or disaster, is authorized to:

(1) Dispense controlled substances; or

(2) Procure or distribute controlled substances, provided that all such procurement is on a special "Civil Defense Emergency Order Form" as prescribed in the Federal Regulations (21 CFR § 1301.27(c)).

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

113. Registration Regarding Ocean Vessels and Aircrafts.

Registration of masters of ocean vessels and aircraft or the medical officers thereof shall be deemed sufficient if they are properly registered with the U.S. Department of Justice, DEA.

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

114. Dispensing of Out-of-State Prescriptions and Orders.

(a) Prescriptions or orders for controlled substances from out-of-state practitioners may be filled in good faith by dispensers provided:

(1) The dispenser knows the recipient; or requires proper ID and notes such on the prescription;

(2) The dispenser makes a good faith inquiry concerning whether the order or prescription is legitimate;

(3) The prescription or order meets all of the requirements of this regulation and the Act, including whether the order or prescription is for legitimate medical purposes, and is within the regular course of practice of the practitioner;

(4) The practitioner who issued the prescription would ordinarily be entitled to issue prescriptions under SC law (i.e., physicians, dentists, veterinarians, and podiatrists are authorized to issue prescriptions; chiropractors, psychologists, etc. are not authorized to prescribe drugs); and

(5) The prescribing practitioner holds a valid individual Federal [D.E.A.] controlled substance registration number in the state, district, or territory of origin of the prescription, or is exempt from such registration requirement under the provisions of Federal Regulation 21 CFR § 1301.24.

(b) Out-of-State prescriptions which do not conform to South Carolina law and which are not otherwise exempted shall not be dispensed.

HISTORY: Amended by State Register Volume 37, Issue No. 6, eff June 28, 2013.

115. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.115 was entitled "Time for application for registration; expiration date". See now R. 61-4.201.

116. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.116 was entitled "Application forms; content; signature". See now R. 61-4.202.

117. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.117 was entitled "Research Protocols". See now R. 61-4.203.

118. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.118 was entitled "Filing an application; joint filings".

119. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.119 was entitled "Acceptance for filing; defective applications".

120. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.120 was entitled "Additional Information". See now R. 61-4.204

121. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.121 was entitled "Amendments to and withdrawal of applications". See now R. 61-4.205.

122. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.122 was entitled "Administrative review generally". See now R. 61-4.301

123. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.123 was entitled "Applications for research in controlled Schedule I substances". See now R. 61-4.302.

124. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.124 was entitled "Application for bulk manufacture of Schedules I and II substances". See now R. 61-4.303.

124.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.124.1 was entitled "Provisional Registration". See now R. 61-4.304.

125. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.125 was entitled "Certificate of Registration; denial of registration". See now R. 61-4.305.

126. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.126 was entitled "Suspension or revocation of registration". See now R. 61-4.306.

127. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.127 was entitled "Suspension of registration pending final order". See now R. 61-4.307.

128. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.128 was entitled "Extension of registration pending final order". See now R. 61-4.308.

129. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.129 was entitled "Order to show cause". See now R. 61-4.309.

130. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.130 was entitled "Hearing generally". See now R. 61-4.310.

131. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.131 was entitled "Purpose of hearing". See now R. 61-4.311.

132. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.132 was entitled "Waiver and modification of rules". See now R. 61-4.312.

133. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.133 was entitled "Request for hearing or appearance; waiver". See now R. 61-4.313.

134. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.134 was entitled "Burden of proof". See now R. 61-4.314.

135. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.135 was entitled "Time and place of hearing". See now R. 61-4.315.

136. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.136 was entitled "Final order". See now R. 61-4.316.

137. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.137 was entitled "Modification in registration". See now R. 61-4.317.

138. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.138 was entitled "Termination of registration". See now R. 61-4.318.

138.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.138.1 was entitled "Termination of registration; Partnerships and Corporations; other business entities". See now R. 61-4.319.

139. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.139 was entitled "Transfer of registration". See now R. 61-4.320.

140. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.140 was entitled "Security requirements generally". See now R. 61-4.401.

141. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.141 was entitled "Physical security controls for non-practitioners; storage areas". See now R. 61-4.402.

142. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.142 was entitled "Physical security controls for non-practitioners; manufacturing areas". See now R. 61-4.403.

143. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.143 was entitled "Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs". See now R. 61-4.404.

144. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.144 was entitled "Physical security controls for practitioners". See now R. 61-4.405.

145. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.145 was entitled "Other security controls of practitioners". See now R. 61-4.406.

146. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.146 was entitled "Significant loss by diversion due to repeated thefts". See now R. 61-4.407.

147. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.147 was entitled "Filing of theft reports". See now R. 61-4.408.

148. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.148 was entitled "Employee screening procedures". See now R. 61-4.409.

149. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.149 was entitled "Employee responsibility to report drug diversion". See now R. 61-4.410.

150. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.150 was entitled "Illicit activities by employees". See now R. 61-4.411.

PART 200

APPLICATION FOR REGISTRATION.

201. Time for Application for Registration; Expiration Date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Bureau Director to such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his or her registration.

(c) Fees for registration for a physician shall be from October 2nd of the year until October 1st of the succeeding year. Fees for registration for any other person required to be registered shall be from April 2nd of the year until April 1st of the succeeding year. In the event any physician shall become registered subsequent to October 1st of any year, the entire registration fee shall be due and no pro-rata of fees will be allowed. In the event any other person required to be registered shall become registered subsequent to April 1st of any year, the entire registration fee shall be due and no pro-rata of fees will be allowed.

HISTORY: Formerly R. 61-4.115. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

202. Application Forms; Content; Signature.

(a) If the person is required to be registered, and is not so registered and is applying for registration;

(1) As a practitioner, pharmacy, mid-level practitioner, animal control, animal shelter, health clinic, EMS, rescue squad, or hospice, he or she shall apply on the applicable DHEC form or its electronic equivalent;

(2) As a narcotic treatment program, he or she shall apply on the applicable DHEC form or its electronic equivalent;

(3) As a distributor, canine unit, researcher, exporter, importer, broker, analytical or forensic laboratory, manufacturer or hospital, he or she shall apply on the applicable DHEC form or its electronic equivalent.

(b) Each application for registration to handle any basic class of controlled substances listed in schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in schedule II, or to conduct research with any Narcotic controlled substance listed in schedule II, shall include the Controlled Substances Control Number for each basic class or substance to be covered by such registration.

(c) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(d) Each application, attachment, or other document files as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. Another person may be authorized to sign for the applicant, if proof of authority (e.g. general power of attorney) accompanies the application.

HISTORY: Formerly R. 61-4.116. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

203. Research Protocols.

(a) Applicants for “Researcher” registration in Schedule I shall submit a research protocol containing all the information required for Federal Schedule I research protocol set forth under 21 CFR § 1301.32.

(b) Practitioners registered with DHEC desiring to perform incidental research on or with controlled substances under the provisions of S.C. Code Ann. § 44-53-300(c) are not required to furnish the formal protocol (except for narcotic substances as is required under Federal law), but shall instead provide a written summary of the proposed research, including the scope, the substance to be utilized, the number of research subjects (and their identity if protection from prosecution is desired), the duration of the research and the estimated usage of the controlled substance. Insofar as is practical, the dispensing of the controlled substance utilized in a valid research project shall be performed by the researcher or a particular dispenser or small group of dispensers in order to maintain adequate control. While not imperative to DHEC, notice of any participating dispensaries or pharmacies should be made to the Bureau of Drug Control in order that inadvertent and unnecessary investigations of normally unusual dispensing practices may be avoided.

(c) DHEC may require additional information or updating of protocols from time to time, but not more often than annually, unless a major change or deviation from previously submitted protocols or summaries is discovered. It is the responsibility of the person conducting the research project to notify to Department prior to any change in a protocol.

HISTORY: Formerly R. 61–4.117. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

204. Additional Information.

The Bureau Director may request an applicant to submit such documents or written statements of fact relevant to the application as he or she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after having been requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Bureau Director in granting or denying the application.

HISTORY: Formerly R. 61–4.120. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

205. Amendments to and Withdrawal of Applications.

(a) An application may be amended or withdrawn without permission of the Bureau Director at any time before the date on which the applicant receives an order to show cause pursuant to § 309 or before the date on which a notice of hearing on the application is published pursuant to § 309 whichever is sooner. An application may be amended or withdrawn with permission of the Bureau Director at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

HISTORY: Formerly R. 61–4.121. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

206. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor’s Note

Former R. 61–4.206 was entitled “Sealing of controlled substances”.

207. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor’s Note

Former R. 61–4.207 was entitled “Labeling for controlled substances dispensed directly to ultimate users”. See now R. 61–4.506.

PART 300

ACTION ON APPLICATIONS FOR REGISTRATION; REVOCATION OR SUSPENSION OF REGISTRATION.

301. Administrative Review Generally.

The Bureau Director may inspect, or cause to be inspected the establishment of an applicant or registrant, pursuant to the Act or this Regulation. The Bureau Director shall review the application for registration and other information gathered by the Bureau of Drug Control regarding an applicant in order to determine whether the applicable standards of the Act have been met by the applicant.

HISTORY: Formerly R. 61-4.122. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

302. Applications for Research in Controlled Schedule I Substances.

(a) In the case of an application for registration to conduct research with controlled substances, the Bureau Director shall refer such application to the Director who shall determine the qualifications and competency of the applicant as well as the merits of the research protocol. The Bureau Director, in determining the merits of a research protocol, shall consider procedures to effectively safeguard against diversion of such controlled substances from legitimate medical or scientific use. If the Bureau Director finds the applicant qualified and competent and the research protocol meritorious and adequately safeguarded, he shall register the applicant unless he finds registration should be denied on a ground specified in the Act.

(b) If the Bureau Director is unable to find the applicant qualified or finds that grounds exist for the denial of the application, the Bureau Director shall issue an order to show cause pursuant to § 309 and, if requested by the applicant, hold a hearing on the application pursuant to § 310.

HISTORY: Formerly R. 61-4.123. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

303. Application for Bulk Manufacture of Schedules I and II Substances.

The Bureau Director shall coordinate applications for bulk manufacture of schedules I and II controlled substances with the DEA of the U.S. Department of Justice. Applications may be received by the Bureau Director for such bulk manufacture, but shall not be acted upon until tentative or conditional approval is made by the appropriate federal agency, and after such notifications, publications, and other actions required by Chapter II, Title 21, Code of Federal Regulations [21 CFR §1301, ff.] are effected by the applicant.

HISTORY: Formerly R. 61-4.124. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

304. Provisional Registration.

(a) The Bureau Director, in his or her discretion, may grant provisional registration as a Researcher, Manufacturer, Distributor, Importer, or Exporter to any applicant, pending such applicant's obtaining a registration under Federal law. The duration of such provisional registration shall not exceed one year, and may not be renewed. Upon the granting of Federal registration, the provisional registration may be converted to a permanent registration by DHEC, which may renew such registration in the same manner as any other regular registration. If the Bureau Director does not find it in the public interest to grant a provisional registration, or to convert a provisional registration into a regular registration in the manner provided above, procedures set forth in S.C. Code Ann. § 44-53-320 for denial of registration shall be followed.

(b) Provisional registration does not entitle the applicant (i.e., the provisional registrant) to conduct any controlled substances activity within this State until such time as the applicant obtains a valid federal [DEA] registration for the identical activity at the same registered location.

HISTORY: Formerly R. 61-4.124.1. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

305. Certificate of Registration; Denial of Registration.

(a) The Bureau Director shall issue a Certificate of Registration to an applicant if the issuance of registration or re-registration is required under the applicable provisions of the Act. In the event that the issuance of registration or re-registration is not required, the Bureau Director shall deny the application. Before denying any application, the Bureau Director shall issue an order to show cause

pursuant to § 309 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 310.

(b) The Certificate of Registration shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Controlled Substances Code Number of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall maintain the Certificate of Registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the DEA or of any federal, state, or local agency engaged in enforcement of laws relating to controlled substances.

HISTORY: Formerly R. 61-4.125. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

306. Suspension or Revocation of Registration.

(a) The Bureau Director may suspend any registration pursuant to the Act for any period of time he determines.

(b) The Bureau Director may revoke any registration pursuant to the Act.

(c) Before revoking or suspending any registration, the Bureau Director shall issue an order to show cause pursuant to § 309 and, if requested by the registrant shall hold a hearing pursuant to § 310. Notwithstanding the requirements of this section, however, the Director may suspend any registration pending a final order pursuant to § 307.

(d) Upon service of the order of the Bureau Director suspending or revoking registration, the registrant shall immediately deliver his or her Certificate of Registration and any forms to his or her possession to the office of the Bureau of Drug Control. The suspension or revocation of a registration shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant. Also, upon service of the order of the Bureau Director suspending or revoking registration, the registrant shall:

(1) Deliver all controlled substances in his or her possession to the office of the Bureau of Drug Control or to authorized agents of the Bureau of Drug Control; or

(2) Place all controlled substances in his or her possession under seal as described in the Act.

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms in his or her possession to the office of the Bureau of Drug Control. The suspension or revocation of a registration, when limited to a particular basic class or classes of controlled substances, shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant for such class or classes. Also, upon service of the order of the Bureau Director revoking or suspending registration, the registrant shall:

(1) Deliver to the office of the Bureau of Drug Control or to authorized agents of the Bureau of Drug Control all of the particular controlled substances or substances affected by the revocation or suspension which are in his or her possession; or

(2) Place all of such substances under seal as described in the Act.

HISTORY: Formerly R. 61-4.126. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

307. Suspension of Registration Pending Final Order.

(a) The Bureau Director may suspend any registration simultaneously with or at any time subsequent to the service upon the registration of an order to show cause why such registration should not be revoked or suspended, in any case where he or she finds there is an imminent danger to the public health or safety. If the Bureau Director so suspends, he or she shall serve with the order to show cause pursuant to § 309 an order of immediate suspension, which shall contain a statement of his or her findings regarding the danger in public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his or her Certificate of Registration and any order forms in his or her possession to the office of the Bureau of Drug Control. The suspension of any registration under this section shall suspend any quota fixed

for the registrant. Also, upon service of the order of the Bureau Director immediately suspending registration, the registrant shall, as instructed by the Bureau Director:

- (1) Deliver all affected controlled substances in his or her possession to the office of the Bureau of Drug Control or to authorized agents of the Bureau of Drug Control; or
- (2) Place all of such substances under seal as described in the Act.

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Bureau Director or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his or her registration at a time earlier than specified in the order to show cause pursuant to § 309, which request shall be granted by the Bureau Director, who shall fix a date for such hearing as early as reasonably possible.

HISTORY: Formerly R. 61–4.127. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

308. Extension of Registration Pending Final Order.

(a) In the event that an applicant for re-registration (who is doing business under a registration previously granted and not revoked or suspended) has applied for re-registration of at least 45 days before the date on which the existing registration is due to expire, and the Bureau Director has issued an order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue to effect until the date on which the Bureau Director so issues his or her order.

(b) The Bureau Director may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for re-registration; at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Bureau Director finds that such extension is not inconsistent with the public health and safety.

HISTORY: Formerly R. 61–4.128. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

309. Order to Show Cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Bureau of Drug Control regarding the applicant, the Bureau Director is unable to make the determinations required by the applicable provisions of the Act to register the applicant, the Bureau Director shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Bureau of Drug Control regarding any registrant, the Bureau Director determines that the registration of such registrant is subject to suspension or revocation to the Act, the Bureau Director shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before a hearing officer at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant shall, if he or she desires a hearing, file a request for a hearing in writing. If a hearing is requested, the hearing officer shall hold a hearing at the time and place stated in the order, pursuant to § 311.

(e) When authorized by the Bureau Director, any agent of the Bureau of Drug Control may serve the order to show cause, or service may be effected by registered or certified mail.

HISTORY: Formerly R. 61–4.129. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

310. Hearing Generally.

(a) In any case where the hearing officer shall hold a hearing on any registration or application therefore, the procedures for such hearing shall be governed generally by the adjudication procedures set forth by statute or by the Attorney General's Office.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act of any other law of this State or the United States.

HISTORY: Formerly R. 61-4.130. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

311. Purpose of Hearing.

If requested by a person entitled to a hearing the hearing officer shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration, and the granting of any application for registration to manufacture in bulk a basic class of controlled substances listed in schedules I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

HISTORY: Formerly R. 61-4.131. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

312. Waiver and Modification of Rules.

The Director or the presiding officer (with respect to matters pending before him or her) may modify or waive any rules in this part by notice in advance of the hearing, if he or she determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

HISTORY: Formerly R. 61-4.132. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

313. Request for Hearing or Appearance; Waiver.

(a) Any person entitled to a hearing pursuant to §§ 302-306 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause, file with the Director a written notice for a hearing.

(b) Any person entitled to and desiring to participate in a hearing pursuant to § 309 shall, within 10 days of the date of the hearing, file with the Director a written notice of his or her intention to participate in such hearing.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to §§ 302-306 may, within the period permitted for filing a request for a hearing or a notice of appearance, file with the Director a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his or her position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to §§ 302-306 fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his or her opportunity for the hearing or to participate in the hearing, unless he show good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Director may cancel the hearing if scheduled, and issue his or her final order pursuant to § 316 without a hearing.

HISTORY: Formerly R. 61-4.133. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

314. Burden of Proof.

(a) At any hearing on an application to manufacture any controlled substance listed in schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to the Act are satisfied. Any other person participating in the hearing pursuant to § 313 shall have the burden of proving any proposition of fact or law asserted to him or her in the hearing.

(b) At any hearing on the granting or denial of an application to be registered to conduct a narcotic treatment program or as a compounder, the applicant shall have the burden of proving that the requirements for each registration pursuant to S.C. Code Ann. § 44-53-290(i) are satisfied.

(c) At any other hearing for the denial of a registration, DHEC shall have the burden of proving that the requirements for such registration pursuant to the Act are not satisfied.

(d) At any hearing for the revocation or suspension of a registration, DHEC shall have the burden of proving that the requirements of the Act for such suspension or revocation are satisfied.

HISTORY: Formerly R. 61–4.134. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

315. Time and Place of Hearing.

The hearing will commence at the place and time designated in the order to show cause or notice of hearing (unless expedited pursuant to § 307) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

HISTORY: Formerly R. 61–4.135. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

316. Final Order and Appeals.

(a) Final order. As soon as practicable after the hearing officer has certified the record to the Director, the Director shall certify his or her order on the granting, denial, revocation, or suspension of registration.

(b) Appeals. A Department decision involving the issuance, denial, renewal, suspension, or revocation of a permit, license, certificate or certification may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Chapter 53; and Title 1, Chapter 23. Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Chapter 53; and Title 1, Chapter 23.

HISTORY: Formerly R. 61–4.136. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

317. Modification in Registration.

Any registrant may apply to modify his or her registration to authorize the handling of additional controlled substances or to change his or her name or address, by submitting a letter of request to the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201. The letter shall contain the registrant's name, address, and registration number as printed on the Certificate of Registration, and the substances and/or schedules to be added to his or her registration or the new name or address and shall be signed in accordance with § 202(d). If the modification in registration is approved, the Bureau Director shall issue a new Certificate of Registration to the registrant, who shall maintain it with the old Certificate of Registration until expiration.

HISTORY: Formerly R. 61–4.137. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

318. Termination of Registration.

The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Bureau Director promptly of such fact.

HISTORY: Formerly R. 61–4.138. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

319 Termination of Registration; Partnerships and Corporations; Other Business Entities.

(a) Upon the transfer of ownership of a controlling interest in any partnership, corporation, holding company, association, or other business entity holding a registration under the Act, which is not a personal registration as an individual or a proprietorship registration involving a single individual registrant, the registration held prior to any transfer of any controlling interest or controlling ownership shall terminate upon the effective date of the transfer, and a new registration shall be obtained if the business entity is to continue controlled substances activity. DHEC may, in its discretion, permit a transferor-registrant to permit the transferee to continue operation pursuant to a written power of attorney for a period of not more than 60 days, during the pendency of obtaining a new registration for the transferee.

(b) If the control of a corporation already registered under the Act shall be acquired by another corporation not registered under the Act, the acquiring corporation need not obtain a separate registration for itself, unless merger takes place; the corporation acquired shall, however, obtain a new registration even if there is no change in corporate officers if it intends to continue controlled substances activity. In the event a merger is effected between the acquiring corporation and the

acquired corporation (regardless of the surviving or ensuing name) the acquiring corporation shall obtain a new registration in its own name, or in the name of the successor or ensuing corporation (if different) prior to engaging in controlled substances activity. Successor corporations shall be deemed to be new business entities, and shall obtain new registration prior to conducting controlled substances activity.

HISTORY: Formerly R. 61–4.138.1. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

320. Transfer of Registration.

No registration or authority conferred thereby shall be assigned or otherwise transferred except upon conditions as the Bureau Director may specifically designate and then only pursuant to his or her written consent.

HISTORY: Formerly R. 61–4.139. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

321. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.321 was entitled “Records for maintenance treatment programs and detoxification treatment programs”.

322. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.322 was entitled “Records for treatment programs which compound narcotics for treatment programs and other locations”.

PART 400 SECURITY REQUIREMENTS

401. Security Requirements Generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Bureau Director shall use the security requirements set forth in §§ 402–406 as standards for the physical security controls and operating procedures necessary to diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§ 402, 403, and 405 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§ 402–406 may be deemed sufficient by the Bureau Director after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Bureau Director may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

- (1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
- (2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or non-usable powders);
- (3) The quantity of controlled substances handled;
- (4) The location of the premises and the relationship such location bears on security needs;
- (5) The type of building construction comprising the facility and the general characteristics of the building or buildings;
- (6) The type of vault, safe, and secure enclosures or other storage systems (e.g., automatic storage and retrieval system) used;
- (7) The type of closures on vaults, safes, and secure enclosures;
- (8) The adequacy of key control systems and/or combination lock control system;
- (9) The adequacy of electric detection and alarm systems if any, including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage area;

(12) The procedures for handling business guests, visitors, maintenance personnel, and non-employees service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel; and

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different scientific schedule, or as a result of a non-controlled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§ 402–406 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§ 402–406 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Bureau Director or to the Compliance Investigations Division, DEA, Department of Justice, Washington, DC 20537.

(e) Physical security controls of locations registered under the Harrison Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§ 402, 403, and 405. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Bureau of Drug Control, shall not necessarily be deemed to comply substantially with the standards set forth in §§ 402, 403, and 405 notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved.

HISTORY: Formerly R. 61–4.140. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

402. Physical Security Controls for Non-practitioners; Storage Areas.

(a) Schedules I and II. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in schedules I and II shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe or steel cabinet:

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-minutes against lock manipulation, and 20 man-minutes against radiological techniques.

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Bureau Director may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system and

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vaults are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½ inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors and ceilings;

(ii) The door and frame of which vault shall conform to the following specifications or the equivalent; 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against local manipulation, and 20 man-hours against radiological techniques.

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a “day-gate” which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant as the Bureau of Drug Control may approve and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) Which vault has one of the following: complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Bureau of Drug Control.

(b) Schedules III, IV and V. Raw materials, bulk materials awaiting further processing and finished products which are controlled substances listed in schedules III, IV, and V shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe which complies with the requirements set forth in paragraph (a)(1) of this section;

(2) A vault which complies with the requirements set forth in either paragraph (a)(2) or (3) of this section; equipped with an alarm system as described in paragraph (b) (4) (v) of this section; or

(3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) Has an electronic alarm system as described in paragraph (b) (4) (v) of this section;

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use, and when in use is kept under direct observation of a responsible employee of the agent or registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded, or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

(4) A cage, located within a building on the premises, meeting the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lag bolts that are pinned or brazed; and

(c) Which are placed no more than 10 feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square;

(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height;

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all of the requirements of subparagraph (b)(3)(ii) of this section; and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency, or a local or state police agency, each having a legal duty to respond, or a 24-hour control station operated by the registrant, or to such other source of protection that the Bureau Director may approve;

(5) An enclosure of masonry or other material, approved in writing by the Bureau Director as providing security comparable to a cage;

(6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor, agency, BNDD, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment from DEA (BNDD) has been received for the area in which such building or enclosure is situated;

(7) Such other secure storage areas as may be approved by the Bureau Director after consulting with DEA and the factors listed in § 401(b)(1) through (14) of this regulation;

(8)(i) Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by paragraph (a) of this section;

(ii) Non-controlled drugs, substances, and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by this section, provided, that permission for such storage of non-controlled substances has been obtained in advance, in writing, from both the Bureau Director and the DEA agent in charge of the area in which such storage area is situated [See 21 CFR § 1301.72 (b)(8)(ii)]. Any such permission shall be based upon the determination that the storage of such items does not diminish security for the controlled substances.

(c) Multiple store areas. Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g. returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) Accessibility to storage areas. The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

HISTORY: Formerly R. 61-4.141. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

403. Physical Security Controls for Non-practitioners; Manufacturing Areas.

All manufacturing activities (including processing, packaging, and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in

writing as responsible for the area. "Limited access" may be provided in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted, provided, that he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his or her knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

HISTORY: Formerly R. 61-4.142. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

404. Other Security Controls for Non-practitioners; Narcotic Treatment Programs and Compounders for Narcotic Treatment Programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the DEA or with the state controlled registration agency to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to alert the registrant of suspicious orders of controlled substances. The registrant shall inform the Bureau of Drug Control of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the office of the Bureau of Drug Control of any theft or loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the contract or common carrier pursuant to subparagraph (e) of this section, upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts shall be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substances in schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer and (3) only in reasonable quantities. Such request shall contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substances desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of Part 900 of the Regulation shall be complied with for any distribution of a controlled substance listed in schedule II. For purposes of this paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance to the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers, which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 402. In addition, the registrant shall employ precautions (e.g. assuring that shipping containers do not indicate the contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detail men), a registrant is responsible for providing adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of etorphine hydrochloride and/or diprenorphine to any person, the registrant shall verify that the person is authorized to handle the substance(s) by contacting the Bureau of Drug Control and DEA.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in

writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his or her specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse (LPN) under the direction of the licensed practitioner, or (4) a pharmacist acting under a prescription or an order issued by the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs shall comply with standards established by the appropriate Federal authorities [see 21 CFR § 1301.74(k)] and the Bureau of Drug Control, and the provisions of S.C. Code Ann. §§ 44-53-710 through 44-53-760 respecting the quantities of narcotic drugs that may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA and the Bureau of Drug Control may exercise discretion regarding the degree of security required in narcotic treatment programs based upon such factors as the location of the program, the number of patients enrolled in a program, and the number of physicians, staff members, and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

HISTORY: Formerly R. 61-4.143. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

405. Physical Security Controls for Practitioners.

(a) Controlled substances listed in schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to non-practitioners authorized to conduct research or chemical analysis under another registration.

(d) Etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

HISTORY: Formerly R. 61-4.144. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

406. Other Security Controls of Practitioners.

(a) The registrant shall not knowingly employ as an agent or employee, who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration denied, or has had his or her registration revoked, at any time.

(b) The registrant shall notify the Bureau of Drug Control, DHEC, of the loss or theft of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DEA Form 106 regarding such loss or theft.

(c) The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to 21 CFR § 1301.74(e), upon discovery of such theft or loss.

(d) Whenever the registrant distributes a controlled substance (without being registered as a distributor, as permitted by § 107(b) and/or §§ 1401 through 1404 of this Regulation) he or she shall comply with the requirements imposed on non-practitioners in § 404(a), (b), and (c).

HISTORY: Formerly R. 61-4.145. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

407. Loss by Diversion Due to Repeated Thefts.

(a) Any registrant who suffers repeated losses of controlled substances by theft due to break-ins, employee theft, mysterious disappearance, or other than through an armed robbery shall be deemed to be providing inadequate security for such controlled substances.

(b) Upon the first such diversion, the registrant shall cause such physical security measures to be instituted to prevent recurrence.

(c) Upon the second such diversion, the registrant shall be required to appear before the designated hearing officer of DHEC to provide, under oath, the security measures that the registrant has effected and plans to effect in the future to prevent further diversion by theft.

(d) Upon the third such diversion, the registrant shall be cited to show cause, if any he or she may have, why his or her registration under the Controlled Substances Act should not be revoked, suspended, or denied pursuant to the provisions of S.C. Code Ann. § 44-53-310(e).

HISTORY: Formerly R. 61-4.146. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

408. Filing of Theft Reports.

Theft reports (DEA Form 106) as required by this regulation shall be filed with the Bureau of Drug Control not later than 30 days following the discovery of the theft. Failure to file theft reports within the thirty-day period shall result in the issuance of an order to show cause for revocation or suspension of registration under the Act.

HISTORY: Formerly R. 61-4.147. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

409. Employee Screening Procedures.

Registrants are required to screen all employees for criminal convictions and/or unauthorized use of controlled substances. An employer's comprehensive employee screening program will include the following inquiries:

(1) Within the past five years have you been convicted of a felony or any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses, or military conviction, except by general court martial.) If the answer is yes, furnish details of the conviction, offense, location, date, and sentence.

(2) In the past three years, have you ever knowingly used any narcotic, barbiturates, or amphetamines, other than prescribed to you by a physician or other practitioner? If the answer is yes, furnish details.

Employers should obtain an authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions. This authorization shall be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person shall be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. This person must also be informed that the information contained in the application and any information disclosed as a result of the authorization will be available to the Bureau of Drug Control in the event of inquiry or investigation.

HISTORY: Formerly R. 61-4.148. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

410. Employee Responsibility to Report Drug Diversion.

An employee who has knowledge or suspicion of drug diversion from his or her employer by a fellow employee shall report such information to a responsible security official of the employer, or to a person in a management position with the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug

security area, or with access to controlled substances. The employer shall inform all employees concerning this policy.

HISTORY: Formerly R. 61-4.149. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

411. Illicit Activities by Employees.

Employees who sell, possess, use, or divert controlled substances will subject themselves not only to state and federal criminal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, and the past record of employment. in determining whether to suspend, transfer, terminate, or take other action against the employee.

HISTORY: Formerly R. 61-4.150. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

412. Separate Registration by Permitted Pharmacies for Installation and Operation of Automated Storage Machines at Long Term Care Facilities.

(a) A permitted pharmacy may install and operate automated storage machines, as defined in § 102(c) of this Regulation, at long term care facilities. No person other than a permitted pharmacy may install and operate an automated storage machine at a long term care facility.

(b) Permitted pharmacies installing and operating automated storage machines at long term care facilities must maintain a separate registration at the location of each long term care facility at which automated storage machines are located.

(c) A permitted pharmacy applying for a separate registration to operate automated storage machines which contain controlled substances at a long term care facility is exempt from application fees for any such additional registrations.

HISTORY: Added by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 500.

LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES.

501. Symbol Required; Exceptions.

(a) Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, shall bear a label complying with the requirement of this part.

(b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him or her the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto:

Schedule	Symbol
Schedule I	I or C-I
Schedule II	II or C-II
Schedule III	III or C-III
Schedule IV	IV or C-IV
Schedule V	V or C-V

The word "schedule" need not be used. No distinction need be made between narcotic and non-narcotic substances.

(d) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.

(e) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

(f) The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

(g) The symbol is not required on a commercial container containing, or on labeling of, a controlled substance intended for export from the United States.

HISTORY: Formerly R. 61-4.202. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

502. Location and Size of Symbol on Label.

(a) The symbol shall be prominently located on the right upper corner of the principal panel of the label of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance listed in schedules I through V. The symbol shall be at least two times as large as the largest type otherwise printed on the label.

(b) In lieu of locating the symbol in the corner of the label, as prescribed in paragraph (a) of this section, the symbol may be overprinted on the label, in which case the symbol shall be printed at least one-half the height of the label and in a contrasting color providing clear visibility against the background color of the label.

(c) In all cases the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

HISTORY: Formerly R. 61-4.203. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

503. Location and Size of Symbol on Labeling.

The symbol shall be prominently located on all labeling other than labels covered by Regulation 203. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

(a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on July 1, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of § 501.

(b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on July 1, 1971, and thereafter transferred to another schedule or is added to any schedule after July 1, 1971, and which is packaged more than 180 days following the dates on which the transfer or addition becomes effective shall comply with the requirements of § 501.

(c) The Bureau Director may, in the case of any controlled substance, require compliance with the requirements of § 501 within a period of time shorter than required by this section if he or she finds that public health or safety necessitates an earlier effective date.

(d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under federal or state law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

HISTORY: Formerly R. 61-4.204. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

504. Effective Dates of Labeling Requirements.

(a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on July 1, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of § 501.

(b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on July 1, 1971, and thereafter transferred to another schedule or is added to any schedule after July 1, 1971, and which is packaged more than 180 days following the dates on which the transfer or addition becomes effective shall comply with the requirements of § 501.

(c) The Bureau Director may, in the case of any controlled substance, require compliance with the requirements of § 501 within a period of time shorter than required by this section if he or she finds that public health or safety necessitates an earlier effective date.

(d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under federal or state law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

HISTORY: Formerly R. 61-4.205. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

505. Sealing of Controlled Substances.

(a) On each bottle, multiple dose vial, other commercial container of any controlled substance listed in schedules I and/or II, and of any narcotic controlled substance listed in schedule III or IV, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper of such container a seal to disclose upon inspection any tampering or opening of the container.

(b) Any seal accepted for use, under federal law prior to July 1, 1971, shall be deemed acceptable for use under this section.

HISTORY: Formerly R. 61-4.206. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

505.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.505.1 was entitled "Registration number required on prescriptions". See now R. 61-4.1004.

506. Labeling for Controlled Substances Dispensed Directly to Ultimate Users.

Controlled substances which are dispensed directly to an ultimate user other than by a prescription dispensed by a pharmacy or by direct administration or application of the substance into or upon the person for whom it is intended, shall bear a label or labeling containing the drug name, the quantity dispensed, the name and address of the dispenser, the name of the ultimate user (i.e., the "patient"), specific directions for use, and the date of the dispensing. The label or labeling shall include any necessary cautionary statement, whether customary or required by state or federal law. A serial number may be utilized at the discretion of the dispenser. The act of dispensing controlled substances shall be performed by the registrant, and shall not be delegated to any person other than a pharmacist acting in the regular course of professional activity. Prescriptions shall be labeled pursuant to the provisions of Part 1000 of this Regulation, unless specifically exempted. No practitioner shall directly dispense more than a thirty-one day supply.

HISTORY: Formerly R. 61-4.207. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

506.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.506.1 was entitled "Information required for filled prescriptions". See now R. 61-4.1006.

507. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.507 was entitled "Dispensing of narcotic drugs for maintenance purposes". See now R. 61-4.1007.

507.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.507.1 was entitled "Federal approval of maintenance programs required". See now R. 61-4.1008.

507.2. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.507.2 was entitled "Withdrawal of drug dependent persons by use of methadone or other narcotic controlled substances". See now R. 61-4.1009.

507.3. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.507.3 was entitled "Approved uses of methadone in hospitals". See now R. 61-4.1010.

507.4. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.507.4 was entitled "Departmental Approval; when required". See now R. 61-4.1011.

507.5. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.507.5 was entitled "Treatment of outpatients with methadone". See now R. 61-4.1012.

508. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.508 was entitled "Requirement of prescription". See now R. 61-4.1101.

508.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.508.1 was entitled "Limitations on prescriptions for schedule II substances". See now R. 61-4.1102.

508.2. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.508.2 was entitled "Practitioner-patient relationship required". See now R. 61-4.1103.

509. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.509 was entitled "Refilling prescription". See now R. 61-4.1104.

510. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.510 was entitled "Partial filling of prescription". See now R. 61-4.1105.

511. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.511 was entitled "Labeling of substance". See now R. 61-4.1106.

512. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.512 was entitled "Filing of prescriptions". See now R. 61-4.1107.

513. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.513 was entitled "Requirement of prescription". See now R. 61-4.1201.

514. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.514 was entitled "Refilling of Prescriptions". See now R. 61-4.1202.

514.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.514.1 was entitled "Limitations on prescriptions for Schedules III, IV, and V substances". See now R. 61-4.1203.

514.2. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.514.2 was entitled "Practitioner-patient relationship required". See now R. 61-4.1204.

514.3. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.514.3 was entitled "Partial Filling of Prescriptions". See now R. 61-4.1205.

515. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.515 was entitled "Labeling of substances". See now R. 61-4.1206.

516. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.516 was entitled "Filing prescriptions". See now R. 61-4.1207.

517. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.517 was entitled "Requirement of prescription".

517.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.517.1 was entitled "Limitation on prescriptions for schedule V substances".

518. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.518 was entitled "Dispensing without prescription". See now R. 61-4.1208.

PART 600.

RECORDS AND REPORTS OF REGISTRANTS.

601. Scope of Part 600.

Inventory and other records and reports required under the Act shall be in accordance with, and contain the information required by, those sections and by the sections of this Part.

HISTORY: Formerly R. 61-4.301. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

602. Persons Required to Keep Records and File Reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this Part, except as exempted by this Section. Any registrant who is authorized to conduct other activities without being registered to conduct these activities, either pursuant to § 107(b) or to §§ 1401 through 1404, shall maintain the records and inventories and shall file the reports required by this Part for persons registered to conduct such activities. The latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately, nor that separate records are required for each activity. The intent of the Bureau of Drug Control is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity. The Bureau of Drug Control does not wish to require separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he or she shall keep a record of the quantity manufactured; when he or she distributes a quantity of the item, he or she shall use and keep invoices or order forms to document the transfer; when he or she imports a substance, he or she keeps as part of his or her records the documentation required to an importer; and when substances are used in

chemical analysis, he or she need not keep a record of this because such a record would not be required of him or her under a registration to do chemical analysis. All of those records may be maintained in one consolidated record system. Similarly, the researcher may store all of his or her controlled items in one place, and every year take inventory of all items in hand, regardless of whether the substances were manufactured by him or her, imported by him or her, or purchased domestically by him or her, or whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

(b) A registered individual practitioner is not required to keep specific records with respect to controlled substances for which he or she issues prescriptions, or orders for administration within an institutional practitioner setting (e.g., hospital "orders"), in the lawful course of his or her professional practice; provided, that a complete record or memorandum of such prescription or order be maintained upon regular patient records.

(c) A registered individual practitioner is required to maintain a readily retrievable record, separate from patient charts, of all controlled substances acquired, dispensed, administered (other than by the issuance of an institutional order or a prescription) distributed, or otherwise disposed of by the practitioner, his or her employees or agents, whether the controlled substance is separately charged for, included in other charges, or is provided at no charge. Practitioners who personally administer narcotic controlled substances in an emergency need only keep a simple record of the date, kind, quantity, and strength of the controlled substance administered in such emergency, and the name of the recipient. Within 72 hours of the emergency administration, a permanent record shall be constituted and included in the readily retrievable records of dispensing required herein. Repeated or excessive emergency administrations will require the registrant to notify the Bureau of Drug Control of such happenstance.

(d) A registered person using any controlled substance in research conducted in conformity with an exemption granted under § 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) as a registered establishment which maintains records in accordance with either of those sections is not required to keep records if he notified the Bureau of Drug Control of the name, address, and registration number of the establishment maintaining such records.

(e) A registered person using any controlled substance in pre-clinical research or in teaching at a registered establishment, which maintains records with respect to such substance, is not required to keep records if he notifies the Bureau of Drug Control of the name, address, and registration number of the establishment maintaining such records.

(f) Notice required by paragraphs (d) and (e) of this section shall be given at the time the person applies for registration or re-registration and shall be made in the form of an attachment to the application, which shall be filed with the application.

HISTORY: Formerly R. 61-4.303. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

603. Maintenance of Records and Inventories.

(a) Every inventory and other record required to be kept under this Part shall be kept by the registrant and be available, for at least two years from the date of such inventory or record, for inspecting and copying by authorized employees of the Bureau of Drug Control, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to 21 CFR § 1305.13) may be kept at a central location rather than at the registered location if the registrant has notified the Bureau of Drug Control of its intention to keep central records. Written notification shall be submitted by registered or certified mail, return receipt requested, in triplicate to the Bureau Director. Unless the registrant is informed by the Bureau Director that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of the return receipt accompanying the notification. All notifications shall include:

- (1) The nature of the records to be kept centrally and the exact location where the records will be kept;
- (2) The name, address, state and DEA registration numbers, and type of registration of the registrant whose records are being maintained centrally;
- (3) Whether central records will be maintained in a manual, or computer readable form.

(b) Each registered manufacturer, distributor, importer, and exporter shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in schedules I and II shall be maintained separately from all of the records of the registrants, and

(2) Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(c) Each registered individual practitioner required to keep records and each institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (b) of this section.

(d) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained as a separate prescription file.

(2) Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(3) Prescriptions for controlled substances shall be maintained in separate files from prescriptions for non-controlled substances. Prescriptions for schedule II controlled substances shall be filed separately from prescriptions for schedules III, IV, and V controlled substances. Compliance with this Section will be deemed proper if the pharmacy maintains not less than three files, those being:

File No. 1-Schedule II Controlled Substances only.

File No. 2-Schedules III, IV, and V Controlled Substances only.

File No. 3-Non-controlled Substances.

Sequential numbering systems of the files shall be at the discretion of the dispenser.

(e) All registrants that are authorized to maintain a central record keeping system shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms, prescriptions, and/or inventories which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information) a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within 2 business days upon receipt of a written request from the Bureau of Drug Control, and if the Bureau of Drug Control chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Bureau of Drug Control to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Bureau Director may cancel such central record keeping authorization, and all other central record keeping authorization held by the registrant without a hearing or other procedures. In the event of cancellation of central record keeping authorization under this paragraph, the registrant shall, within the time specified by the Bureau Director, comply with the requirements of this section that all records be kept at the registered location.

(f) Original documents shall be maintained in addition to those which are stored in computer media for a period of two years from the date of the origination of the document, or from the last transaction contained therein or entered thereupon, whichever is the later date.

HISTORY: Formerly R. 61-4.304. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

604.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.604.1 was entitled "Distribution by Dispenser to another practitioner". See now R. 61-4.1401.

605. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.605 was entitled "Manufacture and distribution of narcotic solutions and compounds by a pharmacist". See now R. 61-4.1402.

606. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.606 was entitled "Distribution to supplier". See now R. 61-4.1403.

607. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.607 was entitled "Distribution upon discontinuance of transfer of business". See now R. 61-4.1404.

608. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.608 was entitled "Incidental manufacture of controlled substances".

609. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.609 was entitled "Procedure for disposing of controlled substances". See now R. 61-4.1501.

PART 700.

INVENTORY REQUIREMENTS.

701. General Requirements for Inventories.

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(c) A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in § 707.

(d) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business, and the date and time the inventory is taken.

(e) An inventory shall be maintained in an indelibly written, typewritten, or printed form. An inventory taken by use of an oral recording device shall be promptly transcribed. Such inventory shall be signed by a responsible individual, who attests to the completeness and accuracy of the inventory.

HISTORY: Formerly R. 61-4.305. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.701 was titled "Schedule I".

702. Inventory upon Transfer of Business; Change of Pharmacist-in-Charge.

(a) Inventory upon transfer of business.

(1) Any registrant transferring his or her business to another person who shall become registered to continue such business shall inventory all controlled substances on hand at the close of business on the day of transfer. The receiving registrant shall either (a) certify the inventory taken as being correct, or (b) shall affect his or her own inventory at the start of business on the date of transfer. Any discrepancy in the inventory shall be reported within 5 days to the Bureau Director.

(2) A new establishment, never before having been registered, and having no prior inventory of controlled substances, shall be deemed to have a zero inventory as of the first day of business.

(3) A registrant discontinuing business shall upon the date of discontinuance inventory all controlled substances and place said controlled substances in sealed containers under adequate protection from theft, until such time as the controlled substances are transferred to another registrant. A copy of this inventory shall be placed with the controlled substances, and a copy retained by the discontinuing registrant.

(b) A complete inventory of all controlled substances on hand shall be performed at the time of a change in pharmacist-in charge.

HISTORY: Formerly R. 61-4.306. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.702 was titled "Schedule II".

703. Annual Inventory Date.

Inventories shall be taken on May 1st of each year unless written permission for another date is granted by the Bureau of Drug Control. If permission for another date is granted, the registrant shall maintain documentation of such permission for a period of two (2) years. In the event that a person commences business with no controlled substances on hand, he or she shall record this fact as his or her initial inventory.

HISTORY: Formerly R. 61-4.307. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.703 was titled "Schedule III".

704. Inventories of Manufacturers.

Each registered manufacturer shall include the following information in his or her inventory:

(a) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form:

(1) The name of the substance; and

(2) The total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971), avoirdupois weights may be utilized where metric weights are not readily available)

(b) For each controlled substance in the process of manufacture on the inventory date:

(1) The name of the substance;

(2) The quantity of the substance in each batch and/or state of manufacture, identified by the batch number or other appropriate identifying number;

(3) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of volume thereof.

(c) For each controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form of the substance (e.g. 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(3) The number of units or volume of each finished form in each commercial container (e.g. 100-tablet bottle or 3-milliliter vial); and

(4) The number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials).

(d) For each controlled substance not included in paragraphs (a), (b), or (c) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounding):

(1) The name of the substance;

(2) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(3) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

HISTORY: Formerly R. 61–4.308. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.704 was titled "Schedule IV".

705. Inventories for Distributors.

Each registered distributor shall include in his or her inventory the same information required of manufacturers pursuant to §§ 704(c) and (d).

HISTORY: Formerly R. 61–4.309. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.705 was titled "Schedule V".

706. Inventories of Dispensers and Researchers.

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to § 601 shall include in his or her inventory the same information required of manufacturers pursuant to §§ 704 (c) and (d). In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(a) If the substance is listed in schedule I or II, he or she shall make an exact count or measure of the contents; and

(b) If the substance is listed in schedule III, IV, V, he or she shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he or she shall make an exact count of the contents. If estimated counts are utilized, quantities shall be recorded as number of finished doses per container. Fractions of containers may not be utilized.

(c) It is the responsibility of the registrant to determine that any estimates are accurate, as audit procedures will be based upon the inventories maintained by the registrant. The Bureau of Drug Control utilizes exact counts in all audit procedures, and will allow only minor leeway for estimated inventories.

HISTORY: Formerly R. 61–4.310. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.706 was titled "Application for exclusion of a non-narcotic substance".

707. Inventories of Importers and Exporters.

Each registered importer or exporter shall include in his or her inventory the same information required of manufacturers pursuant to §§ 704(a), (c), and (d). Each registered importer or exporter who is also registered as a manufacturer or as a distributor shall include in his or her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his or her stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

HISTORY: Formerly R. 61–4.311. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.707 was titled "Excluded substances".

708. Inventories for Chemical Analysis.

Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers pursuant to §§ 704 (a), (c), and (d) as to substances which have been manufactured, imported, or received by the laboratory conducting the inventory. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in schedule I), or less than 20 grams of a hallucinogenic substance listed in schedule I (other than lysergic acid diethylamide), or less than 0.5 grams of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory.

HISTORY: Formerly R. 61-4.312. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.708 was titled "Application for exception of a stimulant or depressant compound".

709. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.709 was entitled "Excepted compounds".

**PART 800.
CONTINUING RECORDS.**

801. General Requirements for Continuing Records.

(a) On and after June 17, 1971 every registrant required to keep records pursuant to § 602 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him or her, except that no registrant shall be required to maintain a perpetual inventory, except as provided in paragraph (e) of this section.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 602. In the event controlled substances are in the possession or under the control of a registrant at a location for which he or she is not registered, the substance shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he or she is registered, except as provided in § 804.

(d) In recording dates of receipt, importation, distribution, exportation or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any packing slips.

(e) DHEC, upon a finding that a registrant has maintained inadequate records, or upon a finding that the registrant has a history of poor or inadequate record keeping, may, in its discretion, require perpetual inventories of all or a part on the controlled substances possessed or otherwise utilized or handled by such registrant (or an applicant for new registration having a history of record keeping deficiencies) as a condition for granting or renewing controlled substances registration. DHEC, upon a finding that adequate record keeping has been maintained for two or more years, pursuant to a perpetual inventory requirement, may remove the requirement and permit the registrant to resume standard record keeping activities with or without a probationary period of registration, as DHEC deems proper.

HISTORY: Formerly R. 61-4.313. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.801 was titled "Hearings".

802. Records of Manufacture.

Each registered manufacturer shall maintain records with the following information.

(a) For each controlled substance in bulk form to be used, or capable of use in, or being used in, the manufacture of the same or other controlled or non-controlled substance in finished form:

(1) The name of the substance;

(2) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him or her, including the date, quantity, and import permit or declaration number for each importation;

(5) The quantity used to manufacture the same substance in finished form, including:

(i) The date and batch or other identifying number of each manufacturer;

(ii) The quantity used in the manufacture;

(iii) The finished form (e.g., 10-milligram tablets or 10 milligram concentrate per fluid ounce or milliliter);

(iv) The number of units of finished form manufactured;

(v) The quantity used in quality control;

(vi) The quantity lost during manufacturing and the causes thereof, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields; and

(ix) Such other information as is necessary to account for all controlled substances used in the manufacturing process.

(6) The quantity used to manufacture other controlled and non-controlled substances, including the name of each substance manufactured and the information required in subparagraph (5) of this paragraph;

(7) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(8) The quantity exported directly the registrant (under a registration as an exporter), including the date quantity, and export permit or declaration number of each exportation;

(9) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed.

(b) For each controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(3) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to subparagraph (5) of paragraph (a) of this section;

(4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the registrant (under a registration as an importer), including the date of and the number of units and for commercial containers to each importation;

(6) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

- (i) The date and batch or other identifying number of each manufacturer;
- (ii) The operation performed (e.g., repackaging or re-labeling);
- (iii) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes therefore, if known; and
- (iv) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(7) The number of commercial containers distributed to other persons, including the date and number of containers in each distribution, and the name, address, and registration number of the person to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

HISTORY: Formerly R. 61-4.314. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

803. Records for Distributors.

Each registered distributor shall maintain records with the following information for each controlled substance:

- (a) The name of the substance;
- (b) Each finished form (e.g. 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
- (c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration of the person from whom the containers were received;
- (d) The number of commercial containers of each such finished form imported directly by the registrant (under a registration as an importer), including the date of and the number of containers in each importation;
- (e) The number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;
- (f) The number of commercial containers of such finished form exported directly by the registrant (under a registration as an exporter), including the date of and the number of containers of each exportation; and
- (g) The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution as complimentary samples), including the date and manner of distribution or disposal, the name and address, and registration number of the person to whom distributed or disposed.

HISTORY: Formerly R. 61-4.315. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

804. Records for Dispensers and Researchers.

Each person registered to dispense or conduct research with controlled substances required to keep records pursuant to § 602 shall maintain records with the following information for each controlled substance:

- (a) The name of the substance;

(b) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;

(d) The number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the dispenser; and

(e) The number of units or volume of such finished form and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

HISTORY: Formerly R. 61–4.316. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

805. Records for Importers.

Each registered importer shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume), and import permit or declaration number for each importation;

(c) The quantity (or number of units or volume in finished form) distributed to other persons, including the date and quantity (or number of units or volume) of each distribution and the name, address, and registration number of each person to whom a distribution was made; and

(d) The quantity disposed of in any other manner by the registrant, except quantities used for manufacturing by an importer under a registration as a manufacturer, which quantities are to be recorded pursuant to § 802(a)(4) or (b)(5) including the date and manner of disposal and the quantities disposed.

HISTORY: Formerly R. 61–4.317. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

806. Records of Exporters.

Each registered exporter shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) The quantity or number of units (or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address, and registration number of each person from whom the substance was received;

(c) The quantity (or number of units or volume in finished form) exported, including the date, quantity or number of units or volume, and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to § 802 (a)(8) or (b)(8); and

(d) The quantity disposed of in any other manner by the registrant including the date and manner of disposal and the quantity disposed.

HISTORY: Formerly R. 61–4.318. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

807. Records for Chemical Analysis.

(a) Each person registered to conduct chemical analysis with controlled substances shall maintain records, with the following information (to the extent known and reasonably ascertainable by him or her) for each controlled substance:

(1) The name of the substance;

(2) The form or forms in which the substance is received, imported, or manufactured by the registrant (e.g., powder, granulation, tablet, capsules, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., 10-milligram concentration per milliliter);

(3) The total number of the forms received, imported, or manufactured (e.g., 100 tablets, thirty 1-milliliter vials, or 10 grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and registration number, if any, of the person from whom the substance was received;

(4) The quantity distributed, exported, or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation or destruction, and the name, address, and registration number, if any, of each person to whom the substance was distributed or exported.

(b) Order forms, import and export permits, import invoices, and export declarations, relating to controlled substances shall be maintained separately from all other records of the registrant.

(c) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(d) Records relating to known or suspected controlled substances received as samples for analysis are not required under paragraph (a) of this section.

HISTORY: Formerly R. 61–4.319. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

808. Reports.

Manufacturers, re-packers, re-labelers, importers, exporters, and distributors who are required to report to ARCOS systems of the DEA, U.S. Department of Justice, need not file copies of such reports with the Bureau of Drug Control, but such registrants shall make copies of the reports available to the Bureau of Drug Control upon its written or oral request. Substantial compliance with the provisions of 21 CFR §§ 1304.31 through 1304.33 shall be deemed sufficient compliance with state reporting requirements.

HISTORY: Formerly R. 61–4.320. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

809. Records for Maintenance Treatment Programs and Detoxification Treatment Programs.

(a) Each person registered or authorized by DHEC to maintain and/or detoxify controlled substances users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

- (1) Name of substance;
- (2) Strength of substance;
- (3) Dosage form;
- (4) Date dispensed;
- (5) Adequate identification of the patient (consumer);
- (6) Amount consumed;
- (7) Amount and dosage form taken home by patient; and
- (8) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with § 804 without reference to § 602.

(c) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use, shall keep a separate batch record of the compounding.

(d) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by this regulation and any other state or federal law or regulation.

HISTORY: Formerly R. 61–4.321. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

810. Records for Treatment Programs Which Compound Narcotics for Treatment Programs and Other Locations.

Each person registered or authorized under the provisions of Section 107 of this Regulation to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:

(a) For each narcotic controlled substance in bulk form to be used in, or capable of being used in, or being used in the compounding of the same or other non-controlled substances in finished form:

- (1) The name of the substance;
- (2) The quantity compounded in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch compounded;
- (3) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;
- (4) The quantity imported directly by the registrant (under a registration as an importer) for use in compounding by him or her, including the date, quantity, and import permit or declaration number of each importation;
- (5) The quantity used to compound the same substance in finished form, including:
 - (i) The date and batch or other identifying number of each compounding;
 - (ii) The quantity used in the compound;
 - (iii) The finished form (e.g., 10-milligram tablets; 10 mg/ml per fluidounce, etc.);
 - (iv) The number of units of finished form compounded;
 - (v) The quantity used in quality control;
 - (vi) The quantity lost through compounding and the causes therefore, if known;
 - (vii) The total quantity of the substance contained in the finished form;
 - (viii) The theoretical and actual yields;
 - (ix) Such other information as is necessary to account for all controlled substances used in the compounding process;
- (6) The quantity used to manufacture other controlled and non-controlled substances, including the name of each substance manufactured and the information required in paragraph (a) (5) of this section;
- (7) The quantity distributed in bulk form to other programs, including the date and quantity of each distribution, and the name, address, and registration number of each program to whom a distribution was made;
- (8) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation; and
- (9) The quantity disposed of by destruction, including the reason, date, and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1501.

(b) For each narcotic controlled substance in finished form:

- (1) The name of the substance;
- (2) Each finished form and the number of units or volume or finished form in each commercial container (e.g., 100-tablet bottle or 3 ml. ampoule, etc.);
- (3) The number of containers of each such commercial finished form compounded from bulk form by the registrant, including the information required by paragraph (a) (5) of this section;
- (4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;
- (5) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of

units and/or commercial containers in, and the import permit or declaration number for, each importation;

(6) The number of units and/or commercial containers compounded by the registrant from units in finished form received from others or imported, including:

(i) The date and batch or other identifying number of each compounding.

(ii) The operation performed (e.g., repackaging or re-labeling);

(iii) The number of units of finished form used in the compound, the number compounded, and the number lost during compounding, with the causes for such losses, if known;

(iv) Such other information as is necessary to account for all controlled substances used in the compounding process.

(7) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address, and registration number of the program to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers, and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date, and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1501.

HISTORY: Formerly R. 61–4.322. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

811. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.811 was entitled "Execution of warrants". See now R. 61–4.1608.

812. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.812 was entitled "Refusal to allow inspection with an administrative warrant". See now R. 61–4.1609.

814. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.814 was entitled "Confidentiality of research subjects". See now R. 61–4.1701.

815. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.815 was entitled "Exemption from prosecution for researcher". See now R. 61–4.1702.

816. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.816 was entitled "Authority for enforcement proceeding". See now R. 61–4.1801.

817. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.817 was entitled "Notice of proceeding; time and place". See now R. 61–4.1802.

818. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61–4.818 was entitled "Conduct of proceeding". See now R. 61–4.1803.

PART 900.
ORDER FORMS.

901. Execution of Order Forms.

DEA Form 222 as issued by the DEA, U.S. Department of Justice, as required by the Federal Controlled Substances Act (21 USC 828) when properly executed and filed will be deemed a sufficient order form as required by the Act.

HISTORY: Formerly R. 61-4.401. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

902. Handling and Filing.

Handling and filing of order forms, and electronic orders, shall be accomplished in the manner provided under Part 1305, 21 C.F.R. (Regulations of the DEA, United States Department of Justice.)

HISTORY: Formerly R. 61-4.402. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

903. Power of Attorney.

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his or her behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed (or was authorized to sign) the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked. The forms are available from Director of the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201.

HISTORY: Formerly R. 61-4.403. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

904. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.904 was entitled "Damaged controlled substances".

905. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.905 was entitled "Responsibility for controlled substances". See now R. 61-4.1904.

906. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.906 was entitled "Prescriptions not required on floor-stocked Controlled Substances". See now R. 61-4.1905.

907. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.907 was entitled "Registry number". See now R. 61-4.1906.

908. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.908 was entitled "Telephone orders". See now R. 61-4.1907.

909. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.909 was entitled "Verbal orders". See now R. 61-4.1908.

910. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.910 was entitled "Controlled substances records". See now R. 61-4.1909.

911. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.911 was entitled "Procedure in case of waste, destruction, contamination, etc". See now R. 61-4.1910.

912. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.912 was entitled "Procedures in case of loss, theft, etc". See now R. 61-4.1911.

914. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.914 was entitled "Controlled substances of physician's office or bag". See now R. 61-4.1912.

915. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.915 was entitled "Dispensing to outpatients". See now R. 61-4.1913.

916. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.916 was entitled "Administering to outpatients". See now R. 61-4.1914.

916.1. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.916.1 was entitled "Emergency Rooms". See now R. 61-4.1915.

917. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.917 was entitled "Storage of controlled substances". See now R. 61-4.1916.

918. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.918 was entitled "Dispensing of controlled substances to employees of hospitals".

919. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.919 was entitled "Availability of records for inspectors.". See now R. 61-4.1917.

920. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.920 was entitled "Labeling of substances. (Schedule II)". See now R. 61-4.1918.

921. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.921 was entitled "Labeling of substances. (Schedules III, IV, V)". See now R. 61-4.1919.

922. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.922 was entitled "Clarification and intent". See now R. 61-4.1920.

923. Deleted by State Register Volume 37, Issue No. 6, eff June 28, 2013.

Editor's Note

Former R. 61-4.923 was entitled "Consultation procedure". See now R. 61-4.1921.

**PART 1000.
PRESCRIPTIONS.**

1001. Persons Entitled to Issue Prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) Licensed by the S.C. Board of Medical Examiners, S.C. Board of Dentistry, S.C. Board of Veterinary Medicine Examiners, S.C. Board of Nursing, S.C. Board of Examiners in Optometry, or the S.C. Board of Podiatry Examiners, and is authorized to prescribe under the type of license issued by the pertinent Board to the individual practitioner; and

(2) Acting in the regular course of professional practice, e.g., a veterinarian prescribing for a human is not within the regular course of professional practice, nor is a dentist when prescribing for illnesses or disease other than those of the oral cavity and adjacent tissues, nor is a podiatrist when prescribing for treatment of disease other than those manifesting themselves in the foot; and

(3) Registered with DHEC under the provisions of the Act.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner. The individual practitioner may not delegate the act of prescribing (i.e., the decision-making process whether to issue a prescription, what drug or substance to prescribe, what dosage, what frequency, and whether to refill the prescription) to a person not authorized to issue a prescription in his or her own right as an individual practitioner.

Example: A nurse or other employee of a physician may transmit an oral prescription (if permissible as a Schedule III, IV, or V substance) to a pharmacist if authorized to do so by the prescribing physician; the transmitting person has no authority to make any change whatsoever in the order of the practitioner, nor to add or delete any information to be transmitted.

HISTORY: Formerly R. 61-4.503. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1002. Purpose of Issue of Prescription.

(a) A prescription for a controlled substance to be effective shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his or her dependence upon such

drugs whether or not in the course of conducting an authorized clinical investigation in the development of a narcotic rehabilitation program.

HISTORY: Formerly R. 61–4.504. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1003. Manner of Issuance of Prescription.

All prescriptions for controlled substances shall be dated as of the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address, and registration number of the practitioner.

(a) Written prescriptions. A practitioner shall sign a prescription on the day when issued and in the same manner as he or she would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter, or other mechanical means of printing, and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this regulation. See also § 1001(b).

(b) Electronic prescriptions. Existing DEA regulations provide practitioners with the option of transmitting electronic prescriptions for controlled substances in lieu of paper prescriptions. In an effort to ensure the integrity of these electronic prescriptions, the electronic application shall comply with the current DEA regulations prior to use.

HISTORY: Formerly R. 61–4.505. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1004. Registration Number Required on Prescriptions.

All prescriptions for controlled substances, whether written by the practitioner or telephoned and subsequently reduced to writing, shall bear the Federal Controlled Substances Registration Number (DEA Number) of the prescribing practitioner.

HISTORY: Formerly R. 61–4.505.1. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1005. Persons Entitled to Fill Prescriptions.

A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his or her professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

HISTORY: Formerly R. 61–4.506. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1006. Information Required for Filled Prescriptions.

A notation shall be placed upon any prescription for controlled substances when originally filled that shall indicate the date filled, the identity or initials of the pharmacist dispensing the prescription and, if different from the quantity prescribed, the quantity dispensed.

HISTORY: Formerly R. 61–4.506.1. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1007. Dispensing of Narcotic Drugs for Maintenance Purposes.

The administering or dispensing directly (but not prescribing of) narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his or her dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term “in the course of his or her professional practice or research” in the Act, provided, that approval is obtained prior to the initiation of such a program by submission of a Notice of Claimed Investigational Exemption for a New Drug to the Food and Drug Administration which will be reviewed concurrently by the Food and Drug Administration for scientific merit and by the DEA for drug control requirements, and that the clinical investigation thereafter accords with such approval.

HISTORY: Formerly R. 61–4.507. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1008. Federal Approval of Maintenance Programs Required.

DHEC will not register any person to conduct an authorized maintenance program for drug dependent persons until approval of such program has been made by the appropriate federal agencies. Upon approval by these agencies, the Bureau of Drug Control shall accept the application for registration as complete.

HISTORY: Formerly R. 61-4.507.1. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1009. Withdrawal of Drug Dependent Persons by Use of Methadone or Other Narcotic Controlled Substances.

Practitioners desiring to withdraw, but not maintain, drug dependent persons addicted to narcotic controlled substances from such substances by the use of methadone or any other schedule II narcotic controlled substance, may do so provided that all of the following criteria are met:

- (a) The drug dependent person shall be a narcotic addict.
- (b) The drug dependent person shall be confined to a hospital, clinic, rest home, or other appropriate location that properly segregates the drug dependent person from contact with possible illicit suppliers.
- (c) The withdrawal program shall be on a reducing dosage basis, preferably through use of oral administration of the narcotic controlled substance used for withdrawal.
- (d) Withdrawal treatment shall not exceed 21 days in length and shall not be available to any drug dependent person more often than once every six months. If, in the opinion of the withdrawing practitioner, longer periods of withdrawal treatment are necessary, application for such longer treatment shall be made to the Director stating the reasons therefore, along with pertinent medical facts including, but not limited to, the following:
 - (1) Medical condition of subject at onset of withdrawal treatment;
 - (2) Amount of drug intake and name of drug at onset of treatment;
 - (3) Initial withdrawal dosage of methadone (or other narcotic controlled substance);
 - (4) Reduction schedule of withdrawal substance;
 - (5) Current medical evaluation of withdrawal regimen;
 - (6) Statement concerning presence or absence from urine sample of drug dependent person of the drug to which he or she was addicted; and
 - (7) Any other pertinent facts deemed necessary by the withdrawing practitioner or by the Director.
- (e) Any maintenance facility shall be approved by DHEC and the appropriate federal agencies.

HISTORY: Formerly R. 61-4.507.2. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1010. Approved Uses of Methadone in Hospitals. Methadone is Approved for the Following Uses for Inpatients of Hospitals Licensed by DHEC.

- (a) Analgesia;
- (b) Pertussis;
- (c) Detoxification (withdrawal) of drug dependent persons under conditions set forth in Section 1009 of this regulation; or
- (d) Temporary maintenance of methadone treatment of a drug dependent person enrolled in a methadone maintenance program licensed by any state or the federal government while such person is institutionalized within a licensed hospital for medical treatment of an illness or malady medically unrelated to drug dependence.

HISTORY: Formerly R. 61-4.507.3. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1011. Departmental Approval; When Required.

- (a) Prior approval by DHEC for methadone use as set forth in § 1010 of this regulation is not required.

(b) Prior approval of DHEC and registration as provided by Title 21, § 1301.22(a)(6) of the Code of Federal Regulations and S.C. Code Ann. § 44-53-290(i), is required of all persons desiring to operate a treatment program utilizing methadone (i.e., a “methadone maintenance program”).

(c) Prior approval by DHEC in the manner set forth by § 1012 of this regulation is not required to dispense methadone to outpatients of a hospital licensed by DHEC. Prior approval of DHEC is not required for “take home” methadone preparations which are lawfully dispensed by a methadone maintenance treatment facility.

(d) Approvals by DHEC, as required by §§ 1009 through 1012 of this regulation, may be granted by the Bureau of Drug Control in its discretion. If the Bureau finds that it cannot approve a request, the request shall be submitted to the Director, along with the Bureau’s reasons for non-approval. The Director, in his or her discretion, may then approve or deny the request, but if he or she shall deny such request, the person making the request shall be entitled to a hearing to determine the public interest, in the manner provided for “contested cases” in the South Carolina Administrative Procedures Act.

(e) DHEC may require further information from any applicant in order to obtain sufficient information to be utilized in approving or denying any request.

HISTORY: Formerly R. 61–4.507.4. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1012. Treatment of Outpatients with Methadone.

(a) If a physician determines that methadone would be the drug of choice as an analgesic for a particular patient, the physician may issue prescriptions for methadone to the patient. Such prescriptions may be dispensed by any pharmacy that has agreed to perform such dispensing function.

(b) The treating physician shall agree to maintain adequate records to substantiate the use of methadone as an analgesic for the patient and shall make such records available to DHEC upon request.

HISTORY: Formerly R. 61–4.507.5. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 1100.

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II.

1101. Requirement of Prescription.

(a) A pharmacist may dispense directly a controlled substance listed in schedule II, which is a prescription drug as determined under the Act, pursuant to one of the following methods:

- (1) As a written prescription signed by the prescribing individual practitioner;
- (2) As an electronic prescription transmitted in accordance with § 1003(b); or
- (3) As provided in paragraphs (d) through (g) of this section.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule II in the course of his or her professional practice without a prescription subject to § 1006.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

- (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period shall be pursuant to a written prescription signed by the prescribing individual practitioner);
- (2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information requested in § 1003 except for the signature of the prescribing individual practitioner;
- (3) If the prescribing individual practitioner is not known to the pharmacist, he or she shall make a reasonable effort to determine that the oral authorization came from a registered individual

practitioner, which may include a callback to the prescribing individual practitioner using his or her phone number as listed in the telephone directory and/or other good faith efforts to insure his or her identity; and

(4) Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1003, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it shall be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Bureau Director if the prescribing individual practitioner fails to deliver a written prescription to him or her; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(e) A prescription prepared in accordance with § 1003 written for a Schedule II narcotic controlled substance, to be compounded for the direct administration to a patient by parenteral, intravenous, intra-muscular, subcutaneous or intra-spinal infusion, may be transmitted by the practitioner or the practitioner's agent by facsimile to a home infusion pharmacy. The facsimile serves as the original prescription for the purposes of this paragraph (e) and it shall be maintained in accordance with § 603. The written, signed prescription shall be maintained in the medical record of the patient.

(f) A prescription prepared in accordance with § 1003 written for a Schedule II substance for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with Section 603 (d). The written, signed and voided prescription shall be maintained in the medical record of the patient. This paragraph (f) is not applicable to prescriptions issued for residents of community residential care facilities or assisted living facilities.

(g) A prescription prepared in accordance with § 1003 written for a Schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII of the Social Security Act, or a hospice program which is licensed by DHEC may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and shall be maintained in accordance with § 603 (d). The written, signed, and voided prescription shall be maintained in the medical record of the patient.

HISTORY: Formerly R. 61-4.508. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1102. Limitations on Prescriptions for Schedule II Substances.

Prescriptions for schedule II controlled substances shall not be issued for more than a thirty-one day supply of the substance. No prescription for schedule II controlled substances shall be dispensed later than 90 days from the date of issue.

HISTORY: Formerly R. 61-4.508.1. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1103. Practitioner-Patient Relationship Required.

Prior to the issuance of a prescription for, or the direct dispensing of any schedule II controlled substances, the prescribing practitioner shall have a valid practitioner-patient relationship established with the recipient of the prescription, such relationship to include, but not be limited to, a sufficient knowledge of the medical need of the patient for such schedule II controlled substance, determination of the benefit to risk ratio of the use of such substance, good faith determination of the identity and address of the patient, a determination of the physical condition of the patient, and such practitioner shall be in personal attendance of the patient at the time of issuance of the prescription. Any prescription issued by any practitioner for any person outside of the reasonable bounds of a practitioner-patient relationship shall be deemed issued other than in the course of professional practice required by the Act. A practitioner cannot usually acquire a valid patient-practitioner relationship with himself or herself, or with a member of his or her immediate family, due to the

likelihood of the loss of or the vitiation of the objectivity required in making the necessary medical decisions in order to properly prescribe or dispense controlled substances. The practitioner may not be able to acquire a sufficient practitioner-patient relationship with non-family members (i.e., fiancé or fiancée, close personal friend, paramour, etc.) if total objectivity in deciding to prescribe or dispense controlled substances cannot be maintained due to such factors as extreme compassion, ardor, extortion, etc. which would vitiate such objectivity. In the event of a bona fide emergency situation, where great detriment to the health or safety of a patient may be involved, a practitioner may administer, dispense or prescribe limited amounts of controlled substances to any person, notwithstanding the provisions of this Section, until such time as another objective practitioner can be contacted.

HISTORY: Formerly R. 61-4.508.2. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1104. Refilling Prescription.

The refilling of a prescription for a controlled substance listed in schedule II is prohibited.

HISTORY: Formerly R. 61-4.509. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1105. Partial Filling of Prescription.

(a) The partial filling of a prescription for a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) Prescriptions for schedule II controlled substances issued for patients in long term care facilities (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities, to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is "terminally ill" or LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial dispensing, the pharmacist shall record on the back of the prescription the date of the partial dispensing, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial dispensings shall not exceed the total quantity prescribed. Schedule II prescriptions, for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication. This paragraph (b) is not applicable to prescriptions issued for residents of community residential care facilities or assisted living facilities.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, identification of LTCF, identification of medication authorized (to include dosage form, strength and quantity), listing of partial dispensings that have been dispensed under each prescription and the information required in paragraph (b) of this section.

(2) Immediate (real time) updating of the prescription record each time a partial dispensing of the prescription is conducted.

(3) Retrieval of partially dispensed Schedule II prescription information is the same as required by §§ 1202(b)(4) and (5) for Schedule III, IV, and V prescription refill information.

HISTORY: Formerly R. 61-4.510. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1106. Labeling of Substance.

The pharmacist filling a written or emergency oral prescription for a controlled substance listed in schedule II shall affix to the package a label showing the drug name, the quantity dispensed, the date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law. See also § 1918.

HISTORY: Formerly R. 61-4.511. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1107. Filing of Prescriptions.

All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of § 603.

HISTORY: Formerly R. 61-4.512. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 1200.

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV, AND V.

1201. Requirement of Prescription.

(a) A pharmacist may dispense a controlled substance listed in schedule III, IV, or V which is a prescription drug as determined under the Act, only pursuant to one of the following methods:

(1) A written prescription signed by a prescribing individual practitioner;

(2) An electronic prescription transmitted in accordance with § 1003(b);

(3) An oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1003, except for the signature of the prescribing individual practitioner; or

(4) A facsimile of a written, signed prescription, transmitted by the practitioner or the practitioner's agent to the pharmacy. A prescription transmitted by facsimile must be received at the pharmacy as it was originally transmitted by facsimile and must include the name and address of the practitioner, the phone number for verbal confirmation, the time and date of transmission, and the name of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law.

(b) An individual practitioner may administer or dispense a controlled substance listed in schedule III, IV, or V in the regular course of his or her professional practice without a prescription.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule III, IV, or V pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 1003 except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

HISTORY: Formerly R. 61-4.513. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1202. Refilling of Prescriptions.

(a) No prescription for a controlled substance listed in schedule III, IV, or V shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription may be refilled more than five times. Additional quantities of controlled substances listed in schedule III, IV, or V may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in § 1201 which shall be a new and separate prescription.

(b) An automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedules III, IV, and V, subject to the following conditions:

(1) Any such proposed computerized system shall provide online retrieval (via CRT display or hard-copy printout) information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to data such as the original prescription number, date

of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized system shall also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III, IV, or V controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV, or V controlled substance is correct shall be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy of each day's controlled substance prescription order refill data, that print-out shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist shall verify that the data indicated is correct and then sign this document in the same manner as he or she would sign a check or legal document (e.g. J.H. Smith or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It shall be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him or her and is correct as shown. Such a book or file shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized system shall have the capability of producing a print-out of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulation. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both.) Such a print-out shall indicate name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist and the number of the original prescription order. In any computerized system employed by a user pharmacy the central record-keeping location shall be capable of sending the print-out to the pharmacy within 48 hours, and if a DEA Special Agent or compliance Investigator or an Inspector from DHEC requests a copy of such print-out from the user pharmacy it shall, if requested to do so by the Agent, Investigator, or Inspector verify the print-out transmittal capability of its system by documentation (e.g. postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy shall have an auxiliary procedure which will be used for the documentation of refills of Schedule III, IV, and V controlled substance prescription orders. This auxiliary procedure shall insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(c) When filing refill information for original prescription orders for Schedule III, IV, or V controlled substances, a pharmacy may use the system described in either paragraph (a) or (b) of this section.

HISTORY: Formerly R. 61-4.514. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1203. Limitations on Prescriptions for Schedules III, IV, and V Substances.

Prescriptions for controlled substances listed in Schedules III, IV, and V shall not be issued for more than a 90 day supply of the substance. If authorized for refill, no prescription shall be refilled sooner

than 48 hours prior to the time that the prescription should be consumed if the prescribed daily dosage is divided into the total prescribed amount. (Example: 4 daily divided into 100 dosage units = 25 days.) Carry over time shall not accrue between refills. In the event that the practitioner does not specify an exact daily dosage, the dispenser shall calculate date of refill from the usual daily dosage recommended by the manufacturer of the controlled substance.

HISTORY: Formerly R. 61-4.514.1. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1204. Practitioner-Patient Relationship Required.

Prior to the issuance of a prescription for controlled substances listed in Schedule III, IV, or V the prescribing practitioner shall have a valid practitioner-patient relationship established with the recipient of the prescription, such relationship to include, but not be limited to, a sufficient knowledge of the medical need of the patient for such schedule III, IV, or V controlled substance, determination of the benefit to risk ratio of the use of such substance, good faith determination of the identity and address of the patient, a determination of the physical condition of the patient, and such practitioner shall be in personal attendance of the patient at the time of issuance of the prescription. Any prescription issued by any practitioner for any person outside of the reasonable bounds of a practitioner-patient relationship shall be deemed issued other than in the course of professional practice required by the Act. A practitioner cannot usually acquire a valid patient-practitioner relationship with himself or herself, now with a member of his or her immediate family, due to the likelihood of the loss or vitiation of the objectivity required in making the necessary medical decisions in order to properly prescribe or dispense controlled substances. The practitioner may not be able to acquire a sufficient practitioner-patient relationship with non-family members (i.e., fiancé or fiancée, close personal friend, paramour, etc.) if total objectivity in deciding to prescribe or dispense controlled substances cannot be maintained due to such factors as extreme compassion, ardor, extortion, etc. which would vitiate such objectivity. In the event of a bona fide emergency situation, where great detriment to the health or safety of a patient may be involved, a practitioner may administer, dispense or prescribe limited amounts of controlled substances to any person, notwithstanding the provisions of this Section, until such time as another objective practitioner can be contacted.

HISTORY: Formerly R. 61-4.514.2. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1205. Partial Filling of Prescriptions.

The partial filling (dispensing) of a prescription for a controlled substance listed in Schedules III, IV, or V is permissible, provided that:

- (a) Each partial filling is recorded in the same manner as a refilling;
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
- (c) No dispensing occurs after six months from the date on which the prescription was issued.

HISTORY: Formerly R. 61-4.514.3. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1206. Labeling of Substances.

The pharmacist filling a prescription for a controlled substance listed in schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the drug name, the quantity dispensed, the serial number of the prescription and the date of the initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescriptions as required by law.

HISTORY: Formerly R. 61-4.515. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1207. Filing Prescriptions.

All prescriptions for controlled substances listed in schedules III, IV, and V shall be kept in accordance with § 603.

HISTORY: Formerly R. 61-4.516. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1208. Controlled Substances Listed in Schedule V - Dispensing Without a Prescription.

A controlled substance in Schedule V, which is not a prescription drug as determined under the Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such distribution is made only by a pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his or her professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist):

(b) Not more than 120 ml. (4 ounces) of any controlled substance listed in Schedule V may be distributed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least 18 years of age;

(d) The pharmacist requires every purchaser of a controlled substance listed in Schedule V not known to him or her to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for distributions of controlled substances listed in Schedule V (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who distributed the substance to the purchaser (the book shall be maintained in accordance with the record keeping requirement of § 603 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to the Act or any other law.

(g) Repetitive sales without prescription of Schedule V controlled substances without positive determination of medical need by the pharmacist selling the non-prescription controlled substance shall be deemed dispensing for other than medical purposes, and shall be prima facie evidence of detriment to the public health and safety.

HISTORY: Formerly R 61-4.518. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 1300. MISCELLANEOUS.

1301. Severability.

If a provision of any section of Part 100 through 1900 of this regulation is held invalid, all valid provisions that are severable shall remain in effect. If a provision of any of this regulation is held invalid in one or more of its applications, the provision shall remain in effect in all its valid applications that are severable.

HISTORY: Formerly R. 61-4.601. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1302. Application of Other Laws.

Nothing in this regulation shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under federal laws or obligations under international treaties, conventions or protocols, or under the law of the state in which he desires to do such act nor shall compliance with such Parts be construed as compliance with other federal or state laws unless expressly provided in such other laws.

HISTORY: Formerly R. 61-4.602. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1303. Exceptions in Regulations.

Any person may apply for an exception to the application of any provision of these regulations by filing a written request stating the reasons for such exception. Requests shall be filed with the Bureau Director. The Bureau Director may grant an exception in his or her discretion, but in no case shall he or she be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

HISTORY: Formerly R. 61-4.603. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 1400.

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES.

1401. Distribution by Dispenser to Another Practitioner.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the purpose of general dispensing by the practitioner to his or her patients, provided that:

(1) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(2) The distribution is recorded by the distributing practitioner in accordance with § 804(e) of this regulation and by the receiving practitioner in accordance with § 804(c) of this regulation;

(3) If the substance is listed in Schedule I or II, an order form (DEA Form 222) is used as required by Part 4 of this regulation;

(4) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section during any 12 month period does not exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the twelve month period. Registrants in existence less than 12 months shall prorate the time period, and shall not distribute more than five percent of the dispensings for any monthly period.

(b) If, at any time during any consecutive 12 month period during which the practitioner is registered to dispense, there is reason to believe that the total number of dosage units of all controlled substance which will be distributed by him or her pursuant to this section will exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by him or her during the 12 month period, the practitioner shall obtain a registration to distribute controlled substances.

HISTORY: Formerly R. 61–4.604.1. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1402. Manufacture and Distribution of Narcotic Solutions and Compounds by a Pharmacist.

As an incident to a distribution under § 1401, a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20 percent of the complete solution, compound, or mixture.

HISTORY: Formerly R. 61–4.605. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1403. Distribution to Supplier.

Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he or she obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance listed in schedule I or II, an order form shall be used in the manner prescribed in Part 900 of these regulations and be maintained as the written record of the transaction.

HISTORY: Formerly R. 61–4.606. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1404. Distribution upon Discontinuance or Transfer of Business.

(a) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his or her South Carolina Controlled Substances Certificate of Registration to the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201. His or her Federal Controlled Substances Certificate of Registration and any un-executed order forms shall be returned to the DEA, 1835 Assembly Street, Suite 1229, Columbia, SC 29201.

(b) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (by transferring such business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to the Bureau Director at least 14 days in advance of the date of the proposed transfer (unless the Bureau Director waives this time limitation in individual instances), the following information:

(1) The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);

(2) The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);

(3) Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed);

(4) Whether the registrant-transferor has a quota to manufacture or procure any controlled substance listed in schedule I or II (if so, the basic class or class of the substance should be indicated); and

(5) The date on which the transfer of controlled substances will occur.

(c) Unless the registrant-transferor is informed by the Bureau Director, before the date on which the transfer was stated to occur, that the transfer may not occur, the registrant-transferor may distribute (without being registered to distribute) controlled substances in his or her possession to the registrant-transferee in accordance with the following:

(1) On the date of transfer of the controlled substances, a complete inventory of all controlled substances being transferred shall be taken in accordance with Part 700 of this Regulation. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with the Bureau of Drug Control unless requested by the Bureau Director. Transfers of any substances listed in schedules I or II shall require the use of order forms in accordance with Part 1305 of the Federal Regulations.

(2) On the date of transfer of the controlled substances, all records required to be kept by the registrant-transferor with reference to the controlled substances being transferred, under Parts 600 through 800 of this Regulation, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

(3) In the case of registrants required to make reports pursuant to Parts 600 through 800 of this Regulation, a report marked "Final" will be prepared and submitted by the registrant-transferor showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him or her, if no further transactions involving controlled substances are consummated by him or her. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant, and the substances transferred to him or her shall be reported as receipts in his or her initial report.

HISTORY: Formerly R. 61-4.607. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 1500.

DISPOSAL OF CONTROLLED SUBSTANCES.

1501. Procedure for Disposing of Controlled Substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Bureau Director for authority and instructions to dispose of such substance.

(b) The Bureau Director shall authorize and instruct the individual in possession to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By destruction in the presence of an agent of the Bureau of Drug Control or other authorized person, or

(3) By such other means as the Bureau Director may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Bureau Director may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Bureau of Drug Control in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Bureau Director summarizing the disposals made by the registrant. In granting such authority, the Bureau Director may place such condition as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

HISTORY: Formerly R. 61-4.609. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 1600. INSPECTIONS.

1601. Authority to Make Inspections.

In carrying out his or her functions under the Act, the Bureau Director, through his or her inspectors, is authorized in accordance with the Act to enter controlled premises and conduct administrative inspections thereof, for the purpose of:

(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and any regulations promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to Parts 600 through 800 of this chapter, order form records required to be kept pursuant to Part 900 of this chapter, prescription and distribution records required to be kept pursuant to Part Parts 1000 through 1200 of this chapter, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage;

(b) Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to this Act;

(c) Making a physical inventory of all controlled substances on hand at the premises;

(d) Collecting samples of controlled substances or precursors (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 84 to the owner, operator, or agent in charge of the premises);

(e) Checking of records and information on distribution of controlled substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased markedly within the past year, and if so, why); and

(f) Except as provided in § 1602, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder.

HISTORY: Formerly R. 61-4.803. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1602. Exclusion from Inspection.

(a) Unless the owner, operator, or agent in charge of the controlled premises so consents, no inspection authorized by the regulations shall extend to:

- (1) Financial data;
- (2) Sales data other than shipping data; or
- (3) Pricing data.

HISTORY: Formerly R. 61-4.804. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1603. Entry.

An inspection shall be carried out by an inspector. Any such inspector, upon:

- (a) Stating his or her purpose and

- (b) Presenting to the owner, operator, or agent in charge of the premises to be inspected:
 - (1) Appropriate credentials, or
 - (2) Written notice of his or her inspection authority under § 1601 and the Act, or
- (c) Receiving informed consent under § 1605 of this Regulation or through the use of administrative warrant issued under the Act shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

HISTORY: Formerly R. 61-4.805. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1604. Notice of Inspection.

The notice of inspection shall contain:

- (a) The name and title of the owner, operator, or agent in charge of the controlled premises;
- (b) The controlled premises name;
- (c) The address of the controlled premises to be inspected;
- (d) The date and time of the inspection;
- (e) A statement that a notice of inspection is given pursuant to the Act;
- (f) A reproduction of the pertinent parts of the Act; and
- (g) The signature of the inspector.

HISTORY: Formerly R. 61-4.806. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1605. Consent to Inspection.

(a) An administrative inspection warrant shall not be required if informed consent is obtained from the owner, operator, or agent in charge of the controlled premises to be inspected.

(b) Wherever possible, informed consent obtained by the inspector shall consist of a written statement signed by the owner, operator or agent in charge of the premises to be inspected.

(c) After August 17, 1974, informed consent may be shown by the production of a completed registration application or certificate, which shall contain printed thereon a preamble and conditions of registration.

HISTORY: Formerly R. 61-4.808. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1606. Application for Administrative Inspection Warrant.

(a) An administrative inspection warrant application shall be submitted to any judge or any magistrate and shall contain the following information:

- (1) The name and address of the controlled premises to be inspected;
- (2) A statement of statutory authority for the administrative inspection warrant, and that the fact that the particular inspection in question is designed to insure compliance with the regulations promulgated under those acts;
- (3) A statement relating to the nature and extent of the administrative inspection, including, where necessary, a request to seize specified items and/or to collect samples of finished or unfinished controlled substances;
- (4) A statement that the establishment either:
 - (i) Has not been previously inspected, or
 - (ii) Was last inspected on a particular date.

(b) The application shall be submitted under oath to an appropriate judge or magistrate.

HISTORY: Formerly R. 61-4.809. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1607. Administrative Probable Cause.

If the judge or magistrate is satisfied that “administrative probable cause” exists, he shall issue an administrative warrant. Administrative probable cause shall not mean criminal probable cause as defined by federal or state statute or case law.

HISTORY: Formerly R. 61-4.810. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1608. Execution of Warrants.

An administrative inspection warrant shall be executed and returned as required by, and any inventory or seizure made shall comply with the requirements of the Act. The inspection shall begin as soon as is practicable after the issuance of the administrative inspection warrant and shall be completed with reasonable promptness. The inspection shall be conducted during regular business hours and shall be completed in a reasonable manner.

HISTORY: Formerly R. 61-4.811. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1609. Refusal to Allow Inspection with an Administrative Warrant.

If a registrant or any person subject to the Act refuses to permit execution of an administrative warrant or impedes the inspector in the execution of that warrant, he shall be advised that such refusal or action constitutes a violation of the Act. If the individual persists and the circumstances warrant, he or she shall be arrested and the inspection shall commence or continue.

HISTORY: Formerly R. 61-4.812. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 1700.

PROTECTION OF RESEARCHERS AND RESEARCH SUBJECTS.

1701. Confidentiality of Research Subjects.

(a) Any person registered to conduct a bona fide research project with controlled substances under the Act who intends to maintain the confidentiality of those persons who are the subjects of such research, shall, upon registration or within a reasonable time thereafter, submit to the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201, a separate request for each research project involving controlled substances, which shall contain the following:

- (1) The researcher's registration number for that project;
- (2) The location of the research project;
- (3) A general description of the research or a copy of the research protocol;
- (4) A specific request to withhold the names and/or any other identifying characteristics of the research subjects; and
- (5) The reasons supporting the request.

(b) Within 60 days from the date of receipt of the request, the Bureau Director shall issue a letter, either granting confidentiality, requesting additional information or denying confidentiality, in which case the reasons for the denial shall be included. A grant of confidentiality shall be limited solely to the specific research project indicated in the request.

(c) Within 30 days after the date of completion of the research project, the researcher shall so notify the Bureau Director.

(d) In addition to the requirements set forth in paragraphs (a), (b), and (c) of this Section, the person requesting confidentiality of research subjects shall also provide the Bureau of Drug Control with a copy of the petition to the Attorney General of the United States required pursuant to the provisions of 21 CFR § 1316.23. In the event that the federal petition for confidentiality is not granted, or is withdrawn by the Attorney General of the United States, the Bureau of Drug Control shall, after notice to the researcher, remove its grant of confidentiality, if previously granted.

HISTORY: Formerly R. 61-4.814. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1702. Exemption from Prosecution for Researcher.

(a) Upon registration of a practitioner to engage in research in controlled substances under the Act, the Bureau of Drug Control, DHEC, on its own motion or upon request in writing from the Director or from the practitioner, may exempt the registrant when acting within the scope of his or her registration, from prosecution under State or local laws for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his or her exemption. However, this exemption does not diminish any requirement of compliance with the Federal Food, Drug and Cosmetic Act (21 USC 301, et seq.) or with the Federal Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801, et seq.).

(b) All petitions for Grants of Exemption from Prosecution for the Researcher shall be addressed to the Director, Bureau of Drug Control, SCDHEC, 2600 Bull Street, Columbia, SC 29201, and shall contain the following:

- (1) The researcher's registration number, if any, for the project;
- (2) The location of the research of the research project;
- (3) The qualifications of the principal investigator;
- (4) A general description of the research or a copy of the research protocol;
- (5) The source of funding for the research project;
- (6) A statement as to the risks posed to the research subjects by the research procedures and what measures of protection will be afforded to the research subjects;
- (7) A statement as to the risks posed to society in general by the research procedures and what measures will be taken to protect the interests of society;
- (8) A specific request for exemption from prosecution by Federal, State, or local authorities for offenses related to the possession, distribution, and dispensing of controlled substances in accord with the procedures described in the research protocol;
- (9) A statement establishing that a grant of exemption from prosecution is necessary to the successful completion of the research project;

(c) Any researcher or practitioner proposing to engage in research requesting both exemption from prosecution and confidentiality of identity of research subjects may submit a single petition incorporating the information required in §§ 1701 and 1702.

(d) The exemption shall consist of a letter issued by the Bureau Director, which shall include:

- (1) The researcher's name and address;
- (2) The researcher's registration number for the research project;
- (3) The location of the research project;
- (4) A concise statement of the scope of the researcher's registration; and
- (5) The limits of the exemption;

(6) The exemption shall apply to all acts done in the scope of the exemption while the exemption is in effect. The exemption shall remain in effect until completion of the research project or until the registration of the researcher is either revoked or suspended or his or her removal of registration is denied. However, the protection afforded by the grant of exemption from prosecution during the research period shall be perpetual.

(e) Within 30 days of the date of completion of the research project, the researcher shall so notify the Bureau Director. The Bureau Director shall issue another letter including the information required in paragraph (d) of this section and stating the date on which the period of exemption concluded; upon receipt of this letter, the researcher shall return the original letter of exemption.

HISTORY: Formerly R. 61-4.815. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 1800.

ADMINISTRATIVE CONFERENCES.

1801. Authority for Administrative Conferences.

An administrative conference may be ordered or granted by the Director of the Bureau of Drug Control, at his or her discretion, to permit any person against whom criminal and/or civil action is contemplated under the Act an opportunity to present his or her views and his or her proposals for bringing his or her alleged violations into compliance with the law. Such administrative conference will also permit him or her to show cause why prosecution should not be instituted, or to present his or her views on the contemplated proceeding.

HISTORY: Formerly R. 61-4.816. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1802. Notice; Time and Place.

Appropriate notice designating the time and place for the administrative conference shall be given to the person. Upon request, timely and properly made, by the person to whom notice has been given,

the time and place of the administrative conference, or both, may be changed if the request states reasonable grounds for such change. Such request shall be addressed to the Bureau Director who issued the notice.

HISTORY: Formerly R. 61–4.817. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1803. Conduct of Administrative Conferences.

Presentation of views at an administrative conference under this Subpart shall be private and informal. The views presented shall be confined to matters relevant to bringing violations into compliance with the Act or to other contemplated proceedings under the Act. These views may be presented orally or in writing by the person to whom the notice was given, or by his or her authorized representative.

HISTORY: Formerly R. 61–4.818. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

PART 1900.

HANDLING AND ADMINISTERING CONTROLLED SUBSTANCES IN HOSPITALS.

1901. Hospital Registration.

All hospitals (except those owned and operated by the federal government) shall be registered with DHEC in controlled substances schedules II through V inclusive.

HISTORY: Formerly R. 61–4.901. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1902. Practitioners' Registration.

Physicians and other practitioners who prescribe or order controlled substances for, or administer controlled substances to, patients in a hospital, shall be registered under the provisions of Article 3 of Chapter 53 of Title 44 of the 1976 Code.

HISTORY: Formerly R. 61–4.902. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1903. Residents' Registration.

A resident may prescribe or order the administration of controlled substances for patients within a hospital or residency training program, provided, that such resident has completed his or her course of study in a recognized college of medicine and has been duly licensed by the Board of Medical Examiners of South Carolina to practice medicine within this state, and has duly registered with DHEC and the DEA under the respective Controlled Substances Acts.

HISTORY: Formerly R. 61–4.903. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1904. Responsibility for Controlled Substances.

The administrative head of the hospital as a registrant under the Controlled Substances Act is responsible for the proper safeguarding and handling of controlled substances within the hospital. Responsibility for storage, accountability, and proper dispensing of controlled substances from the pharmacy may be delegated to a pharmacist employed by the hospital. Likewise, the Director of Nursing is usually delegated the authority for proper storage at nursing stations, and use, as directed by physician orders. However, delegation of authority does not relieve the administrator of the hospital of supervisory responsibility to insure detection and correction or any diversion of mishandling. The administrator shall be certain that all possible control measures are observed, and that any suspected diversion or mishandling of controlled substances is reported immediately to the Bureau of Drug Control for investigation. The administrator is ultimately responsible that all thefts be reported to DHEC pursuant to §§ 410 through 411 of this Regulation.

HISTORY: Formerly R. 61–4.905. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1905. Prescriptions not Required on Floor-Stocked Controlled Substances.

(a) Physicians and other practitioners who may be authorized according to state law, and who may be privileged and credentialed to place orders for patients within the hospital, shall enter such orders in the patient's medical record and no prescription shall be required. The nursing station floor stock used in administering controlled substances in any schedule shall be accounted for in a readily

retrievable format. The practitioner's order shall be checked against the medication administration record (MAR) and the controlled substances control sheet or hospital-specific record periodically by pharmacy personnel.

(b) Due to finite limits of nursing unit controlled substances storage areas, controlled substances that are not kept as floor stock will be occasionally ordered. Proper accountability for these controlled substances not included in floor stock require that they be issued on an individual demand basis with an accompanying sign-out control sheet. Any amount of these controlled substances which are not administered to or ingested by the patient shall be returned to the pharmacy within 72 hours after the medication order is discontinued by the individual practitioner treating the patient.

(c) Controlled substances secured from or obtained by prescription from retail sources outside the hospital are to be stored securely with all other controlled substances on the nursing unit. These controlled substances are to be monitored as to their administration to the patient by a supplemental controlled substances disposition sheet. This sheet should be designated with a control number or an identifying mark in order to distinguish it from regular hospital stock. If the patient is discharged before all of these controlled substances are administered, the amount sent home with the patient (if any) shall be noted on the disposition sheet and signed and dated by a registered nurse involved in the discharge process, who shall cause the sheet to be transmitted to the hospital pharmacy. In the event there are controlled substances obtained from outside sources which are not to be sent home with the patient, or if the patient expires and there are unutilized controlled substances from these sources, the balance of the medication shall be noted on the sheet by the Registered Nurse, and the sheet and the medication shall be returned to the hospital pharmacy for disposition.

(d) All non-electronic orders shall be manually signed by the practitioner.

(e) All controlled substances within a hospital that are not located within the hospital pharmacy shall be accompanied by either an electronic documentation, a disposition sheet, or a sign-out sheet upon which to record the administration of the substance, whether the substance originated as hospital stock, from a retail source outside the hospital, or was brought into the hospital by the patient with the consent of the hospital and the patient's practitioner.

HISTORY: Formerly R. 61-4.906. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1906. Registry Number.

The physician's full name shall appear on the physician's order sheet. The physician's registry number is not required on the sheet, but shall be recorded within the pharmacy or drug room.

HISTORY: Formerly R. 61-4.907. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1907. Telephone Orders.

Telephone orders for patients are permissible only in absolute necessity. The nurse receiving the order shall enter it into the patient's medical record, authenticate the practitioner's name, and the nurse's signature. The order for the controlled substance shall be authenticated according to hospital policy.

HISTORY: Formerly R. 61-4.908. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1908. Verbal Orders.

Verbal (oral) orders for hospital patients are permitted in a bona fide emergency. Such orders shall be handled in the same manner as telephone orders.

HISTORY: Formerly R. 61-4.909. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1909. Controlled Substances Records.

All non-electronic orders and non-electronic records of controlled substances shall be in ink, typed, or indelible pencil. Mechanical or electronic systems may be used to collect and store this data. All data shall be kept in a readily retrievable manner as set forth in §§ 601, 602, 603, 801, and 804 of this regulation. Any mechanical or electronic system shall be designed to retrieve data in such a manner as to show individual controlled substance activity per nursing unit as well as individual controlled substance volume in its entirety. This shall include, but is not limited to, control numbers, date

dispensed, identity of the controlled substance, strength, quantity dispensed, and location within the hospital.

HISTORY: Formerly R. 61–4.910. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1910. Procedure in Case of Waste, Destruction, Contamination, etc.

(a) Aliquot part of solutions used for drugs: The nurse shall use the proper number of tablets or ampoules from nursing unit stock. The nurse shall record the number of tablets or ampoules used and the dose given in the proper columns of the controlled substances disposition sheet, in the automated storage machine, or in a hospital-specified format. The nurse shall properly dispose of that portion of the solution not used. The aliquot shall be witnessed and recorded by the witness according to hospital policy. This information must be readily retrievable by hospital staff.

(b) Prepared dose refused by patient or canceled by physician: When a dose of a controlled substance has been prepared for a patient but not used due to refusal by the patient or cancellation by the physician, or has been accidentally contaminated during the regular course of administering the drug to the patient for whom it has been ordered (e.g., blood aspirated into a syringe when beginning the administration of an intra-muscular medication) the nurse shall properly dispose of the solution, and record on the back of the disposition sheet, in the automated storage machine, or in a hospital-specified format the reason why the controlled substance was not administered. This information must be readily retrievable by hospital staff.

(c) Accidental destruction of controlled substance: When a solution, tablet, ampoule or substance is accidentally destroyed on a nursing unit, the person responsible shall indicate the accidental loss by writing “wasted; see waste report” on the line allowed for the record on the controlled substances disposition sheet, in the automated storage machine, or in a hospital-specified format. The responsible person shall record a complete report of the accident and sign the statement.

(d) Contaminated or broken hypodermic tablets and contaminated controlled substance solutions: When a controlled substance hypodermic tablet is contaminated or broken or a controlled substance solution is contaminated, the person responsible or the head nurse shall place the tablets, particles, or solution in a suitable container and label. The person responsible, or the head nurse, shall record on the disposition sheet, in the automated storage machine, or in a hospital-specified format the wastage. He or she shall write and sign a complete report, or document the situation electronically with an electronic signature. Regardless of which system is used, a witness shall co-sign the report. The container with the contaminated controlled substance shall be returned to the pharmacy or medication room. The pharmacist or person in charge of the medication room will receive it and note on the controlled substances disposition sheet covering the particular substance that it has been returned. The hospital shall properly dispose of the material.

HISTORY: Formerly R. 61–4.911. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1911. Procedures in Case of Loss, Theft, etc.

(a) Discrepancies in controlled substances count: Those involving small amounts (such as single doses) shall be reported to a responsible supervisory official. An investigation should be made to determine the cause of the loss. A copy of the report of the investigation, signed by the responsible supervisor shall be filed with the hospital controlled substance records, and appropriate action taken to prevent recurrence.

(b) Recurring shortages: In cases of recurring shortages or loss of significant quantities of controlled substances (several doses), a thorough investigation shall be made, making every effort to determine the reason for the shortages, and the person responsible for the shortage, if possible. A complete report of the incident and findings shall be made to the administrative authority of the hospital. Appropriate action shall be taken immediately to prevent recurrence. A copy of the report, including any findings resulting from the local investigations, and a theft report, as required by §408, shall be forwarded to the Bureau of Drug Control, DHEC, 2600 Bull Street, Columbia, SC 29201.

HISTORY: Formerly R. 61–4.912. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1912. Controlled Substances of Physician's Office or Bag.

It is unlawful for a physician to obtain substances for his or her office or bag use from the controlled substances stock of the hospital. A physician may obtain his or her controlled substances from a drug wholesaler by invoice; Schedule II substances shall be acquired through the use of order forms supplied by the DEA, U. S. Department of Justice (DEA Forms 222). Those hospitals maintaining permitted retail pharmacies, or otherwise licensed as a "drug outlet" by the S.C. Board of Pharmacy, may at their option, furnish controlled substances to practitioners pursuant to the provisions of § 1401 of this Regulation.

HISTORY: Formerly R. 61-4.914. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1913. Dispensing to Outpatients.

It is unlawful for a hospital to dispense controlled substances to outpatients on physicians' orders. Such dispensing shall be done only on the prescription of a duly licensed physician and only from the pharmacy holding a permit as a retail pharmacy of a hospital registered under Article 3 of Chapter 53 of Title 44 of the 1976 Code, and by or under the immediate supervision of a registered pharmacist. With the permission of the hospital, a practitioner may personally dispense limited quantities of controlled substances to their patients for take-home purposes, provided that such substances are properly packaged and labeled as required by provisions elsewhere within this regulation, and in compliance with statutory provisions.

HISTORY: Formerly R. 61-4.915. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1914. Administering to Outpatients.

Controlled substances may be administered to outpatients or emergency patients when admitted to the emergency room of the hospital when ordered by the physician in charge of the case, provided a record is kept showing the name and address of the patient, kind and quantity of controlled substance administered, date and physician's order. Under no conditions may the patient be given controlled substances to take out of the hospital except as provided in § 1913.

HISTORY: Formerly R. 61-4.916. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1915. Emergency Rooms.

The stock of controlled substances maintained in hospital emergency rooms or outpatient facilities is kept for the use by or at the direction of physicians in the emergency room. Therefore, in order to receive such medication, a patient shall be examined by a physician in the emergency room or outpatient facility and the need for the particular controlled substance determined by such physician. It is not possible under federal requirements for the use of controlled substances for a physician to see a patient outside of the emergency room setting, or talk to the patient over a telephone, and then call the emergency room and order the administration of a stocked controlled substance upon the patient's arrival at the emergency facility. Cf., S.C. Code Ann. § 44-53-110, "administer" [". . . in his presence. . ."]; §§ 1103 and 1204 of this Regulation, requiring personal attendance, etc.

HISTORY: Formerly R. 61-4.916.1. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1916. Storage of Controlled Substances.

All controlled substances shall be kept in a locked, secure place. Large reserve stocks should be kept in a strong safe, substantial enough to deter entry and heavy enough to prevent being carried away. Other valuable property may be kept in the safe provided adequate security of the controlled substances contained therein is maintained. See also §§ 401 through 406, inclusive.

(a) Nursing station controlled drug box: Responsibility: Only a very limited number of persons should possess the key to the controlled substances on the nursing station. When such person(s) are relieved from duty, the person(s) taking charge should count and transfer the controlled substances in the presence of the person(s) being relieved, and all controlled substances should be accounted for. The responsibility rests with the person(s) assigned to possession of the key on each shift. The administrator shall be responsible for control of these keys. This responsibility may be delegated to the Director of Nursing. Written documentation of accountability of controlled substances (i.e., shift

change nurses' signatures) shall be stored in a readily retrievable manner and maintained for a period of not less than two years, after which they may be destroyed.

(b) Responsibility of drug room: In those hospitals not maintaining a pharmacy under the supervision of a registered pharmacist, the drug room shall be restricted to the Director of Nurses, a designated assistant, or a designated registered nurse, not more than one of whom shall be in possession of the key to the drug room at the same time. The nurse in possession of the key to the drug room shall be responsible for all transactions in the drug room on his or her respective shift. (Observance of (a) and (b) does not relieve the Administrator of his or her responsibilities.)

HISTORY: Formerly R. 61-4.917. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1917. Availability of Records for Inspectors.

The administrative head of the hospital shall, upon service of an inspection warrant by an inspector of the Bureau of Drug Control, DHEC, or if such administrative head chooses, voluntarily without inspection warrant, (acting pursuant to the informed consent to inspection delineated as a condition of registration upon the application for registration and the registration certificate issued to the registrant by DHEC) make available to such inspector all dispensing and administering records of controlled substances, for the purpose of audit of said controlled substances, as well as records of receipt and disposition of all controlled substances acquired by the hospital. Inspectors shall not divulge information contained on patient records that do not concern controlled substances or other drugs restricted to prescription use only.

HISTORY: Formerly R. 61-4.919. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1918. Labeling of Substances. (Schedule II)

The requirements of § 1106 do not apply when a controlled substance listed in schedule II is prescribed for administration to an ultimate user who is institutionalized; Provided, that:

- (1) Not more than 7-day supply of the controlled substance listed in schedule II is dispensed at one time;
- (2) The controlled substance listed in schedule II is not in the possession of the ultimate user prior to the administration;
- (3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substances listed in schedule II; and
- (4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

HISTORY: Formerly R. 61-4.920. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1919. Labeling of Substances. (Schedules III, IV, V).

The requirements of §1201 do not apply when a controlled substance listed in schedule III or IV is prescribed for administration to an ultimate user who is institutionalized; Provided, that:

- (1) Not more than a 30-day supply or 100 dosage units, whichever is less, of the controlled substance listed in schedule III, IV or V is dispensed at one time.
- (2) The controlled substance listed in schedule III, IV or V is not in the possession of the ultimate user prior to administration;
- (3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing and storage of the controlled substance listed in schedule III, IV or V; and
- (4) The system employed by the pharmacist in dispensing a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

HISTORY: Formerly R. 61-4.921. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1920. Clarification and Intent.

These regulations are considered to be a general but minimal required control level in the opinion of the Bureau of Drug Control, DHEC. More stringent control for the institution in question or special interpretations of these regulations may be approved by a special meeting with the Bureau of Drug Control, and the administrator or designated pharmacy and therapeutics committee of the respective hospital every 3 to 5 years when the need is felt for such clarification. The intent of Part 1900 of this regulation is to insure adequate control and accountability of controlled substances utilized in health care without duly hindering or restraining the delivery of such care. Accountability and an accurate audit at periodic intervals are the crux of the adequate control system.

HISTORY: Formerly R. 61-4.922. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

1921. Consultation Procedure.

At the request of the institution under examination and/or the Bureau of Drug Control, DHEC, the S.C. Society of Hospital Pharmacists may furnish a recognized local authority on Institutional Medication Delivery and Control Systems to accompany the agent/or inspector and act as a consultant to the institution in question on rectifying flaws in the system under scrutiny.

HISTORY: Formerly R. 61-4.923. Renumbered by State Register Volume 37, Issue No. 6, eff June 28, 2013.

61-6. Repealed by State Register Volume 36, Issue No. 3, eff March 23, 2012.

Editor's Note

Former R. 61-6 was titled "Capital Expenditure Reviews under Section 1122, Social Security Act".

61-7. Emergency Medical Services.

(Statutory Authority: S.C. Code §§ 44-61-10 et seq., 44-78-10 et seq., and 44-80-10 et seq.)

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SECTION 100—DEFINITIONS, LICENSURE, AND CERTIFICATION

101. Definitions.

A. Abandoned. For the purpose of Section 302.B.3.h, unilateral termination by the EMS Personnel of the provider-Patient relationship when continuing care was still needed. This includes the termination of care without the Patient's consent or without assurance that a level of care meeting the assessed needs of the Patient's condition is present and available. The provider-patient relationship must have been established for abandonment to occur and the event must be without extenuating circumstances such as provider safety or patients who act against medical advice (AMA).

B. Abuse. Physical Abuse or Psychological Abuse.

1. Physical Abuse. The act of intentionally inflicting or allowing infliction of physical injury on a Patient by an act or failure to act. Physical Abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, burning, actual or attempted sexual battery, use of medication outside the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical Abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that of a therapeutic procedure prescribed by a licensed physician or other legally authorized healthcare professional. Physical Abuse does not include altercations or acts of assault between Patients.

2. Psychological Abuse. The deliberate use of any oral, written, or gestured language or depiction that includes disparaging or derogatory terms to a Patient or within the Patient's hearing distance, regardless of the Patient's age, ability to comprehend, or disability, including threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

C. Advanced Emergency Medical Technician (AEMT). An advanced level emergency medical services provider certified by the Department to provide basic and limited advanced emergency medical care and transportation for Patients.

D. Advanced Life Support (ALS). An advanced level of prehospital, interhospital, and emergency service care, which includes Basic Life Support functions, cardiac monitoring, cardiac defibrillation, telemetered electrocardiography, administration of antiarrhythmic agents, intravenous therapy, administration of specific medications, drugs and solutions, use of adjunctive ventilation devices, trauma care, and other techniques and procedures authorized by the Department.

E. Adverse Incident. An unexpected event, including any accidents, that could potentially cause harm, injury, or death to Patients, EMS Personnel, or third-party individuals.

F. Air Ambulance. Any aircraft that is intended to be used and is maintained or operated for transportation of persons who are sick, injured, or otherwise incapacitated.

1. Fixed Wing. Any aircraft that uses fixed wings to allow it to take off, fly, and land.

2. Rotorcraft. A helicopter or other aircraft that uses a rotary blade to allow vertical and horizontal flight without the use of wings.

G. Ambulance. A vehicle maintained or operated by a Licensed Agency that has obtained the necessary permits and licenses for the transportation of persons who are sick, injured, wounded, or otherwise incapacitated.

H. Attendant. A trained and qualified individual responsible for the operation of an Ambulance and the care of Patients, regardless of whether the Attendant also serves as the Driver.

I. Attendant-driver. A person who is qualified as an Attendant and a Driver.

J. Basic Life Support (BLS). A basic level of prehospital care, which includes Patient stabilization, airway clearance, cardiopulmonary resuscitation, hemorrhage control, initial wound care and fracture stabilization, and other techniques and procedures authorized by the Department pursuant to regulation.

K. Certificate. An official acknowledgment by the Department that an individual has completed successfully one of the appropriate Emergency Medical Technician training programs, successfully completed the requisite examinations, and which entitles that individual to perform the functions and duties as delineated by the classification for which the Certificate was issued.

L. Condition Requiring an Emergency Response. The sudden onset of a medical condition manifested by symptoms of such sufficient severity, including severe pain, which a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect without medical attention, to result in:

1. Serious illness or disability;
2. Impairment of a bodily function;
3. Dysfunction of the body; or
4. Prolonged pain, psychiatric disturbance, or symptoms of withdrawal.

M. Continuing Education Program. A Department-approved program offered by an EMS Agency that provides Continuing Education for the recertification of South Carolina certified EMT-basics, AEMTs, and Paramedics.

N. Department. The South Carolina Department of Health and Environmental Control.

O. Do Not Resuscitate Bracelet ("Bracelet"). A standardized identification bracelet that:

1. Meets the specifications established under S.C. Code Section 44-78-30(B) or that is approved by the Department under S.C. Code Section 44-78-30(B);
2. Bears the inscription "Do Not Resuscitate"; and
3. Signifies that the wearer is a Patient who has obtained a Do Not Resuscitate Order that has not been revoked.

P. Do Not Resuscitate Order for Emergency Services ("DNR Order"). A document made pursuant to the Emergency Medical Services Do Not Resuscitate Order Act, S.C. Code Sections 44-78-10, et seq., to prevent Emergency Medical Services personnel from employing resuscitation measures or any other medical process that would only extend the Patient's suffering with no viable medical reason to perform the procedure.

Q. Driver. An individual who drives or otherwise operates an Ambulance.

R. Electronic Patient Care Reports (ePCR). Patient care reports authored and submitted electronically into the Department's EMS data system.

S. Elopement. An instance when a Patient who wanders, walks, runs away, escapes, or otherwise leaves unsupervised or unnoticed from the scene, transport unit, or prior to care being assumed by the receiving facility.

T. Emergency. A situation in which a prudent layperson has identified a potential medical threat to life or limb such that the absence of immediate medical attention could reasonably be expected to result in placing the individual's health in serious jeopardy, serious impairment of bodily functions, or serious dysfunction of bodily organs.

U. Emergency Medical Responder Agency. An Agency licensed by the Department to provide medical care at the EMT-basic level or above, as a nontransporting emergency medical responder. May also be referred to as an EMT Rapid Responder Agency.

V. Emergency Medical Service Agency. An Agency licensed by the Department to provide non-transport and/or transport emergency medical services in South Carolina, including public, private, volunteer, fire departments, or other type of Ambulance services and Emergency Medical Responder Agencies. May also be referred to as EMS Agency or Agency.

W. Emergency Medical Services Personnel. Persons trained and certified or licensed to provide emergency medical care, whether on a paid or volunteer basis, as part of a Basic Life Support or Advanced Life Support prehospital Emergency Medical Services, in an emergency department, pediatric critical care, or specialty unit in a licensed hospital. May also be referred to as EMS Personnel.

X. Emergency Medical Technician (EMT). An individual possessing a valid EMT-basic, Advanced EMT (AEMT), or Paramedic Certificate issued by the Department.

Y. Emergency Transport. Services and transportation provided after the sudden onset of a medical condition manifesting itself by acute symptoms of such severity, including severe pain, that the absence of medical attention could reasonably be expected to result in the following:

1. Placing the Patient's health in serious jeopardy;

2. Causing serious impairment of bodily functions or serious dysfunction of bodily organ or part;
or

3. A situation resulting from an accident, injury, acute illness, unconsciousness, or shock, for example, requiring oxygen or other emergency treatment, or requiring the Patient to remain immobile because of a fracture, stroke, heart attack, or severe hemorrhage.

Z. EMT-basic. An EMT certified by the Department at the basic level.

AA. Endorsement. A provision added to a Certificate, pursuant to approval by the Department, enhancing the scope of practice or authorization of specific activities within the EMS system.

BB. Exploitation. 1) Causing or requiring a Patient to engage in an activity or labor that is improper, unlawful, or against the reasonable and rational wishes of a Patient; 2) an improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a Patient by an individual for the profit or advantage of that individual or another individual; or 3) causing a Patient to purchase goods or services for the profit or advantage of the seller or another individual through undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the Patient through cunning arts or devices that delude the Patient and cause him or her to lose money or other property.

CC. Federal Aviation Administration (FAA). The agency of the federal government that governs aircraft design, operations, and personnel requirements.

DD. Flight Nurse. A licensed registered nurse who is trained in all aspects of Emergency care.

EE. Investigative Review Committee. A professional peer review committee that may be convened by the Department, in its discretion, when the findings of an official investigation against an entity or an individual regulated by the Department may warrant suspension or revocation of a License or Certificate.

FF. License. An authorization issued by the Department to a person, firm, corporation, or governmental division or agency to provide emergency medical services.

GG. Licensee. Any person, firm, corporation, or governmental division or agency possessing a License to provide emergency medical services in South Carolina.

HH. Medical Control. Medical Control is provided by a licensed Agency's physician who is responsible for the care of the Patient by the Agency's medical Attendants. Actual Medical Control may be direct by two-way voice communications (on-line) or indirect by Protocols (off-line) control.

1. Off-Line Medical Control. An Agency's Medical Control Physician assists in development and implementation of Protocols and Patient care guidelines.

2. On-Line Medical Control. The physician directly communicates with EMS Personnel regarding Patient care en-route or on-scene.

II. Medical Control Physician. A physician with a current unrestricted license to practice medicine by the South Carolina Board of Medical Examiners, retained by an EMS Agency to provide Off-line Medical Control, who participates in the review or evaluation of the services provided, and who maintains quality control of the Patient care provided by the EMS Agency. May also be referred to as EMS Medical Director.

JJ. Moral Turpitude. Behavior that is not in conformity with and is considered deviant by societal standards.

KK. National Emergency Medical Services Information System (NEMSIS). The national database that is used to store EMS data from the U.S. States and Territories. NEMSIS is a collaborative system to improve Patient care through the standardization, aggregation, and utilization of point of care EMS data at a local, state, and national level.

LL. National Registry of Emergency Medical Technicians (NREMT). A national certification agency that provides a valid and uniform process to assess the knowledge and skills required for competent practice by EMS professionals throughout their careers and maintains a registry of certification status.

MM. Nonemergency Transport. Services and transportation provided to a Patient whose condition is considered stable, including prearranged transports scheduled at the convenience of the service, the Patient, or medical facility. A stable Patient is one whose condition by caregiver consensus can

reasonably be expected to remain the same throughout the transport and for whom none of the criteria for Emergency Transport has been met.

NN. Palliative Treatment. The degree of treatment that must be provided to a Patient in the routine delivery of emergency medical services, which assures the comfort and alleviation of pain and suffering to all extents possible, regardless of whether the Patient has executed a document as provided for in Chapter 78, Title 44 of the S.C. Code of Laws. May also be referred to as Palliative Care.

OO. Paramedic. The highest level of EMT certified by the Department.

PP. Patient. An individual who is sick, injured, wounded, or otherwise incapacitated or helpless.

QQ. Permit. An authorization issued by the Department for an Ambulance which meets the standards of this regulation.

RR. Physician Orders for Scope of Treatment (POST) Form. A designated document designed for use as part of advance care planning, the use of which must be limited to situations where the Patient has been diagnosed with a serious illness or, based upon medical diagnosis, may be expected to lose capacity within twelve (12) months and consists of a set of medical orders signed by a Patient's Physician or other Authorized Healthcare Provider addressing key medical decisions consistent with Patient goals of care concerning treatment at the end of life that is portable and valid across health care settings.

SS. Prehospital Care: Assessment, stabilization, and care of a Patient, including, but not limited to, the transportation to an appropriate receiving facility.

TT. Protocols. Written orders signed, dated, and issued by a Medical Control Physician that allow EMT-basics, AEMTs, and Paramedics to administer particular medications and perform treatment modalities in specific situations without On-line Medical Control. May also be referred to as Standing Orders.

UU. Public Safety Answering Point (PSAP). A communications facility operated on a twenty-four (24) hour basis which first receives 911 calls from persons in a 911 service area and which may directly dispatch public safety services or extend, transfer, or relay 911 calls to appropriate public safety agencies.

VV. Resuscitative Treatment. Artificial stimulation of the cardiopulmonary systems of the human body, through either electrical, mechanical, or manual means including, but not limited to, cardiopulmonary resuscitation.

WW. Revocation. An action by the Department to cancel or annul a License, Permit, or Certificate by recalling, withdrawing, or rescinding the Agency's or individual's authorization to operate or practice.

XX. Special Purpose EMT. A South Carolina licensed registered nurse (RN) or a Nurse Licensure Compact (NLC) State RN who works in a critical care hospital setting, and is an EMT certified by the Department to provide a continuance of critical care during transport while aboard Ambulances equipped for their specialty area.

YY. "Star of Life". A six (6) barred blue cross outlined with a white border of which all angles are sixty (60) degrees, and upon which is superimposed the staff of Aesculapius in white. This is a registered trademark of the United States Department of Transportation.

ZZ. Suspension. An action by the Department requiring a Licensee, Permit or Certificate holder to cease operations or providing Patient care until such time as the Department rescinds that restriction.

AAA. Variance. An alternative method that ensures the equivalent level of compliance with the standards in this regulation.

BBB. Volunteer EMS Agency. A not-for-profit EMS Agency that serves its local community with emergency medical service coverage at any level and is staffed by at least ninety percent (90%) non-paid staff. For the purpose of this regulation, token stipends received by volunteer EMS Agencies are not considered paid remuneration or a primary wage.

102. Licensure.

A. No person, firm, corporation, association, county, district, municipality, or metropolitan government or agency, either as owner, agent, or otherwise, shall furnish, operate, conduct, maintain, advertise, or otherwise engage in or profess to engage in the business or service of providing

emergency medical response or Ambulance service, or both, without obtaining a License and Ambulance Permit issued by the Department. When it has been determined by the Department that services are being provided and the owner, agent, or otherwise has not been issued a License from the Department, the owner, agent, or otherwise shall cease operation immediately and ensure the safety, health, and well-being of Patients. Current and/or previous violations of the South Carolina Code and/or Department regulations may jeopardize the issuance of a License or the licensing of any party(ies) to provide emergency medical response or Ambulance service or both that is owned/operated by the applicable party(ies). An EMS Agency shall not operate or advertise that it provides a level of life support above the level for which it is licensed. (1)

B. An EMS Agency that applies to the Department for any additional initial or amended EMS Agency Licenses shall be in substantial compliance with this regulation to obtain any additional initial or amended EMS Agency Licenses.

C. Issuance and Terms of License.

1. The EMS Agency shall ensure the License issued by the Department is posted in a conspicuous place in a public area.

2. The EMS Agency's License is not assignable or transferable and is subject to Revocation at any time by the Department for the EMS Agency's failure to comply with the laws or regulations of this state.

3. A License shall be effective for a specified EMS Agency, at a specific location, and for a period of two (2) years following the date of issue. A License shall remain in effect until the Department notifies the EMS Agency of a change in that status.

D. EMS Agency Name. Proposed and existing EMS Agencies shall not have the same or similar name of any other EMS Agency licensed in South Carolina.

E. Amended License. An EMS Agency shall request issuance of an amended License by application to the Department prior to any of the following circumstances:

1. Change of level of services provided;
2. Change of EMS Agency headquarters location from one geographic site to another; or
3. Changes in EMS Agency's name or address (as notified by the post office).

F. Change of Licensee. An EMS Agency shall request issuance of a new License by application to the Department prior to any of the following circumstances:

1. A change in the controlling interest even if, in the case of a corporation or partnership, the legal entity retains the identity and name; or
2. A change in the legal entity, for example, sole proprietorship to or from a corporation or partnership to or from a corporation, even if the controlling interest does not change.

103. EMS Agency License Application.

A. Application. Applicants for licensure as an EMS Agency shall submit to the Department a complete and accurate application on a form prescribed and furnished by the Department prior to initial licensing. The EMS Agency shall ensure the application is signed by the owner(s) if an individual or partnership; by two (2) officers if a corporation; or by the head of the governmental department having jurisdiction if a governmental unit. Corporations or limited partnerships, limited liability companies, or any other organized business entity shall be registered with the South Carolina Secretary of State's Office if required to do so by state law.

B. The EMS Agency shall include the following with the application:

1. The name and address of the owner of the EMS Agency or proposed EMS Agency;
2. The name under which the EMS Agency applicant is doing business or proposes to do business;
3. A copy of the business license, if applicable, of the EMS Agency or proposed EMS Agency for the location of the service;
4. The number of Ambulances and/or emergency medical responder service vehicles and a description of each vehicle including the make, Vehicle Identification Number (VIN), aircraft tail

number, model, year of manufacture, and other distinguishing characteristics to be used to designate the applicant's vehicles;

5. The location and description of the place or places, including substations, from which the EMS Agency is intending to operate;

6. Personnel roster representing all employees, members, volunteers, and affiliates associated with the service including, but not limited to, EMT-basics, AEMTs, Paramedics, Drivers, pilots, registered nurses, certification numbers, and expiration dates of their South Carolina and NREMT credentials, if applicable;

7. EMS Agency type(s) and the levels of capability for each type pursuant to Sections 504 and 505 to be provided at each location;

8. Name, email address, and phone number of the following, if applicable;

- a. EMS Director;
- b. EMS Assistant Director;
- c. Training Officer;
- d. Data Manager;
- e. Infection Control Officer;
- f. Pediatric Emergency Care Coordinator, if applicable; and
- g. Medical Control Physician.

9. A copy of current Protocols and an authorized medication list both signed and dated by the Medical Control Physician;

10. Records for each Driver, pursuant to Section 503;

11. Liability insurance information, to include name of insurance company, agent, phone number, and type of coverage. A copy of insurance policies shall be furnished to the Department upon request. The minimum limits of coverage shall be six hundred thousand dollars (\$600,000.00) liability and three hundred thousand dollars (\$300,000.00) malpractice per occurrence. Applicants that claim "self-insured" status shall provide documentation showing the specific coverages as outlined above;

12. A copy of the EMS Non-Dispensing Drug Outlet Permit from the South Carolina Board of Pharmacy, when applicable;

13. A copy of the EMS Agency's current registration Certificate from the Department's Bureau of Drug Control and registration Certificate from the United States Drug Enforcement Administration, when applicable;

14. A copy of the EMS Agency's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver from the federal Centers for Medicare and Medicaid Services (CMS), when applicable;

15. A copy of the EMS Agency's Infectious Waste Generator Registration issued by the Department, or if an out of state EMS Agency, the respective home state equivalent; and

16. Additional information if requested by the Department, such as affirmative evidence of the applicant's ability to comply with this regulation.

C. License Renewal. The EMS Agency shall submit a complete and accurate application on a form prescribed and furnished by the Department prior to the License expiration date and shall not have pending enforcement actions by the Department. If the License renewal is delayed due to enforcement actions, the renewal License shall be issued only when the matter has been resolved by the Department, or when the adjudicatory process is completed, whichever is applicable.

104. Emergency Medical Technicians.

A. No person may hold himself or herself out as an EMT-basic, AEMT, or Paramedic, or provide Patient care that is within the scope of an EMT-basic, AEMT, or Paramedic as defined in South Carolina Code Section 44-61-20 and this regulation without obtaining a proper Certificate from the Department. When it has been determined by the Department that an individual is engaged as an EMT-basic, AEMT, or Paramedic, and the individual has not been issued a Certificate from the Department, the individual shall cease engaging as an EMT-basic, AEMT, or Paramedic immediately.

Current and/or previous violation(s) of the South Carolina Code of Laws or Department regulations may jeopardize the issuance of an EMT-basic, AEMT, and Paramedic Certificate. (I)

B. No person shall provide Patient care within the scope of an Emergency Medical Technician (EMT-basic, AEMT, or Paramedic) without a current Certificate from the Department. The EMT shall: (I)

1. Engage only in those practices for which he or she has been trained, within the scope of the Department-issued Certificate, and as authorized by the EMS Agency's Medical Control Physician; and
2. Perform procedures only under the direction and oversight of a Medical Control Physician.

105. Initial EMT-basic, AEMT, and Paramedic Certification.

A. Applicants for an initial EMT-basic, AEMT, or Paramedic Certificate shall submit to the Department a completed application on a form prescribed, prepared, and furnished by the Department prior to issuance of an initial Certificate. The applicant shall submit, along with the application, the following:

1. Documentation that he or she has successfully passed the National Registry of Emergency Medical Technicians (NREMT) examination for the level of certification desired and possesses a current NREMT credential. In lieu of the NREMT credential, the Special Purpose EMT applicant shall submit documentation demonstrating that he or she is a licensed registered nurse who works in a critical care hospital setting;
2. A Criminal History Background Check. A person seeking EMT-basic, AEMT, or Paramedic certification shall undergo a state criminal history background check supported by fingerprints by the South Carolina Law Enforcement Division (SLED) and a national criminal history background check supported by fingerprints by the Federal Bureau of Investigation (FBI) and report the results of the criminal history background check to the Department; and (I)
3. The Department may require additional information including affirmative evidence of the applicant's ability to comply with this regulation.

106. Issuance and Terms of Certification.

A. The EMT-basic, AEMT, and Paramedic Certificate is issued pursuant to South Carolina Code Sections 44-61-80 et seq. and this regulation.

B. The EMT-basic, AEMT, and Paramedic Certificate is not assignable or transferable and shall be subject to Denial, Suspension, or Revocation by the Department for failure to comply with the South Carolina Code of Laws and this regulation.

C. The EMT-basic, AEMT, and Paramedic Certificate shall be valid for a period not exceeding four (4) years from the date of issuance. A Certificate shall remain in effect until the Department notifies the EMT-basic, AEMT, or Paramedic of a change in that status.

D. EMS Personnel shall at all times while on duty or otherwise rendering Patient care have the Department-issued identification on their person and available for view upon request. Patches from other certifying or licensing agencies are not an acceptable substitute.

E. The EMT-basic, AEMT, and Paramedic shall maintain current information in the Department's credentialing system.

107. EMT-basic, AEMT, or Paramedic Certification Renewal.

A. To renew his or her EMT-basic, AEMT, or Paramedic Certificate, the EMT-basic, AEMT, or Paramedic shall submit a complete application with the Department, on a form prescribed, prepared, and furnished by the Department, at least thirty (30) calendar days prior to the expiration date of his or her Certificate and shall not have pending enforcement actions by the Department. If the Certificate renewal is delayed due to enforcement actions, the Certificate renewal shall be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, whichever is applicable. The EMT-basic, AEMT, or Paramedic shall submit, along with the renewal application, the following:

1. Documentation of current NREMT credentials for the appropriate level of certification, EMT-basic, AEMT, or Paramedic, or documentation that the EMT-basic, AEMT, or Paramedic was certified by the Department prior to October 1, 2006, and has continuously maintained Certification.

In lieu of the NREMT credential, the Special Purpose EMT shall submit documentation demonstrating he or she is a licensed registered nurse who works in a critical care hospital setting;

2. A state and national criminal history background check pursuant to S.C. Code Section 44-61-80 (D); and

3. Department-approved CPR credential for all EMTs and Department-approved Advanced Cardiac Life Support (ACLS) credential for all Paramedics.

108. Special Purpose EMT.

A. A Special Purpose EMT certified by the Department prior to the effective date of the most recent regulatory amendment shall be considered grandfathered in terms of their Certification and shall be recognized as a Special Purpose EMT so long as he or she possesses a current Certificate issued by the Department, renews his or her Certificate pursuant to Section 107 of this regulation, and maintains employment in an EMS Agency.

B. The Special Purpose EMT shall only engage in those practices for which he or she has been trained.

109. Reciprocity.

A. Candidates seeking reciprocity in South Carolina as an EMT-basic, AEMT, or Paramedic shall:

1. Hold either an NREMT credential or a current certification from another state for the level for which they are applying; and

2. Complete the criminal history background check in accordance with S.C. Code Section 44-61-80(D) and pursuant to Section 105.A.2.

B. Candidates seeking reciprocity who hold a current and valid NREMT certification may apply for direct reciprocity at the level of the NREMT credential they hold by creating an up-to-date profile in the Department's credentialing system and submitting a complete reciprocity application in a format as determined by the Department. The candidate shall submit the following with the application:

1. A properly completed out-of-state certification verification form;

2. A copy of their current NREMT certification for the level of reciprocity for which they are applying; and

3. All other requirements as established by the Department.

C. Candidates not certified in South Carolina who hold a current and valid EMT-basic, AEMT, or Paramedic certification from other states and do not hold a current NREMT certification may apply for a one (1) year provisional certification at the level they hold. Candidates for provisional certification shall create an up-to-date profile in the Department's credentialing information system and submit a complete reciprocity application in a format as determined by the Department. The candidate shall submit the following with the application:

1. A copy of their current state certification identification card for the level for which he or she is applying that includes the certification expiration date. All candidates with provisional Certificates shall have no less than six (6) months remaining on their out-of-state certification by the time the Department receives all required documentation necessary for certification; and

2. All other documentation and requirements as established by the Department.

D. South Carolina provisional Certificates for all levels of certification shall expire one (1) year from the date of issue. Provisional certifications are non-renewable, and extensions are not permitted. An active military service member deployed outside of South Carolina may submit a written request in a format as determined by the Department for an extension on his or her provisional Certification and submit a copy of the active duty orders with the request.

E. To convert a South Carolina provisional certification to a conventional South Carolina Certification, the provisional Certificate holder shall obtain a NREMT certification and complete the recertification requirements pursuant to Section 107 prior to expiration.

110. Certification Examinations.

Applicants for an EMT-basic, AEMT, and Paramedic Certificate shall successfully complete a Department-approved training program that meets or exceeds the NREMT standards for the desired level of certification. After completion of the training program and prior to certification, the applicant

shall successfully pass the NREMT cognitive and the Department-approved psychomotor examinations.

111. Training Programs. (II)

A. Training programs are offered in approved technical colleges, other colleges and universities, vocational schools, and State Regional EMS training offices. No training program shall advertise as an EMT-basic, AEMT, or Paramedic training program or conduct EMT-basic, AEMT, or Paramedic training prior to approval as a training program from the Department. The training program applicant shall:

1. Submit a complete application to the Department in a format determined by the Department. Training program applicants shall submit documentation of accreditation as required by the NREMT with their application to the Department;
2. Designate one (1) person as the EMT-basic, AEMT, or Paramedic program coordinator; and
3. Have equipment for training purposes as approved by the Department available and in working condition.
4. The provisions of this Section shall not affect training programs approved by the Department as of the date of this regulation.

B. Departmental approval of a training program is granted for four (4) years. The training program shall complete a renewal application, in format as determined by the Department, prior to the expiration date to be re-approved. The training program shall not conduct courses with an expired Department approval.

C. The training program shall ensure all courses are taught by Department-certified EMT-basic, AEMT, and Paramedic instructors and shall not conduct class without equipment pursuant to Section 111.A.3. The training program may utilize specialty instructors, such as physicians, nurses, anatomists, and other subject matter experts, for portions of instruction as determined by the training program.

D. The training program shall retain a Medical Control Physician to provide medical oversight for their program.

E. The training program shall maintain a seventy percent (70%) first time pass rate as defined by NREMT, calculated using a three (3) year rolling history, on the cognitive and psychomotor portions of the NREMT Examination.

112. Certified EMT-basic, AEMT, and Paramedic Instructors.

A. All EMT-basic, AEMT, and Paramedic instructors shall be certified by the Department prior to providing any instruction in a training program and meet the following requirements:

1. Submit a complete and signed certified EMT-basic, AEMT, or Paramedic instructor application in a format as determined by the Department;
2. Have three (3) years' experience at the level for which he or she intends to teach;
3. Possess a high school diploma or GED;
4. Possess a current state EMT-basic, AEMT, or Paramedic Certificate. The certified EMT-basic, AEMT, or Paramedic instructor shall only teach at or below the level of his or her Certificate level;
5. Successfully complete a forty (40) hour instructor methodology course offered by the National Association of EMS Educators (NAEMSE), International Fire Service Accreditation Congress (IF-SAC), ProBoard or Department of Defense (DOD) fire instructor, South Carolina Criminal Justice Academy, or other Department-approved course; and
6. Possess a current and valid CPR instructor credential.

B. Instructor Candidates. Instructor candidates may provide instruction in a training program under the supervision of a Department-certified instructor.

C. Instructor Certification Renewal. The certified instructor shall submit a complete and signed renewal application certification prior to the last day of the month in which his or her state EMT certification expires. The renewal application shall include:

1. A copy of a current South Carolina and NREMT EMT-basic, AEMT, or Paramedic certification; and
2. A copy of a current and valid CPR instructor credential.

D. The Department may suspend or revoke an EMT-basic, AEMT, or Paramedic instructor certification for any of the following reasons:

1. Any act of misconduct as outlined in Section 303.B.;
2. Suspension or Revocation of the holder's South Carolina or NREMT certification;
3. Failure to maintain required credentials necessary for instructor designation;
4. Any act of sexual or other harassment toward another instructor or candidate;
5. Conducting classes while under the influence of drugs that negatively impair the ability to instruct (prescribed, non-prescribed, or illegal); and
6. Falsification of any documents pertaining to the course (such as attendance logs, equipment checklist).

113. Continuing Education (CE) Program. (II)

A. No EMS Agency shall begin or conduct a CE Program prior to receiving approval by the Department. EMS Agencies seeking approval for a CE program shall file an application with the Department in a format as determined by the Department.

B. The EMS Agency's CE Program approval shall be effective for no more than four (4) years. The CE Program shall submit a renewal application in a format as determined by the Department prior to the expiration date of the Department's approval.

C. The EMS Agency shall ensure all CE Programs meet the requirements established by the NREMT for recertification.

D. CE Programs may verify skills for currently credentialed state and NREMT personnel on their roster. Provisional credentialed EMTs must have their NREMT skills verified at a Department-approved NREMT testing site.

114. Continuing Education Units (CEUs).

A. The Department may approve additional CEUs on a case-by-case basis from medical schools, hospitals, simulation centers, formal conventions, seminars, workshops, educational classes, symposiums, and other Department approved continuing education events.

B. Applicants for CEUs shall submit requests in writing for approval from the Department at least thirty (30) calendar days prior to the scheduled event.

C. The written requests for approval shall include the following:

1. Date, time, and agenda of the event;
2. Topics covered; and
3. List of speakers and their credentials.

115. Pilot Programs.

A. The EMS Agency that wishes to initiate a pilot program shall provide in writing to the Department a detailed proposal of the program and any supporting materials requested by the Department. The South Carolina Medical Control Committee and the South Carolina EMS Advisory Council shall provide a written recommendation to the Department.

B. The EMS Agency shall not initiate a pilot program without prior written approval by the Department. (I)

C. The EMS Agency, approved by the Department to initiate a pilot program, shall ensure participating EMT-basics, AEMTs, and Paramedics perform the pilot procedures under their Medical Control Physician's oversight during the period of the pilot program.

D. The EMS Agency shall present a detailed report to the Medical Control Committee and EMS Advisory Council upon the conclusion of the pilot program which includes all information requested by the approving committees.

116. Endorsement of Specialty Credentials.

A. A Department-endorsed specialty credential may include, but is not limited to, the following areas of specialized training:

1. Community Paramedic;

2. Critical Care Paramedic; and
3. Tactical Paramedic.

B. The applicant for Endorsement shall meet the minimum educational and clinical guidelines as established by the Department and submit a complete application in a format as determined by the Department that includes:

1. Documentation of the Department-required training;
2. Documentation that he or she is currently employed by an EMS Agency in one of the specialized training areas pursuant to Section 116.A; and
3. Documentation that he or she has successfully passed the International Board of Specialty Certification examination or other Department-approved national certifying board requirements.

C. Endorsement Renewal. The Department-endorsed Paramedic shall complete twenty-four (24) hours of Department-approved continuing education above the NREMT certification requirements. The Department-endorsed Paramedic shall submit documentation of the continuing education with each Certificate renewal application.

D. Endorsement Reciprocity. A Paramedic seeking Endorsement through reciprocity shall submit a complete application in a format as determined by the Department that includes:

1. Documentation of training and/or certification in his or her current state. The Department may issue a one (1) year provisional Endorsement provided the Paramedic meets the minimum educational and clinical guidelines as established by the Department prior to expiration of the provisional specialty Endorsement; and
2. Documentation that the applicant is currently employed by or has a conditional employment offer from a Licensed Agency to provide the level of service.

E. The Endorsement shall only be granted by the Department to Paramedics that are currently certified by the Department. If a Paramedic's Certification is expired, suspended, or revoked by the Department, the Endorsement follows the same status as their certification.

F. The specialty endorsed Paramedic shall only practice their skills within the scope of practice of their Department-approved agency, under a South Carolina licensed Medical Control Physician. Specialty endorsed Paramedics are not independent healthcare practitioners.

G. The types of care rendered by specially endorsed Paramedics shall include, but are not limited to, critical care interfacility services, prehospital services, preventative care, social service referrals, chronic care support, follow-up care and maintenance, and tactical medical support of law enforcement.

H. Licensed Agencies providing these specialized services shall:

1. Be licensed at the ALS level and provide Community Paramedic, Critical Care Paramedic, or Tactical Paramedic services;
2. Have specific Protocols approved by the Department;
3. Develop and implement a Department-approved written training plan for training new employees and providing continuing education for each specialty endorsed Paramedic; and
4. Ensure at least one (1) crew member on each ground Ambulance providing Critical Care is a certified EMT and two (2) advanced level personnel (Paramedic, RN, Physician, or Respiratory Therapist) are in the Patient compartment during transport.

117. Certification Patches.

A. An individual initially certified in South Carolina at any level shall receive a complimentary patch for the level which he or she received his or her certification.

B. Additional patches may be purchased for individuals for services which meet the following criteria:

1. The individual holds a current South Carolina certification; or
2. The individual is an EMS agency director, logistics officer, or training officer and is purchasing patches in bulk for his or her service.

118. Variance.

An EMS Agency, EMT-basic, AEMT, Paramedic, training program, or instructor may request a Variance to a provision or provisions of this regulation in a format specified by the Department. Variances shall be considered on a case-by-case basis by the Department. The Department may revoke issued Variances as determined to be appropriate by the Department.

SECTION 200—ENFORCEMENT OF REGULATIONS

201. Inspections and Investigations. (I)

A. The EMS Agency is subject to Department inspections prior to initial licensing and subsequently as deemed appropriate by the Department.

B. All EMS Agencies, permitted Ambulances, equipment, and vehicles, EMTs, training programs, and instructors are subject to inspection by individuals authorized by the Department at any time without prior notice. The EMS Agency, EMT, training program, and instructor shall provide the Department all requested records and documentation in the manner and within the timeframe specified by the Department.

C. The EMS Agency shall maintain records that include approved Patient care report forms, employee or member rosters, or both, and training records. The EMS Agency shall grant individuals authorized by the Department access to all properties and areas, objects, requested records, and documentation at the time of the inspection or investigation. The EMS Agency shall provide the Department with photocopies of documentation and records required in the course of inspections or investigations for the purpose of enforcement of regulations. The Department shall maintain confidentiality of the documentation in accordance with South Carolina Code Section 44-61-160.

202. Plan of Correction.

When the Department cites a violation of this regulation, the EMS Agency, EMT-basic, AEMT, or Paramedic, Training Program, or EMT-basic, AEMT, or Paramedic Instructor shall submit an acceptable plan of correction in a format determined by the Department. The EMS Agency, EMT-basic, AEMT, or Paramedic, Training Program, or EMT-basic, AEMT, or Paramedic Instructor shall ensure:

A. The plan of correction is signed by the EMS Agency administrator or individual and returned by the date specified on the report of inspection or investigation.

B. The plan of correction describes: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar); and
3. The actual or expected completion dates of those actions.

203. Consultations.

Consultations may be provided by the Department as requested by the Licensee or Certificate holder, or as deemed appropriate by the Department.

SECTION 300—ENFORCEMENT ACTIONS

301. General.

The Department may suspend a License pending an investigation of an alleged violation or complaint. The Department may impose a civil monetary penalty up to five hundred dollars (\$500.00) per offense per day to a maximum of ten thousand dollars (\$10,000.00), revoke, or Suspend the License if the Department finds that an EMS Agency has:

1. Allowed uncertified personnel to perform Patient care;
2. Falsified forms or documentation as required by the Department;
3. Failed to maintain required equipment as evidenced by past compliance history;
4. Failed to maintain a Medical Control Physician;
5. Failed to maintain equipment in working order; or
6. Failed to respond to a call within the EMS Agency's service area without providing for response by an alternate service provider.

302. Enforcement Actions against EMT-basics, AEMTs, and Paramedics.

A. General. When the Department determines that a Certificate holder is in violation of any statutory provision, rule, or regulation, the Department, upon proper notice to the Certificate holder, may deny, suspend, or revoke the Certificate or assess a monetary penalty in accordance with Section 305.A or both.

B. The Department may take enforcement action, including suspending or revoking a certification and/or assessing a monetary penalty, against the holder of a Certificate at any time it is determined that the certification holder:

1. No longer meets the prescribed qualifications set forth by the Department;

2. Has failed to provide to Patients emergency medical treatment of a quality deemed acceptable by the Department, including failure to meet generally accepted standards for provision of care; or

3. Is guilty of Misconduct. Misconduct, constituting grounds for an enforcement action by the Department, means that while holding a Certificate, the holder:

a. Used a false, fraudulent, or forged statement or document or practiced a fraudulent, deceitful, or dishonest act in connection with the certification requirements or official documents required by the Department;

b. Was convicted of or currently under indictment for a felony or another crime involving Moral Turpitude, drugs, or gross immorality. The Certificate holder shall report in writing any arrest to the Department as soon as possible but not to exceed five (5) business days following the arrest or release from custody;

c. Is addicted to alcohol or drugs to such a degree as to render him or her unfit to perform as an EMT-basic, AEMT, or Paramedic;

d. Sustained a mental or physical disability that renders further practice by him or her dangerous to the public;

e. Obtained fees or assisted another in obtaining fees under dishonorable, false, or fraudulent circumstances;

f. Disregarded an appropriate order by a physician concerning emergency treatment, including protocol violations without appropriate justification;

g. At the scene of an accident or illness, refused to administer emergency care based on the age, sex, race, religion, creed, or national origin of the Patient;

h. After initiating care of a Patient at the scene of an accident or illness, discontinued care or Abandoned the Patient without the Patient's consent or without providing for the further administration of care by an equal or higher medical authority;

i. Revealed confidences entrusted to him or her in the course of medical attendance, unless this revelation was required by law or is necessary to protect the welfare of the individual or the community;

j. By action or omission and without mitigating circumstance, contributed to or furthered the injury or illness of a Patient under his or her care;

k. Was careless, reckless, or irresponsible in the operation of an emergency vehicle;

l. Performed skills above the level for which he or she was certified or endorsed or performed skills that he or she was not trained to do;

m. Observed the administration of substandard care by another EMT-basic, AEMT, Paramedic, or other medical provider without documenting the event and notifying a supervisor;

n. By his or her actions or inactions, created a substantial possibility that death or serious physical harm could result;

o. Did not take or complete remedial training or other courses of action as directed by the Department as a result of an investigation or inquiry;

p. Was found to be guilty of the falsification of documentation as required by the Department;

q. Breached a section of the Emergency Medical Services Act of South Carolina or a subsequent amendment of the Act or any rules or regulations published pursuant to the Act;

r. Has acted to disrespect, demean, disparage the Patient; has used profane, vulgar, or obscene language to or directed at the Patient; or has derogated from standard professional conduct; or

s. Was found guilty of a violent crime as defined in S.C. Code Section 16-1-60.

C. The Department may suspend a Certificate pending the investigation of any complaint or allegation regarding the commission of an offense including those listed in Section 302.B.

303. Investigative Review Committee.

The Department may convene, at its discretion, the Investigative Review Committee when the findings of an official investigation against an entity or an individual regulated by the Department may warrant Suspension or Revocation of a License or Certificate. This committee shall consist of the State Medical Control Physician, three (3) regional EMS office representatives, at least one (1) Paramedic, and at least one (1) emergency room physician who is also a Medical Control Physician.

304. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the persons being served, other employees, or the general public; or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be considered a subsequent violation.

B. Class II violations are those other than Class I violations the Department determines to have a negative impact on the health, safety or well-being of those being served, other employees, or the general public. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be considered a subsequent violation.

D. Class IV violations are those that are specific to vehicle inspections. These violations may escalate based on the frequency and the point value accrued per deficiency identified in the vehicle inspections conducted by the Department.

E. The notations “(I)” or “(II)”, placed within sections of this regulation, indicate that those standards are considered Class I or II violations, if they are not met, respectively. Standards not so annotated are considered Class III violations. Class IV violations are specific to vehicle reinspection which may escalate to Class III violations.

F. In arriving at a decision to take enforcement actions, the Department shall consider the following factors: specific conditions and their impact or potential impact on the health, safety, or well-being of those being served, other employees and the general public, efforts by the EMT-basic, AEMT, Paramedic, EMS Agency, training program or EMT-basic, AEMT, or Paramedic instructor to correct cited violations; behavior of the entity in violation that reflects negatively on that entity’s character, such as illegal or illicit activities; overall conditions; history of compliance; and any other pertinent factors that may be applicable to current statutes and regulations.

305. Monetary Penalties.

A. When imposing a monetary penalty against an EMS Agency, EMT-basic, AEMT, or Paramedic the Department may utilize the following schedule to determine the dollar amount:

FREQUENCY OF VIOLATION	CLASS I	CLASS II	CLASS III
1 st	\$300 - 500	\$100 - 300	\$50 — 100
2 nd	\$500 - 1,500	\$300 - 500	\$100 — 300
3 rd	\$1,000 - 3,000	\$500 - 1,500	\$300 — 800
4 th	\$2,000 - 5,000	\$1,000 - 3,000	\$500 -1,500
5 th	\$5,000 - 7,500	\$2,000 - 5,000	\$1,000 - 3,000
6 th or more	\$10,000	\$7,500	\$2,000 - 5,000

B. When a licensed Agency fails a vehicle reinspection, a Class IV penalty may be levied upon the agency. Pursuant to S.C. Code Section 44-61-70, the following Class IV penalty schedule shall be used

when a permitted Ambulance or licensed Emergency Medical Responder Agency loses points upon reinspection:

FREQUENCY OF VIOLATION	CLASS IV Points	Penalty
1 st	0–24	\$25–50
2 nd	25–50	\$50–100
3 rd	51–100	\$100–300
4 th	101–500	\$300–500
5 th	501–1,000	\$500–1,500
6 th or more	Over 1,000	\$1,000–3,000

SECTION 400—POLICIES AND PROCEDURES (II)

- A. The EMS Agency shall implement and be in full compliance with its policies and procedures.
- B. The EMS Agency shall maintain written policies and procedures to include at least:
 - 1. Staffing patterns to ensure compliance with en route times pursuant to Sections 504.B.2 and 505.A.2;
 - 2. If electing to participate in a tiered response system, policies and procedures and, if necessary, mutual aid agreements in place to identify the acuity of the incoming EMS requests in order to properly triage the response and dispatch the appropriate level of Ambulance;
 - 3. Continuing Patient transport if a vehicle becomes disabled;
 - 4. Employee records retention and conducting background checks for credentialed and non-credentialed personnel;
 - 5. Governing the identification of EMS Personnel while providing care or while responding that includes level of certification;
 - 6. Reporting and investigating Adverse Incidents pursuant to Section 601;
 - 7. Infection control and prevention;
 - 8. Addressing the clean appearance of the EMT-basics, AEMTs, Paramedics, and Drivers;
 - 9. Ensuring all EMS Personnel receive annual blood-borne pathogen training and maintain documentation of the training;
 - 10. Smoking Policy, including prohibiting the use of tobacco products or tobacco-like products (such as electronic cigarettes) in the Patient compartment, the operator compartment of Ambulances, or within twenty (20) feet of the Ambulance or any other apparatus in which oxygen is carried;
 - 11. Recognizing out-of-service vehicles, which includes a highly visible mechanism at the Driver’s position;
 - 12. Defining, implementing, and reviewing Quality Assurance and/or process improvement practices with regard to medical care provided by its EMS Personnel;
 - 13. Medication Management to include written Protocols for storage and maintenance of controlled substances; periodic inspection and inventory of maintained controlled substances by the EMS Agency Director, EMS Agency Assistant Director, Medical Control Physician and/or Assistant Medical Control Physician; and
 - 14. Maintaining service in the event of the sudden or unexpected loss of the primary Medical Control Physician.
- C. The EMS Agency shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented and signed by the EMS Agency director. The EMS Agency shall ensure all policies and procedures are accessible to the EMS Agency personnel, printed or electronically, at all times.

SECTION 500—PERSONNEL REQUIREMENTS

501. General. (I)

- A. The EMS Agency shall ensure an EMT-basic, AEMT, or Paramedic is in the Patient compartment at all times during Patient transport.

B. The EMS Agency may utilize registered nurses and physicians from a transferring or receiving medical facility as Ambulance Attendants to assist EMTs in the performance of their duties during transport when any of the following requirements are met:

1. The required medical care of the Patient is beyond the scope of practice for the certification level of the EMT; or
2. The responsible physician, transferring or receiving, assumes responsibility of the Patient or provides appropriate written orders to the registered nurse for Patient care.

502. Medical Control Physician. (I)

A. The EMS Agency shall retain a Medical Control Physician, who shall have independent authority to execute his or her duties and responsibilities, to:

1. Provide oversight to ensure that all EMT-basics, AEMTs, and Paramedics for which he or she provides direction are properly educated and certified pursuant to this regulation;
2. Provide oversight to ensure that an effective method of quality assurance and improvement, with assistance of the EMS Agency Director, Data Manager, and other EMS Personnel, is integrated into the emergency medical provider services for which he or she provides Medical Control; and
3. Provide off-line Medical Control by Protocols.

B. The EMS Agency shall ensure that Protocols and authorized medication lists updated by the Medical Control Physician are submitted to the Department within five (5) business days of the updates in a manner prescribed by the Department.

C. The EMS Agency's primary Medical Control Physician may designate medical oversight authority to assistant or associate Medical Control Physicians. The EMS Agency's Medical Control Physician may withdraw, at his or her discretion, the authorization for EMS Personnel to perform any or all Patient care procedure(s) or responsibilities. The EMS Agency shall notify the Department when the Medical Control Physician withdraws the authorization to perform any or all Patient care procedure(s) or responsibilities within three (3) calendar days. The EMS Agency's Medical Control Physician may respond to scene calls to render care, function as medical providers, provide medical direction, and/or exercise their medical oversight authority.

D. The EMS Agency shall ensure all initial Medical Control Physicians attend a Medical Control Physician Workshop conducted by the Department within twelve (12) months of being designated as Medical Control Physician and complete all Department mandated continuing education updates.

E. The EMS Agency shall not engage in EMS response without a Medical Control Physician.

503. Driver. (II)

A. The EMS Agency shall:

1. Ensure each Ambulance Driver is at least eighteen (18) years of age;
2. Ensure each Ambulance Driver has in their possession at the time of vehicle operation a valid driver's license issued by the South Carolina Department of Motor Vehicles or from the state of his or her residence;
3. Conduct a state criminal background check from the South Carolina Law Enforcement Division (SLED) prior to the date of hire on each Ambulance Driver;
4. Secure and review a certified copy of each Ambulance Driver's three (3)-year driving record;
5. Not employ an Ambulance Driver who is registered or required to be registered as a sex offender with the South Carolina Law Enforcement Division (SLED) or any national registry of sex offenders;
6. Ensure each Ambulance Driver has documentation of completion of a nationally accredited driving safety course specific to Ambulances, which includes practical skill evolutions, within six (6) months of hire; and
7. Ensure each Ambulance Driver has a current Department-approved CPR credential and First Aid training.

B. The EMS Agency shall maintain documentation to ensure the EMS Agency meets the requirements pursuant to Section 503.A and submits to the Department upon request.

C. The EMS Agency shall ensure all Patients are transported with certified EMS Personnel in addition to the Driver.

D. In emergencies that may require a third crew member, such as multiple casualty incidents (MCIs), disasters, or where immediate local EMS resources are taxed, an Ambulance may, out of necessity, be driven to the hospital by a member of a fire department, law enforcement agency, or rescue squad. These out-of-necessity Drivers are exempt from Section 503.A, B, and C.

504. Emergency Medical Responder Agency. (II)

A. The Emergency Medical Responder Agency shall ensure the Emergency Medical Responder vehicles are not used for the transportation of Patients.

B. Personnel. The Emergency Medical Responder Agency shall ensure and document in its employee records that each of its EMT-basics, AEMTs, and Paramedics holds a current Certificate from the Department. The Emergency Medical Responder Agency shall:

1. Ensure that vehicles are staffed in accordance with Section 504.B.2 and en route to all emergent calls within five (5) minutes from the time the call is dispatched and en route within ten (10) minutes for non-emergency calls. If the Emergency Medical Responder Agency is requested to respond, an EMT-basic must respond on calls for a BLS Agency and a Paramedic must respond for an ALS Agency eighty percent (80%) of the time.
2. Meet the staffing required for each response level as follows:(I)
 - a. BLS, at least one (1) EMT-basic or higher; and
 - b. ALS, at least one (1) Paramedic.
3. Documentation. The Emergency Medical Responder Agency shall maintain the following documentation available as requested by the Department:
 - a. Staffing patterns to ensure compliance with en route times;
 - b. Approved Patient care report forms, employee and member rosters, time sheets, call rosters, training records; and
 - c. Dispatch logs that show at least the time the call was received, the type of call, and en route times.

505. Ambulance Service Agency. (II)

A. Personnel. The EMS Agency shall ensure all Ambulance Attendants have a valid EMT-basic, AEMT, or Paramedic Certificate. The EMS Agency shall maintain documentation that each of its EMT-basics, AEMTs, and Paramedics holds a current certification from the Department. The Ambulance Service Agency shall:

1. Ensure that vehicles are staffed in accordance with Section 505.A.2 and en route to all emergent calls within five (5) minutes from the time the call is dispatched and en route within ten (10) minutes for non-emergency calls.
2. Have equipment and staff on all Ambulances to ensure the level of trained and qualified personnel coincide with the requirements for its vehicle classification:(I)
 - a. BLS level service shall provide care and transport with at least one (1) EMT and one (1) Driver.
 - b. ALS level service shall provide care and transport with at least one (1) EMT and one (1) Paramedic. The EMS Agency shall ensure Ambulances transporting Patients requiring ALS level service are fully equipped as an ALS unit with a Paramedic, physician, or RN in the Patient compartment at all times.
3. If the Ambulance Service Agency only has one (1) EMT available to staff the Ambulance, the Ambulance Service Agency shall ensure that the EMT is the Patient care provider and supervise the care being provided.

B. The EMS Agency shall maintain documentation that demonstrates compliance with all en route requirements and make it available to the Department upon request.

506. Special Response Vehicle (SRV).

The EMS Agency may utilize a non-permitted Special Response Vehicle (SRV) as a first response vehicle. The EMS Agency shall ensure each SRV is staffed with a minimum of one (1) EMT that is

credentialed at the BLS or ALS level as determined by the Medical Control Physician. The EMS Agency shall ensure the SRV is equipped as authorized by the Medical Control Physician.

507. Tiered Response System. (II)

A. An EMS Agency utilizing a tiered response system shall have a dispatch process in place to specifically and reliably identify the acuity of the incoming EMS request to properly triage the response and dispatch the appropriate level of care.

B. The EMS Agency may operate an ALS level-equipped Ambulance with BLS level personnel provided an ALS credentialed responder intercepts the Ambulance.

C. If an ALS responder intercepts a BLS Ambulance, the EMS Agency shall ensure equipment and personnel needed to provide ALS care is transferred and onboard the Ambulance prior to commencing Patient transport.

508. Volunteer EMS Agencies.

A. A Volunteer EMS Agency shall have an EMT-basic, AEMT, or Paramedic attending to the Patient at the scene and in the Ambulance while transporting the Patient to the hospital.

B. Volunteer Emergency Medical Responder Agencies without onsite EMT-basics, AEMTs, or Paramedics shall be en route with at least one (1) EMT to all emergent calls within ten (10) minutes from the time the call is dispatched.

C. If the Volunteer EMS Agency service has a written response policy in place in which an EMT is allowed to respond directly to the scene from home or work, the EMS Agency may respond to the scene of the Emergency even if an EMT is not on board the Ambulance. The EMS Agency shall make the response policy available for inspection by the Department upon request.

D. If the Volunteer EMS Agency's EMT responding directly to the scene is delayed and another EMS Agency is immediately available with the required EMS Personnel, the Patient shall be transported by that Agency. If no other service is immediately available, the volunteer EMS Agency shall not transport a Patient without at least one (1) EMT on board.

E. If only one (1) EMT is available to staff the Ambulance crew, the Volunteer EMS Agency shall ensure that the EMT is the Patient care provider and/or supervises the Patient care being provided. The volunteer EMS Agency shall ensure a sole EMT is not the Driver of the Ambulance when a Patient is being transported.

F. The Volunteer EMS Agency shall preplan for the lack of staffing by written mutual aid agreements with neighboring agencies and by alerting the local Public Safety Answering Point (PSAP) as early as possible when it is known that EMT level staffing is not available. The Volunteer EMS Agency shall ensure sufficient staffing through preplanning, mutual aid agreements, and continual recruitment programs.

G. The Volunteer EMS Agency shall ensure in all cases where the level of care is either EMT-basic, AEMT, or Paramedic, the transporting unit is fully equipped to perform at that level of care.

SECTION 600—REPORTING

601. Adverse Incident Reporting.

A. The requirements of Section 601 will take effect (1) year following the date of publication of this regulation in the *State Register*.

B. The EMS Agency shall maintain a record of each Adverse Incident. The EMS Agency shall retain all documented Adverse Incidents reported pursuant to this section two (2) years after the Patient contact or transport.

C. The EMS Agency shall report Adverse Incidents to the Department via the Department's electronic reporting system or other format as determined by the Department as soon as possible, but not to exceed seventy-two (72) hours from becoming aware of the Adverse Incident. Failure to report the following Adverse Incidents may result in a Class II violation: (II)

1. Confirmed or suspected Abuse, Neglect, or Exploitation against a Patient by EMS Personnel;
2. Crimes committed against Patients by any EMS Personnel;
3. Unexpected or unexplained death of a Patient while under the care of the EMS Agency;

4. Any suspected overdose reversal administered to on duty EMS Personnel;
5. Elopement of Patient;
6. Any injury caused by EMS Personnel, including injuries involving the use of physical and/or chemical restraints;
7. Medication error with adverse effects or that would cause potential harm to the Patient;
8. Suicide and/or attempted suicide while under the EMS Agency's care;
9. Any Patient that is dropped or falls while under the care of an EMS Agency, including where no injury occurs, to include stretcher drops due to malfunction or operator error; and
10. Any suspected or confirmed use of illicit or un-prescribed medications or alcohol by a crew member while on duty, to include providing Patient care and/or the operation of an EMS Agency vehicle.

D. The EMS Agency shall submit a separate written investigation report within five (5) calendar days of every Incident required to be immediately reported to the Department pursuant to Section 601.C via the Department's electronic reporting system or in a format as determined by the Department. The EMS Agency's report of investigation to the Department shall include the following information: (II)

1. EMS Agency name, License number, type of Adverse Incident, the date the accident and/or Adverse Incident occurred;
2. Number of Patients, staff, or by-standers directly injured or affected;
3. ePCR number, if applicable;
4. Patient name, age, and gender;
5. Witness(es) name(s); and
6. Identified cause of the Adverse Incident, internal investigation results if cause unknown, a brief description of the Adverse Incident including location where occurred, treatment of injuries, and cause of errors or omission in Patient care rendered, if applicable.

602. Collisions.

The EMS Agency shall notify the Department within seventy-two (72) hours of any collision involving any EMS Agency's vehicle or aircraft used to provide emergency medical services that results in any degree of injury to personnel, pedestrians, Patients, passengers, observers, students, or other persons. The EMS Agency shall submit the Ambulance Permit, if applicable, to the Department if the damage renders the Ambulance out of service for more than two (2) weeks. The EMS Agency shall submit the investigating law enforcement agency's accident report regarding the collision to the Department upon the EMS Agency's receipt.

603. Administration Changes.

A. The EMS Agency shall notify the Department in writing within seventy-two (72) hours of any expansion or contraction of the service, level of care, upgrade or downgrade, or if the physical locations are changed.

B. The EMS Agency shall notify the Department in writing or a means as otherwise determined by the Department within seventy-two (72) hours of any change in status of the EMS Director or EMS Training Officer. The EMS Agency shall provide the Department in writing within ten (10) calendar days the name of the person(s) appointed or hired into those positions and the effective date of the appointment or hire.

C. The EMS Agency shall within twenty-four (24) hours notify the Department of any change in status to the Medical Control Physician. The EMS Agency shall notify the Department in writing or other means as determined by the Department the name of the newly appointed Medical Control Physician, the effective date, the authorized medication list, Protocols, and standing orders within ten (10) calendar days after the change.

604. Accounting of Controlled Substances. (I)

Any EMS Agency registered with the Department's Bureau of Drug Control and the United States Drug Enforcement Administration shall report any theft or loss of Controlled Substances to local law enforcement and to the Department's Bureau of Drug Control within seventy-two (72) hours of the

discovery of the loss and/or theft. Any Agency permitted by the South Carolina Board of Pharmacy shall report the loss or theft of drugs or devices in accordance with S.C. Code Section 40-43-91.

605. Agency Closure.

A. Prior to the permanent closure of an EMS Agency, the Licensee shall notify the Department in writing of the intent to close and the effective closure date. Within ten (10) calendar days of the closure, the EMS Agency shall notify the Department of the provisions for the maintenance of all records including the custodian of the Patient care reports. On the date of closure, the EMS Agency shall return its License and all Ambulance Permits to the Department.

B. In instances where an EMS Agency temporarily closes, the Licensee shall notify the Department in writing within fifteen (15) calendar days prior to temporary closure. In the event of temporary closure due to an emergency, the EMS Agency shall notify the Department within twenty-four (24) hours of the closure via telephone or email. At a minimum, this notification shall include, but not be limited to, the reason for the temporary closure, the manner in which the records and Patient care reports are being stored, and the anticipated date for reopening.

C. If the EMS Agency is closed for a period longer than six (6) months and there is a desire to reopen, the EMS Agency shall reapply to the Department for licensure and shall be subject to all licensing requirements at the time of that application.

SECTION 700—PATIENT CARE

701. General.

A. The EMS Agency shall create and submit an ePCR for each Patient contact regardless of Patient transport decision.

B. The EMS Agency shall ensure the primary Attendant documents all ePCRs within twenty-four (24) hours of the completion of the call.

C. The EMS Agency shall submit all completed ePCRs into the Department's EMS data system within seventy-two (72) hours of the completion of the call.

D. The EMS Agency shall make available each ePCR to the receiving facility within sixty (60) minutes of the completion of the call. The EMS Agency may substitute a paper information sheet, provided the ePCR is made available to the receiving facility no later than twenty-four (24) hours from completion of the call. The EMS Agency may use a custom Preliminary Patient Transfer Form as long as the following minimum components are documented:

1. Incident type, date, location, and tracking number;
2. EMS Agency name;
3. Ambulance identifier;
4. EMS personnel name(s) and certification number(s);
5. Time of Dispatch, at-patient time, scene departure time, and destination arrival time;
6. Patient information to include Patient name, address, and date of birth;
7. Assessment and/or Treatment information to include the chief complaint; vital signs, including Rapid Artery occlusion Evaluation (RACE), Glasgow Coma Score (GCS), and Revised Trauma Score (RTS) if applicable; signs, symptoms, procedures, and interventions with pertinent times; medications with times; and a brief narrative; and
8. Transfer of care information to include the receiving nurse, physician, or EMS Personnel with signature.

702. Data Manager.

The EMS Agency shall appoint a Data Manager to ensure accuracy, HIPAA compliance, security, and timely submission of ePCRs and to ensure the ePCRs reflect all the Attendants, including Drivers. The EMS Agency shall notify the Department of any change in the Data Manager within ten (10) calendar days.

703. Content.

A. The EMS Agency shall ensure each ePCR reflects services, treatment, and care provided directly to the Patient including information required to properly identify the Patient, a narrative description

of the call from time of first Patient contact to final destination, all EMS Personnel and non-EMS responders on the call, and other information as determined by the Department.

B. The EMS Agency shall ensure all ePCRs are coherently written, authenticated by the author, and time stamped.

C. The EMS Agency shall ensure EMS Personnel complete ePCRs involving refusals that include the following: details of any assessment performed; information regarding the Patient's capacity to refuse; information regarding an informed refusal by the Patient; information regarding EMS Personnel's efforts to convince the Patient to accept care; and any efforts by the EMS Personnel to protect the Patient after the refusal if the Patient becomes incapacitated.

D. The EMS Agency shall ensure all data submissions from the ePCR software maintain a minimum quality score as determined by the Department. The EMS Agency shall have ninety (90) calendar days from the Department's notification to successfully correct data quality.

704. Report Maintenance.

A. The EMS Agency shall ensure data submissions from ePCR software into the Department's EMS data system meet the Department's requirements.

B. The EMS Agency shall provide accommodations and equipment for the protection, security, and storage of Patient care reports.

C. The EMS Agency shall maintain a copy of the original data, all attachments, and appended versions of each ePCR for no less than ten (10) years for all adult Patients and thirteen (13) years for minor Patients. The EMS Agency shall ensure attachments to ePCRs include EKGs, waveform capnography records, code summaries, short reports, and other forms of recorded media.

D. In the event of a change of ownership, the EMS Agency shall ensure Patient care reports are transferred to the new Licensee.

E. The EMS Agency shall ensure the ePCRs are made available only to individuals authorized by the Licensee and/or state and federal laws.

705. Do Not Resuscitate (DNR) Order. (II)

A. EMT-basics, AEMTs, and Paramedics shall not use any Resuscitative Treatment when called to render emergency medical services if the Patient has a DNR Order and the document is presented to the EMT, AEMT, or Paramedic upon their arrival or if the Patient is wearing a Bracelet.

B. EMT-basics, AEMTs, and Paramedics shall provide the degree of Palliative Care called for under the circumstances that exist at the time treatment is rendered.

C. EMT-basics, AEMTs, and Paramedics shall give full resuscitative measures as are medically indicated in all cases in the absence of a DNR Order or a Bracelet.

D. EMT-basics, AEMTs, and Paramedics shall follow the request of the Patient and shall not provide resuscitative measures when the Patient has a DNR Order or is wearing a Bracelet, except where the:

1. DNR Order is revoked pursuant to S.C. Code Section 44-78-60; or
2. Bracelet, when applicable, appears to have been tampered with or removed.

E. EMT-basics, AEMTs, and Paramedics who cannot honor the DNR Order or Bracelet shall immediately transfer care of the Patient pursuant to S.C. Code Section 44-78-45.

706. Physician Orders for Scope of Treatment (POST). (II)

A. EMT-basics, AEMTs, and Paramedics shall deem a POST form executed in South Carolina as provided in the POST Act or a similar form executed in another jurisdiction in compliance with the laws of that jurisdiction. EMT-basics, AEMTs, and Paramedics shall accept a completed, executed, and signed POST form deemed as valid expression of a Patient's wishes as to health care.

B. EMT-basics, AEMTs, and Paramedics may accept a properly executed POST form as a valid expression of whether the Patient consents to the provision of health care in accordance with Section 44-66-60 of the Adult Health Care Consent Act.

C. An EMT-basic, AEMT, or Paramedic who is unwilling to comply with an executed POST form based on policy, religious beliefs, or moral convictions shall contact the Patient's health care representative, health care agent, or the person authorized to make health care decisions for the Patient pursuant

to Section 44–66–30 of the Adult Health Care Consent Act, and the EMT-basic, AEMT, or Paramedic shall allow the transfer of the Patient pursuant to S.C. Code Section 44–80–40.

SECTION 800—[RESERVED]

SECTION 900—[RESERVED]

SECTION 1000—[RESERVED]

SECTION 1100—[RESERVED]

SECTION 1200—MEDICATIONS

1201. General. (I)

The EMS Agency shall manage medications, including controlled substances, medical supplies, and those items necessary for the rendering of first aid, in accordance with federal, state, and local laws and regulations. The EMS Agency shall ensure such medication management includes securing, storing, administering, and disposal of discontinued or expired drugs, including controlled substances.

1202. Medication Orders. (I)

A. The EMS Agency shall ensure medications are administered to Patients only upon orders of a physician. All verbal and written orders for controlled substances shall be signed and dated by a physician no later than fourteen (14) days after the order is given. A physician's signature shall be present on all controlled substance administrations or if an electronic record is utilized the controlled medication section must have a separate and distinct approval utilizing electronic digital signatures, separate from the ePCR content.

B. The EMS Agency shall ensure all orders for controlled substances are documented, signed, and dated by the approving physician. EMS Agencies employing electronic signatures or computer-generated signature codes shall ensure orders for controlled substances are authenticated by the prescribing Physician. The EMS Agency shall ensure each ePCR includes either the emergency room physician or local Medical Control Physician approval using electronic digital signatures. The EMS Agency shall not utilize a phrase such as "Per Protocol" in lieu of the approving physician's signature.

1203. Administering Medication and/or Treatments. (I)

The EMS Agency shall ensure doses of medication, including controlled substances, are administered by the same EMS Personnel who prepared them for administration. The EMS Agency shall maintain records of receipt, administration, and disposition of all medications, including controlled substances, to enable an accurate reconciliation including:

A. The first and last name of the EMS personnel who administered the medication using either of the following methods:

1. An electronic signature in a computerized recordkeeping system; or
2. A legible manual signature of a hard copy record.

- B. The name of the EMS Agency;
- C. The Patient name and run number;
- D. The name and strength of the medication administered;
- E. The date of administration;
- F. The time of administration;
- G. The amount of the dose administered in milliliters (ml);
- H. The amount of waste; and
- I. The name of physician ordering the medication.

1204. Medication Storage.

A. The EMS Agency shall ensure all medications are stored at the temperature range established by the manufacturer.

B. The EMS Agency shall store all medications in accordance with applicable state and federal laws. The EMS Agency shall maintain an inventory of the stock and distribution of all controlled substances

in a manner that the disposition of any particular item is readily traced and pursuant to Regulation 61–4, Controlled Substances.

C. The EMS Agency shall ensure controlled substances listed in Schedules II, III, IV, and V shall be stored in a double locked system and kept in a manner consistent with Regulation 61–4 and federal Drug Enforcement Administration (DEA) regulations. The EMS Agency shall ensure medications are monitored and attended to prevent access by unauthorized individuals. The EMS Agency shall ensure expired or discontinued medications are not to be stored with current medications.

1205. Disposition of Controlled Substances.

A. The EMS Agency shall dispose and destroy Controlled Substance in accordance with requirements of the federal Drug Enforcement Administration.

B. The EMS Agency shall upon closure notify the federal Drug Enforcement Administration and the Department’s Bureau of Drug Control and surrender controlled substances registrations.

SECTION 1300—[RESERVED]

SECTION 1400—[RESERVED]

SECTION 1500—[RESERVED]

SECTION 1600—[RESERVED]

SECTION 1700—SANITATION AND INFECTION CONTROL

1701. General.

A. The EMS Agency shall maintain and implement personnel practices that promote conditions that prevent the spread of infectious, contagious, or communicable diseases, including but not limited to standard precautions, transmission-based precautions, contact precautions, airborne precautions, and isolation techniques. The EMS Agency shall ensure proper disposal of toxic and hazardous substances. The EMS Agency shall ensure the preventive measures and practices are in compliance with applicable guidelines of the Bloodborne Pathogens Standard of the Occupational Safety and Health Act of 1970; the Centers for Disease Control and Prevention; R.61–105, Infectious Waste Management; and other applicable federal, state, and local laws and regulations.

B. The EMS Agency shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions such as gloves in accordance with established guidelines.

1702. Exterior Ambulance Surfaces.

A. The EMS Agency shall ensure the exterior of the vehicle has a reasonably clean appearance.

B. The EMS Agency shall ensure exterior lighting is kept clear of foreign matter (insects, road grime, or other) to ensure adequate visibility.

1703. Interior Ambulance Surfaces Patient Compartment.

A. The EMS Agency shall ensure interior surfaces of each Ambulance are of a nonporous material to allow ease of cleaning and that carpet-type materials are not used on any surface of the patient compartment.

B. The EMS Agency shall ensure:

1. The floors of each Ambulance are free from sand, dirt, and other residue that may have been tracked into the compartment;

2. The wall, cabinet, and bench surfaces of each Ambulance are kept free of dust, sand, grease, or any other accumulated surface matter;

3. The interiors of cabinets and compartments of each Ambulance are kept free from dust, moisture, or other accumulated foreign matter;

4. Bloodstains, vomitus, feces, urine, and other similar matter are cleaned from each Ambulance and all equipment after each call, using an agent or sodium hypochlorite solution described in Section 1703.C;

5. Window glass and cabinet doors of each Ambulance are clean and free from foreign matter;

6. Each Ambulance is equipped with a receptacle provided for the deposit of trash, litter, and all used items; and

7. A container specifically designed for the safe deposit and secure retainment of contaminated needles or syringes and a second container for contaminated or infectious waste is provided on each Ambulance that is easily accessible from the Patient compartment.

C. The EMS Agency shall utilize an Environmental Protection Agency-recommended germicidal and viricidal agent or a hypochlorite solution of ninety-nine (99) parts water and one (1) part bleach to clean Patient contact areas. The agency shall utilize alcohol or sodium hypochlorite solution for surfaces where such an EPA solution is recommended; however, alcohol should not be used for disinfection of large surfaces. The EMS Agency shall ensure the contact time for the hypochlorite solution is in accordance with the respective EPA registration for the select pathogen.

D. EMS Agencies shall clean all vehicles after each call.

1704. Linen.

A. The EMS Agency shall ensure that each Ambulance stores and maintains dry, clean linen.

B. The EMS Agency shall ensure each Ambulance is equipped with at least six (6) sets of freshly laundered or disposable linens to be used on cots and pillows and changed after each Patient is transported.

C. The EMS Agency shall ensure soiled linen is transported on the Ambulance in a closed plastic bag or container and removed from the Ambulance as soon as possible.

D. The EMS Agency shall ensure each Ambulance maintains blankets and towels that are intact, in good repair, and cleaned or laundered after each Patient use. The EMS Agency shall ensure that the blankets are a hypoallergenic material designed for easy maintenance.

1705. Oxygen Administration Apparatus. (II)

A. The EMS Agency shall ensure oxygen administration devices such as masks, cannulas, and delivery tubing are disposable and only used once.

B. The EMS Agency shall ensure all masks, cannulas, and delivery tubing are individually wrapped and unopened until used on a Patient.

C. The EMS Agency shall ensure oxygen humidifiers are only filled with distilled or sterile water upon use and cleaned after each use. The EMS Agency may utilize disposable single-use oxygen humidifiers in lieu of multi-use types.

D. The EMS Agency shall ensure each Ambulance that carries portable oxygen tanks maintains a non-sparking oxygen wrench for use with the oxygen tanks.

1706. Resuscitation Equipment. (II)

A. The EMS Agency shall ensure bag mask assemblies and masks are free from dust, moisture, and other foreign matter and stored in the original container, jump kit, or a closed compartment on the Ambulance. The EMS Agency shall ensure each Ambulance maintains additional equipment needed to facilitate the use of a bag valve mask, such as a syringe, stored with the bag mask assembly. The EMS Agency shall ensure all masks, valves, reservoirs, and other items or attachments for bag mask assemblies are clean and manufacturer's recommendations on single-use equipment are followed where indicated.

B. The EMS Agency shall utilize an EPA-recommended germicidal and viricidal agent or a sodium hypochlorite solution of ninety-nine (99) parts water and one (1) part bleach to clean resuscitation equipment not specifically addressed as single-use. The EMS Agency shall utilize alcohol or sodium hypochlorite solution to clean resuscitation equipment surfaces where such an EPA solution is recommended.

1707. Suction Unit. (II)

A. The EMS Agency shall ensure suction hoses are clean and free from foreign matter and manufacturers' recommendations on single-use equipment are followed where indicated.

B. The EMS Agency shall ensure the suction reservoir of each suction unit is clean and dry.

C. The EMS Agency shall ensure suction units are clean and free from dust, dirt, or other foreign matter.

D. The EMS Agency shall ensure tonsil tips and suction catheters are of the single-use disposable type and stored in sealed sterile packaging until used.

E. The EMS Agency shall ensure suction units with attachments are cleaned and sanitized after each use.

1708. Splints. (II)

The EMS Agency shall ensure:

A. Padded splints are neatly covered with a non-permeable material and clean, and when the outside cover of the splint becomes soiled, they are thoroughly cleaned or replaced;

B. Commercial splints are free of dust, dirt, or other foreign matter;

C. Traction splints with commercial supports are clean and free from accumulated material;

D. All splinting materials are stored in such a manner as to promote and maintain cleanliness;

E. Splints are in functional working order with the recommended manufacturer's attachments; and

F. Manufacturer's recommendations on single-use splint equipment are followed where indicated.

1709. Spinal Motion Restriction Device. (II)

A. The EMS Agency shall ensure all pillows, mattresses, and spinal motion restriction devices (SMRDs) that are not single-use items are covered with a non-permeable material and in good repair. The EMS Agency shall remove any compromised stretcher or spine board from service.

B. The EMS Agency shall ensure

1. All stretchers, cots, pillows, SMRDs, and spine boards are clean and free from foreign material;

2. Canvas or neoprene covers on portable-type stretchers are in good repair;

3. All restraint straps and/or devices are kept clean and washed immediately if soiled;

4. Spinal motion restriction devices are manufactured from an appropriate material to facilitate cleaning; and

5. All spinal motion restriction devices are free from rough edges or areas that may cause injury.

1710. Bandages and Dressings. (II)

A. The EMS Agency shall ensure all bandages are clean and individually wrapped or stored in a closed container or cabinet. The EMS Agency shall ensure triangular bandages are single-use disposable type.

B. The EMS Agency shall ensure dressings are sterile, individually packaged and sealed, stored in a closed container or compartment, and if the seal is broken or wrap is torn, the dressing is discarded.

C. The EMS Agency shall ensure burn sheets are sterile and single-use only.

D. The EMS Agency shall ensure all bandages or dressings that have been exposed to moisture or soiled are replaced.

1711. Obstetrical (OB) Kits. (II)

A. The EMS Agency shall ensure all OB kits are sterile and wrapped with cellophane or plastic, and if the wrapper is torn or the kit is opened but not used, the items in the kit that are not individually wrapped are discarded and replaced.

B. The EMS Agency shall ensure all OB kits are single-use only.

C. The EMS Agency shall ensure all items in each OB kit past the expiration date are replaced individually if other items are individually sealed and sterile.

1712. Oropharyngeal Appliances. (II)

The EMS Agency shall ensure single-use instruments inserted into a Patient's mouth or nose are individually wrapped and stored properly. The EMS Agency shall ensure all instruments inserted into a Patient's mouth that are not intended for single-use only are cleaned and decontaminated following manufacturer's guidelines.

1713. Communicable Diseases. (II)

A. The EMS Agency shall ensure that when an Ambulance has been contaminated with blood, body fluids, or other potentially infectious material (OPIM), to include potential contamination from

respiratory droplets if transporting a Patient with signs or symptoms consistent with a respiratory illness of an infectious cause, the vehicle is taken out of service until decontamination is completed.

B. The EMS Agency shall ensure all linen used during any transport is removed from the cot and properly disposed of, or immediately placed in a designated, leak-proof bag or container and sealed until cleaned. The EMS agency shall ensure all used linen is treated as contaminated and handled as per standard precautions.

C. The EMS Agency shall ensure all Patient contact areas, equipment, and any surface soiled during the call is cleaned and disinfected pursuant to Section 1703.C.

1714. Equipment.

The EMS Agency shall ensure all reusable equipment used for direct Patient care is in good repair and cleaned as it becomes soiled, and kept free from foreign matter.

1715. Equipment and Materials Storage Areas.

The EMS Agency shall ensure all equipment not used in direct Patient care is in storage spaces or compartments to prevent contamination or damage to direct Patient care equipment or materials.

1716. Personnel.

The EMS Agency shall ensure uniforms and clothing are clean or changed if they become soiled, contaminated, or exposed to vomitus, blood, or other potentially infectious material (OPIM).

SECTION 1800—AMBULANCE PERMITS. (I)

1801. General.

A. The EMS Agency shall ensure that each Ambulance for which the Permit is issued meets all requirements as to design, medical equipment, supplies, and sanitation as set forth in this regulation. The EMS Agency shall have each Ambulance inspected by the Department prior to issuance of the initial permit.

B. The EMS Agency shall display the Permit decal for each specific Ambulance on the rear door or rear window of the Ambulance or aircraft portfolio, as applicable.

C. The EMS Agency shall not make an entry on, deface, alter, remove, or obliterate an Ambulance Permit.

D. The EMS Agency shall return an Ambulance Permit to the Department within ten (10) business days when the vehicle chassis is sold, removed from service, or when the window is replaced due to damage.

1802. Temporary Ambulance Permit.

A. The EMS Agency may request in writing, and the Department grant at its discretion, a temporary Permit in cases where a temporary asset or short-term solution to an Ambulance is needed. The EMS Agency shall ensure these temporary assets meet all Ambulance permitting and equipment requirements for the level of service of its intended use.

B. The EMS Agency shall be issued a temporary Ambulance Permit for a period not to exceed ninety (90) calendar days and may only be extended in extenuating circumstances at the Department's discretion.

C. The EMS Agency shall ensure each Ambulance with a temporary Permit, with¹ the exception of Air Ambulances, has the following minimum exterior markings:

1. Illumination devices pursuant to Sections 1901.G;
2. Emblems and markings pursuant to Section 1901.B affixed on vehicles with temporary markings; and
3. The name on the face of the EMS Agency's License affixed with temporary lettering not less than three (3) inches in height.

SECTION 1900—AMBULANCES. (II)

1901. Ambulance Design.

A. The EMS Agency shall ensure all Ambulances meet the design requirements established by the Department for Ambulances permitted and utilized in South Carolina and are effective with the

publication of this regulation. The EMS Agency shall ensure all equipment, lighting, interior and exterior doors, and environmental equipment operates as designed¹ at all times when the Ambulance is in service.

B. Base Unit. The EMS Agency shall ensure the chassis of each Ambulance is at least three-quarter ton. In the case of modular or other type body units, the EMS Agency shall ensure the Ambulance chassis is proportionate to the body unit, weight, and size; power train is compatible and matched to meet the performance criteria listed in the Federal KKK-A-1822 F Specification, NFPA 1917 or Commission on Accreditation of Ambulance Services Ground Vehicle Standard for Ambulances version 2.0. After updates are released to the Federal KKK-A- 1822 F Specification, NFPA 1917 or Commission on Accreditation of Ambulance Services Ground Vehicle Standard for Ambulances version 2.0, the EMS Agency shall make applicable safety-related upgrades to each Ambulance on timetables as determined by the Department.

C. Emblems and Markings. The EMS Agency shall ensure all items in this section are of reflective quality and in contrasting color to the background on which it is applied. The EMS Agency shall ensure:

1. There is a continuous stripe, of not less than three (3) inches on cab and six (6) inches on Patient compartment, to encircle the entire Ambulance with the exclusion of the hood panel. The EMS Agency shall ensure reflective chevrons, Battenberg patterns, or other markings are at least six (6) inches in height and meet the requirements of this section; and

2. Emblems and markings are of the type, size and location as follows:

- a. Side: Each side of the Patient compartment has the "Star of Life," not less than twelve (12) inches in height, the word "AMBULANCE", not less than six (6) inches in height, under or beside each star, and the name of the EMS Agency as stated on the EMS Agency's License, of lettering not less than three (3) inches in height; and

- b. Rear: The word "AMBULANCE", not less than six (6) inches in height, two (2) "Star of Life" emblems of not less than twelve (12) inches in height, and the name of the EMS Agency as stated on the EMS Agency's License, of lettering not less than three (3) inches in height.

D. The EMS Agency shall ensure that prior to private sale of Ambulances to the public, all emblems and markings in Section 1901.C are removed.

E. Interior Patient Compartment Dimensions. The EMS Agency shall ensure the interior Patient compartment has the following dimensions:

1. Length: A minimum of twenty-five (25) inches clear space at the head, ten (10) inches at the foot of a seventy-six (76) inch cot, and a minimum inside length of one hundred twenty-two (122) inches;

2. Width: A minimum inside width of sixty-nine (69) inches;

3. Height: A minimum dimension of sixty (60) inches from floor to ceiling; and

4. A minimum of twelve (12) inches of clear aisle walkway between the edge of the primary Patient cot and base of the nearest vertical feature measured along the floor.

F. Access to Ambulance.

1. Driver Compartment.

- a. The EMS Agency shall ensure the Driver's seat has an adjustment to accommodate the fifth (5th) percentile to ninety fifth (95th) percentile adult male.

- b. The EMS Agency shall ensure there is a functional door on each side of the Ambulance in the Driver's compartment.

- c. The EMS Agency shall ensure each Ambulance provides separation between the Driver compartment and the Patient compartment to provide privacy for radio communication and to protect the Driver from an unruly Patient. The EMS Agency shall ensure provision for both verbal and visual communication between Driver and Attendant by a sliding shatter resistant material partition or door. The EMS Agency shall ensure the bulkhead of each Ambulance is strong enough to support an Attendant's seat in the Patient area at the top of the Patient's head and to withstand deceleration forces of the Attendant in case of accident.

2. Patient Compartment.

a. The EMS Agency shall ensure there is a functional door on the right side of the Patient compartment near the Patient's head area of the compartment. The EMS Agency shall ensure the side door allows EMT-basics, AEMTs, and Paramedics to position themselves at the Patient's head and quickly remove the Patient from the side of the vehicle if the rear door is jammed.

b. The EMS Agency shall ensure the rear doors of the Patient compartment swing clear of the opening to allow full access to the Patient's compartment.

c. The EMS Agency shall ensure the Patient compartment doors incorporate a holding device to prevent the door closing unintentionally from wind or vibration. The EMS Agency shall ensure that when Patient compartment doors are open, the holding device shall not protrude into the access area.

d. The EMS Agency shall ensure that Ambulances carrying spare tires position the spare tire to be removed without disturbing the Patient.

G. Interior Lighting.

1. Driver Compartment: The EMS Agency shall ensure lighting is available for both the Driver and an Attendant, if riding in the Driver compartment, to read maps, records, etc. The EMS Agency shall ensure there is shielding of the Driver's area from the lights in the Patient compartment.

2. Patient Compartment: The EMS Agency shall ensure illumination provides an intensity of forty (40)-foot candles at the level of the Patient. The EMS Agency shall ensure lights are controllable from the entrance door, the head of the Patient, and the Driver's compartment. The EMS Agency may utilize a rheostat control of the compartment lighting or by a second system of low intensity lights to reduced lighting levels.

H. Illumination Devices.

1. Flood and load lights. The EMS Agency shall ensure there is least one (1) flood light mounted not less than seventy-five (75) inches above the ground and unobstructed by open doors located on each side of the vehicle. The EMS Agency shall ensure a minimum of one (1) flood light, with a minimum of fifteen (15) foot candles, is mounted above the rear doors of the vehicle.

2. Warning Lights. The EMS Agency shall ensure the Ambulance emergency warning light system contains a minimum of twelve (12) fixed red lights, one (1) fixed clear light, and one (1) fixed amber light. The EMS Agency shall ensure the upper body warning lights are mounted at the extreme upper corner areas of the Ambulance body, below the horizontal roofline. The EMS Agency shall ensure the single clear light is centered between the two (2) front-facing, red, upper corner lights. The EMS Agency shall ensure doors or other ancillary equipment do not obstruct the standard warning lights. The EMS Agency shall ensure the amber light is symmetrically located between the two (2) rear-facing red lights. The EMS Agency shall ensure there are two (2) red grille lights. The EMS Agency shall ensure the lateral facing intersection lights are mounted as close as possible to the front upper edge of each front fender and may be angled forward a maximum of thirty degrees (30°).

I. Seats:

1. Driver Compartment. The EMS Agency shall ensure a seat for both Driver and Attendant is provided in the Driver's compartment and that each seat shall have armrests on each side of the Driver's compartment.

2. Patient Compartment. The EMS Agency shall ensure two (2) fixed seats that are padded, eighteen (18) inches wide by eighteen (18) inches high to head of Patient behind the Driver; the other seat may be a square-bench type located on the curb (right) side of the vehicle.

J. Safety Factors for Patient Compartment.

1. Cot Fasteners. The EMS Agency shall ensure crash-stable fasteners are provided to secure cot(s).

2. Cot Restraint. If the cot is floor-supported on its own support wheels, the EMS Agency shall provide a means to secure it in position under all conditions. The EMS Agency shall ensure all untitled Ambulances purchased for use in South Carolina after July 1, 2017, meet all seating and cot restraint mandates outlined in the Federal KKK-A-1822F, all change notices included.

3. Patient Restraint. The EMS Agency shall ensure a restraining device is provided to prevent longitudinal or transverse dislodgement of the Patient during transit or to restrain an unruly Patient to prevent further injury or aggravation to the existing injury.

4. Safety Belts for Drivers and Attendants. The EMS Agency shall ensure quick-release, retractable, and self-adjustable safety belts are provided for the Driver, the Attendants, and all seated Patients.

5. Mirrors.

a. The EMS Agency shall ensure there are two (2) exterior rear view mirrors, one (1) mounted on the left side of the vehicle and one (1) mounted on the right side. The EMS Agency shall ensure the location of mounting provides maximum rear vision from the Driver's seated position.

b. The EMS Agency shall ensure there is an interior rear view mirror or rear view camera to provide the Driver with a view of occurrences in the Patient compartment.

6. Windshield Wipers and Washers. The EMS Agency shall ensure each vehicle is equipped with two (2) electrical windshield wipers and washers in addition to defrosting and defogging systems.

7. Sun Visors. The EMS Agency shall ensure there is a sun visor for both Driver and Attendant.

8. Exterior Visual Lighting. The EMS Agency shall ensure there are operational headlights (high and low beam), taillights, brake lights, and turn signals that can be operated by the Driver of the vehicle.

K. Environmental Equipment: Driver/Patient Compartment.

1. Heating. The EMS Agency shall ensure each Ambulance has the capability to heat the Patient and Driver compartments to a temperature of seventy-five degrees Fahrenheit (75°F) within a reasonable period while driving in an ambient temperature of zero degrees Fahrenheit (0°F). The EMS Agency shall ensure the heating system is designed to recirculate inside air and is capable of introducing twenty percent (20%) of outside air with minimum effect on inside temperature. Fresh air intake shall be located in the most practical contaminant-free air space on the vehicle.

2. Heating Control. The EMS Agency shall ensure heating is thermostatically or manually controlled and the heater blower motors are at least a three (3) speed (high, medium, and low) design. The EMS Agency shall ensure separate switches are installed in the Patient compartment.

3. Air Conditioning. The EMS Agency shall ensure the air conditioning in each Ambulance has a sufficient capacity to lower the temperature in the Driver's and Patient's compartment to seventy-five degrees Fahrenheit (75°F) within a reasonable period and maintain that temperature while operating in an ambient temperature of ninety-five degrees Fahrenheit (95°F). The EMS Agency shall ensure each air conditioning unit is designed to deliver twenty percent (20%) of fresh outside air of ninety-five degrees Fahrenheit (95°F) ambient temperature while holding the inside temperature specified. The EMS Agency shall ensure all parts, equipment, and workmanship are in keeping with accepted air conditioning practices.

4. Air Conditioning Controls. The EMS Agency may utilize manual or thermostatic air delivery controls to operate the unit. The EMS Agency is not required to have a reheat type system in the Driver's compartment unit. The EMS Agency shall ensure switches or other controls are within easy reach of the Driver in his normal driving position. The EMS Agency shall ensure air delivery fan motors are at least a three (3) speed design. The EMS Agency shall ensure switches and other control components exceed in capacity the amperage and resistance requirements of the motors.

5. Environmental Control and Medications. The EMS Agency shall ensure the temperature in the Patient compartment or anywhere medications are stored (SRVs, fire apparatus, rapid response vehicles, carry-in bags, and other) is monitored for temperature extremes to prevent drug adulteration. The EMS Agency shall ensure medications (excluding oxygen) and IV fluids are removed and discarded if the temperatures reach or exceed one hundred degrees Fahrenheit (100°F), or thirty-eight degrees Celsius (38°C). The EMS Agency shall ensure medications and IV fluids are removed and discarded if temperatures in the drug storage area drop below twenty degrees Fahrenheit (20°F), or negative seven degrees Celsius (-7°C).

6. Insulation. The EMS Agency shall ensure the entire body, side, ends, roof, floor, and Patient compartment doors are insulated to minimize conduction of heat, cold, or external noise entering the vehicle's interior. The EMS Agency shall ensure the insulation is vermin- and mildew-resistant,

fireproof, non-hygroscopic, non-setting type. The EMS Agency may consider plywood floor when undercoated sufficient insulation for the floor area.

L. Storage Cabinets. The EMS Agency shall ensure all cabinets meet the criteria as stated in the most current edition of the Federal KKK-A-1822 Specification, NFPA 1917, or similar specification standards accepted by the Department as to types of surfaces, design, and storage. The EMS Agency shall ensure cabinets are of a size and configuration to store all necessary equipment and all equipment in interior cabinets is accessible to Attendants at all times.

M. Two-Way Radio Mobile. The EMS Agency shall include on each vehicle two-way radio mobile equipment that will provide a reliable system operating range of at least a twenty (20) mile radius from the base station antenna. The EMS Agency shall ensure the mobile installation provides microphones for transmitting to at least Medical Control and receiving agencies, at both the Driver's position and in the Patient compartment. The EMS Agency shall ensure selectable speaker outputs, singly and in combination are provided at the Driver's position, in the Patient's compartment, and through the public address system.

1. The EMS Agency shall provide the Department with all radio frequencies utilized by the EMS Agency as requested by the Department.

2. In the event technological advancements render the above components obsolete, the Department may make determinations as to the efficacy of proposed technology on an individual basis prior to allowing its use. The EMS Agency may utilize cell phones with hand-held radios that are able to reach Medical Control, dispatch center, and receiving facilities as backup.

N. Siren-Public Address. The EMS Agency shall ensure all siren and public address systems provide a power output with a minimum one hundred (100) watts, and in voice operation the power output is at least forty-five (45) watts through two (2) exterior mounted speakers. The EMS Agency shall ensure the public address amplifier is independent of the mobile radio unit.

O. Antenna. The EMS Agency shall mount each antenna with coaxial or other cable if a radio system is installed.

P. Glass Windows. The EMS Agency shall ensure all windows, windshield, and door glass are shatter resistant.

Q. The EMS Agency shall establish a means to immediately identify that a vehicle is out of service for any operator who might have reason to use the vehicle. The EMS Agency shall ensure any vehicle that is "out of service", whether for mechanical or staffing issues, is readily identifiable to the public and the Department. The EMS Agency shall identify out of service vehicles by one (1) of the following means:

1. A sign on the outside of the Driver's door near the door handle, minimum eight and one half inches by eleven inches (8.5" × 11") and red in color;

2. A special bag that covers the steering wheel, red in color, and labeled "Out of Service"; or

3. A large sign on the Driver's window, red in color, reading "Out of Service," laminated, or a permanent, commercially manufactured type, minimum eight and one half inches by eleven inches (8.5" × 11"). If the unit is being driven and is out of service, the sign may be placed in the far right hand corner of the front window so as to not obstruct the Driver's vision but so as to be visible from the exterior of the vehicle.

1902. Ambulance Re-mounted Design and Equipment.

After July 1, 2022, EMS Agencies choosing to utilize Ambulance Re-mounts shall ensure these units are compliant with the Commission on Accreditation of Ambulance Services (CAAS) "Ground Vehicle Standards for Ambulances" or other nationally recognized standards as approved by the Department.

SECTION 2000—[RESERVED]

SECTION 2100—MEDICAL EQUIPMENT

A. The EMS Agency shall ensure the following equipment is maintained on all in-service vehicles in accordance with the response:

Required (R); Medical Control Option (MCO); Not Applicable (N/A)

Item, and Quantity	EMERGENCY RESPONSE		AMBULANCE			
	EMT-Basic	Paramedic	EMT-Basic	AEMT	Paramedic	Air/Critical Care
Personal Protective Equipment						
1. Eye protection or face shield for each medical crew member One (1)	R	R	R	R	R	R
2. Labeled Non-sterile, latex-free exam gloves — two (2) sizes Five (5) pairs each	R	R	R	R	R	R
3. Mask/Face shield for each Crew Member One (1) each	R	R	R	R	R	R
4. Protective clothes covering	R	R	R	R	R	R
Automatic External Defibrillator (AED)						
5. AED: secured and positioned for easy access to Attendants One (1)	R	R	R	R	N/A	N/A
6. Paddles or pads and cables, Adult and Pediatric, compatible with AED	R	R	R	R	R	R
Monitor/Defibrillator						
7. Four (4) lead wave form, twelve (12) lead/EKG, SpO2 waveform with numeric reading, waveform capnography, and invasive pressure ports for adult and pediatric, and neonate, if applicable. Printable and transmittable and secured and positioned so displays are visible to Attendants. All components are required, but not all on one device. One (1)	N/A	R	N/A	N/A	R	R
8. ECG Electrodes Twenty (20)	MCO	MCO	MCO	MCO	R	R
9. Extra roll of compatible printer paper One (1)	N/A	R	N/A	MCO	R	R
10. Internal rechargeable battery pack One (1)	N/A	R	N/A	MCO	R	R
11. Extra battery or AC adapter and cord One (1)	N/A	R	N/A	MCO	R	R

12.	Defibrillator: May be integrated into cardiac monitor module. One (1)	N/A	R	N/A	MCO	R	R
13.	Pads — Pediatric and Adult (Neonatal sizes if transports are conducted)	N/A	R	N/A	N/A	R	R
14.	Transcutaneous Pace — Adult and Pediatric capabilities (stand-alone unit or integrated into cardiac monitor modular)	N/A	R	N/A	N/A	R	R
Oxygen Delivery							
15.	Nasal Cannulas — Adult Two (2)	R	R	R	R	R	R
16.	Nasal Cannula- Pediatric Two (2)	MCO	MCO	R	R	R	R
17.	Non-Rebreather Mask — Adult Two (2)	R	R	R	R	R	R
18.	Non-Rebreather Mask — Infant Two (2)	N/A	N/A	N/A	N/A	N/A	R
19.	Non-Rebreather Mask — Pediatric Two (2)	R	R	R	R	R	R
20.	Disposable Nebulizer Two (2)	MCO	R	MCO	R	R	R
21.	NPA 16 French through 34 French (12, 16, 20, 24, 28, 32, 36) One (1) each	MCO	R	R	R	R	R
22.	Nonmetallic oropharyngeal airways (OPAs): sizes 0–5. One (1) each	R	R	R	R	R	R
23.	Positive Pressure Airway device One (1)	MCO	R	MCO	R	R	R
24.	Individual use circuit for Positive pressure device compatible with the device Two (2)	MCO	R	MCO	R	R	R
25.	Portable Oxygen Cylinder (min 1000 PSI) with working regulator One (1)	R	R	R	R	R	R
26.	Spare Portable Oxygen Cylinder One (1)	R	R	R	R	R	R
27.	On-Board Oxygen Cylinder (min 2000L)	N/A	N/A	R	R	R	R

With working regulator

One (1)

Bag Valve Mask Ventilation Units (BVM)

28.	Adult BVM One (1)	R	R	R	R	R	R
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29.	Pediatric BVM One (1)	R	R	R	R	R	R
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30.	Neonate BVM One (1)	MCO	MCO	R	R	R	R
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Bandage Material

31.	ABD pad at least five by nine inches (5" × 9") Two (2)	R	R	R	R	R	R
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32.	Adhesive bandages Five (5)	R	R	R	R	R	R
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33.	Individually wrapped four by four inch (4" × 4") Sterile Gauze Pads Fifteen (15)	R	R	R	R	R	R
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34.	Individually wrapped Sterile Gauze bandage rolls two (2) different Sizes Required One (1) each size	R	R	R	R	R	R
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35.	Four by four inch (4" × 4") Commercial Sterile Occlusive Dressing or Chest Seal Two (2)	R	R	R	R	R	R
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36.	Hypoallergenic Adhesive Tape — One inch (1") One (1)	R	R	R	R	R	R
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37.	Hypoallergenic Adhesive Tape — Two Inch (2") One (1)	MCO	MCO	MCO	MCO	MCO	MCO
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38.	Hypoallergenic Adhesive Tape — Three Inch (3") One (1)	MCO	MCO	R	R	R	R
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39.	Large Trauma Bandage Shears One (1)	R	R	R	R	R	R
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40.	Sterile Water or Normal Saline for irrigation Minimum of 250 ml.	R	R	R	R	R	R
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41.	Arterial Tourniquet Two (2)	R	R	R	R	R	R
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42.	Hemostatic Agent or Bandage (non-granular) Two (2)	MCO	MCO	MCO	MCO	MCO	MCO
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Assessment Tools

43.	Thermometer One (1)	MCO	MCO	R	R	R	R
44.	Sphygmomanometer, cuff, bladder, and tubing in sizes for each age and size (Minimum of 3 sizes) One (1) each size	R	R	R	R	R	R
45.	Adult Stethoscope One (1)	R	R	R	R	R	R
46.	Pediatric Capable Stethoscope One (1)	R	R	R	R	R	R
47.	Pulse Oximeter with numeric reading with Adult and Pediatric capabilities One (1)	R	R	R	R	R	R
48.	Penlight Two (2)	R	R	R	R	R	R
Miscellaneous							
49.	Commercial antimicrobial and waterless hand cleanser	R	R	R	R	R	R
50.	EPA recommended Germicidal/viricidal agent or sodium hypochlorite solution - ninety-nine (99) parts water and one (1) part bleach for cleaning equipment.	R	R	R	R	R	R
51.	Portable Suction	R	R	R	R	R	R
52.	Wall Mounted Suction	N/A	N/A	R	R	R	R
53.	Suction Tubing	MCO	MCO	R	R	R	R
54.	Rigid suction Tip	MCO	MCO	R	R	R	R
55.	Flexible Suction Tip Four (4) sizes	MCO	R	R	R	R	R
56.	Naloxone Administration Kit	MCO	MCO	MCO	MCO	MCO	MCO
57.	Epinephrine Administration Kit	MCO	MCO	MCO	MCO	MCO	MCO
58.	Sharps container (fixed with locking mechanism) One (1)	N/A	N/A	R	R	R	R
59.	Portable Sharps Container One (1)	R	R	R	R	R	R
60.	Current color-coded Pediatric weight and length-based drug dose chart One (1)	MCO	R	MCO	R	R	R
61.	Antiseptic pads for injection sites	R	R	R	R	R	R

Twenty-four (24)							
62.	18–20g needles at least one and one-half inch (1 ½") length Two (2) sets	N/A	R	N/A	R	R	R
63.	23g–25g needles at least one and one-half inch (1 ½") length Two (2) sets	N/A	R	N/A	R	R	R
64.	1 ml Syringes Two (2)	N/A	R	N/A	R	R	R
65.	3–5 ml Syringes Two (2)	N/A	R	N/A	R	R	R
66.	10–20 ml Syringes Four (4)	N/A	R	N/A	N/A	R	R
67.	Sterile burn sheet One (1)	R	R	R	R	R	R
68.	Triangular Bandages Two (2)	R	R	R	R	R	R
69.	Traction-type, lower extremity splint (Bipolar or Uni-polar type is acceptable) One (1)	MCO	MCO	R	R	R	MCO
70.	Padded splints: 15" × 3" (or other approved commercially available splints for arm or leg fractures) Two (2)	R	R	R	R	R	MCO
71.	Padded Splints: 36" × 3" (or other approved commercially available splints for arm or leg fractures) Two (2)	MCO	MCO	R	R	R	MCO
72.	Pelvic Splint One (1)	MCO	MCO	MCO	MCO	MCO	MCO
73.	Long Spine Board: at least 16" × 72". (A folding backboard may be used as a substitute.) One (1)	MCO	MCO	R	R	R	MCO
74.	Cervical collars: Adjustable or available in sizes of short, regular, or tall. Adult and Pediatric Minimum of one (1) each	R	R	R	R	R	MCO
75.	Commercially or Pre-made Head Immobilization Device — Adult and Pediatric One (1) each	MCO	MCO	R	R	R	MCO
76.	Nine (9) foot straps (one (1) set 10-point spider straps may be used)	MCO	MCO	R	R	R	R

Minimum of three (3) each

77.	Triage Tag (Compatible with the state system)	R	R	R	R	R	MCO
78.	Patient Restraints one (1) set	N/A	N/A	R	R	R	R
79.	Obstetrical Kit: Sterile, latex free. (Contains the following: gloves, scissors or surgical blades, umbilical cord clamps or tapes, dressing, towels, perinatal pad, bulb syringe and a receiving blanket) One (1)	R	R	R	R	R	R
80.	Glucometer or Blood Glucose Measuring Device One (1)	R	R	R	R	R	R
81.	Emesis basin or bag One (1)	R	R	R	R	R	R
82.	Bedpan and urinal One (1) each	MCO	MCO	R	R	R	R
83.	ABC Fire Extinguisher (minimum of 5 LBS, properly mounted) One (1)	R	R	R	R	R	R
84.	Battery Operated Flashlight (non-penlight) Two (2)	MCO	MCO	R	R	R	MCO
85.	High Visibility vest or reflective clothing Two (2)	R	R	R	R	R	R
86.	Protective Work Gloves 2 Pair	MCO	MCO	MCO	MCO	MCO	MCO
87.	Protective Helmet Two (2)	MCO	MCO	MCO	MCO	MCO	R
88.	Flameless Flare, Glow Sticks, Cones, or Reflective Triangles Three (3)	R	R	R	R	R	MCO
89.	Blankets/ Linen Three (3) each	MCO	MCO	R	R	R	R
Advanced Airway and Ventilatory Support							
90.	Laryngoscope handle with extra set of batteries and bulbs (Compatible with Blades) One (1)	N/A	R	N/A	N/A	R	R
91.	Laryngoscope blades — 0-4 Miller, 1-4 Macintosh - Adult/Pediatric/Neo-	N/A	R	N/A	N/A	R	R

	nate sizes (Compatible with handle) One (1) each						
92.	Video Laryngoscope One (1)	N/A	MCO	N/A	N/A	MCO	MCO
93.	Disposable ET tube sizes 2.5 through 8mm with stylets sized for each tube One (1) each	N/A	R	N/A	N/A	R	R
94.	Bougie type device One (1)	N/A	MCO	N/A	N/A	MCO	MCO
95.	ET Placement Detector One (1)	N/A	R	N/A	N/A	R	R
96.	Water soluble lubricating jelly Four (4) each	R	R	R	R	R	R
97.	Blind Insertion Airway Device (BIAD) — Age and weight sizes as defined by FDA. Syringe(s) needed to inflate bulbs shall be included in packaging, if not, appropriate size(s) carried by provider.	R	R	R	R	R	R
98.	Mucosal Atomizer Device One (1)	N/A	MCO	N/A	N/A	MCO	MCO
99.	Positive End-Expiratory Pressure (PEEP) valve (may be incorporated into BVMs) — age appropriate	R	R	R	R	R	R
100.	Mechanical ventilator and circuit - age/weight appropriate, including neonate, if applicable, includes measurement of: Fraction of inspired oxygen (FiO ₂); Tidal volume (V _t); Respiratory rate (RR) or frequency; and PEEP.	N/A	N/A	N/A	N/A	MCO	R
101.	Continuous Positive Airway Pressure (CPAP), able to be incorporated within the mechanical ventilator mechanical and with appropriate setting and attachments for adult, pediatric, and neonate Patients, if applicable	N/A	N/A	N/A	MCO	MCO	R
102.	Bi-level Positive Airway Pressure (BiPap),	N/A	N/A	N/A	N/A	MCO	MCO

able to be incorporated within the mechanical ventilator mechanical and with appropriate setting and attachments for adult, pediatric, and neonate Patients, if applicable

103.	Chest Decompression Kit One (1)	N/A	R	N/A	N/A	R	R
104.	Printable waveform End-tidal CO2 continuous monitoring capabilities. May be incorporated within cardiac monitor modular	N/A	R	N/A	N/A	R	R
Venous Access							
105.	Intravenous catheters 14g-20g Two (2) each	N/A	R	N/A	R	R	R
106.	Intravenous catheters 22g-24g for pediatric/neonate transport Two (2) each	N/A	R	N/A	R	R	R
107.	Intraosseous needles — 15mm, 25mm, 45mm One (1) each	N/A	MCO	N/A	R	R	R
108.	Macro drip sets, 10-20 gtts/ml Two (2)	N/A	R	N/A	R	R	R
109.	Micro drip set One (1)	N/A	R	N/A	N/A	N/A	N/A
110.	IV start kits containing latex free tourniquet, antiseptic solution, and latex free catheter dressing. Three (3)	N/A	R	N/A	R	R	R
111.	Intravenous fluids: may be combination of sizes 100mL-1000mL variety such as Lactated Ringers, Normal Saline, D5W. Capability to be administered warm. 4000 ml total	N/A	R (2000 ml total)	N/A	R	R	R
112.	IV Pressure Infuser One (1)	N/A	MCO	N/A	MCO	R	R

B. The EMS Agency shall maintain the equipment used in the provision of Patient care clean, in good repair, and operating condition, within the manufacturer expiration date, and in accordance with Occupational Safety and Health Administration (OSHA) Standard 1910.1030.

C. Local Medical Control Option (MCO). The EMS Agency shall ensure all local MCO medical equipment is incorporated into its Protocols pursuant to Section 502.B.

SECTION 2200—AIR AMBULANCE

2201. Permitting. (I)

A. No EMS Agency, Ambulance service provider, agent or broker shall secure or arrange for Air Ambulance service originating in South Carolina unless the Air Ambulance service meets the provisions of S. C. Code Sections 44–61–10, et seq. and these regulations. The EMS Agency providing Air Ambulance services that transport Patients in the prehospital setting shall be permitted as Advanced Life Support. The EMS Agency shall have each Air Ambulance inspected prior to issuance of the initial Permit and inspected thereafter at a frequency as determined by the Department.

B. The EMS Agency shall submit an application to the Department, in a format as determined by the Department, prior to being issued an initial Air Ambulance Permit and Air Ambulance Permit renewals. The EMS Agency shall submit the following documentation with the application:

1. A copy of current FAA operational certificate including designation for Air Ambulance operations;
2. Proof of accreditation from the Commission on Accreditation of Medical Transport Systems (CAMTS). After updates are released to the CAMTS Air Ambulance Standards, the EMS Agency shall make applicable safety related upgrades to each Air Ambulance on timetables as determined by the Department; and
3. A letter of agreement verifying each aircraft meets the specifications of this regulation if the aircraft is leased from a pool.

C. The EMS Agency shall ensure that prior to issuance of an initial or renewal Air Ambulance Permit that the Air Ambulance for which the Permit is issued meets all requirements as set forth in this regulation. Each Permit shall be issued for a specific Air Ambulance and is not transferrable to another vehicle.

D. The EMS Agency shall ensure each Air Ambulance conforms to all federal and state laws and regulations, including Title 14 of the Code of Federal Regulations (14 CFR) part 135.

E. Out-of-State Air Ambulances.

1. EMS Agencies from out of state with Air Ambulances transporting Patients from locations originating in South Carolina shall obtain an EMS Agency License from the Department prior to engaging in operations and shall have applicable current and valid licenses and permits in their home state, except where exempt pursuant to S.C. Code Section 44–61–100(D).

2. EMS Agencies from out of state operating Air Ambulances in a state where no license and/or permit is available shall obtain a EMS Agency License in South Carolina and meet all requirements in Section 1200.

3. EMS Agencies from out of state with Air Ambulances transporting Patients from locations originating in South Carolina shall submit ePCRs to the Department within seventy-two (72) hours of completing the transport.

2202. Aircraft.

The EMS Agency shall ensure all operations comply with all federal aviation regulations which are adopted by reference, FAA Part 135. The EMS Agency shall ensure each aircraft meets the following specifications:

A. Configured in such a way that the medical Attendants have adequate access for the provision of Patient care within the cabin to give cardiopulmonary resuscitation and maintain the Patient's life support. The EMS Agency shall ensure:

1. The aircraft has an entry that allows loading and unloading without excessive maneuvering (no more than forty-five (45) degrees about the lateral axis and thirty (30) degrees about the longitudinal axis) of the Patient; and
2. The configuration does not compromise functioning of monitoring systems, intravenous lines, and manual or mechanical ventilation.

B. Has at least one (1) stretcher or cot that can be carried to the Patient and allow loading of a supine Patient by two (2) Attendants. The EMS Agency shall ensure:

1. The maximum gross weight allowed on the stretcher or cot (inclusive of Patient and equipment) as consistent with manufacturer's guidelines;

2. The aircraft stretchers and cots, and the means of securing them in-flight, are consistent with federal aviation regulations;
3. The stretcher or cot is sturdy and rigid enough that it can support cardiopulmonary resuscitation;
4. The head of the cot is capable of being elevated at least thirty (30) degrees for Patient care and comfort; and
5. The Patient placement allows for safe personnel egress.

C. Has appropriate communication equipment to ensure both internal crew and air to ground exchange of information between individuals and agencies appropriate to the mission, including at least Medical Control, air traffic control, emergency services (EMS, law enforcement agencies, and fire), and navigational aids;

D. Is equipped with radio headsets that ensure internal crew communications and transmission to appropriate agencies;

E. The pilot is able to control and override radio transmissions from the cockpit in the event of an Emergency situation;

F. Lighting. The EMS Agency shall ensure each Air Ambulance has a supplemental lighting system installed in the aircraft which includes standard lighting and is sufficient for Patient care; The EMS Agency shall ensure:

1. The lighting system includes a self-contained lighting system powered by a battery pack or a portable light with a battery source is available;

2. That red lighting or low intensity lighting may be used in the Patient care area if not able to isolate the Patient care area from effects on the cockpit or on a pilot; and

3. For those flights meeting the definition of "long range," the EMS Agency shall have additional policies in place to address how cabin lighting will be provided during fueling and/or technical stops to ensure proper Patient assessment can be performed and adequate Patient care provided.

G. Has hooks and/or devices for hanging intravenous fluid bags;

H. Rotor Wing Aircraft must have an external landing light and tail-rotor position light;

I. Design does not compromise Patient stability in loading, unloading, or in-flight operations;

J. Temperature. The EMS Agency shall ensure:

1. The interior of the Air Ambulance is climate controlled to avoid adverse effects on Patients and personnel on board;

2. The thermometer is mounted inside the Air Ambulance cabin; and

3. The Air Ambulance cabin temperatures are measured and documented every fifteen (15) minutes during a Patient transport until temperatures are maintained within the range of fifty degrees Fahrenheit (50°F) to ninety-five degrees Fahrenheit (95°F), or ten degrees Celsius (10° C) to thirty-five degrees Celsius (35° C) for aircraft.

K. Electric power outlet. The EMS Agency shall ensure each Air Ambulance aircraft is equipped with an inverter or appropriate power source of sufficient output to meet the requirements of the complete specialized equipment package without compromising the operation of any electrical aircraft or Ambulance equipment. The EMS Agency shall ensure each Air Ambulance maintains extra batteries onboard for critical Patient care equipment.

2203. Aircraft Flight Crew.

A. Rotorcraft Pilot. The EMS Agency shall ensure:

1. Each Rotorcraft pilot possess at least a commercial Rotorcraft-helicopter and instrument helicopter rating of 05.04.03;

2. Prior to an assignment with a medical service, the Rotorcraft pilot in command possesses two thousand (2,000) total flight hours, or total flight hours of at least fifteen hundred (1,500) hours, and recent experience that exceeds the operator's pre-hire qualifications such as current air medical and/or search and rescue experience or Airline Transport Pilot (ATP) rated that include the following:

- a. At least twelve hundred (1,200) helicopter flight hours;

- b. At least one thousand (1,000) of those hours must be as Pilot-in-Charge (PIC) in Rotorcraft;
 - c. One hundred (100) hours unaided, if the pilot is not assigned to a Night Vision Goggles (NVG) base or aircraft;
 - d. Fifty (50) hours unaided as long as the pilot has one hundred (100) hours aided, if assigned to an NVG base or aircraft; and
 - e. A minimum of five hundred (500) hours of turbine time.
3. The pilot is readily available within a defined call-up time to ensure an expeditious and timely response; and
4. ATP certificate and instrument currency is strongly encouraged.

B. Rotorcraft Mechanic. The EMS Agency shall ensure:

1. The mechanic primarily assigned to a specific Air Ambulance is factory schooled or equivalent in an FAA approved program on the type of specific airframe, the power plant and all related systems. The EMS Agency shall ensure the primarily assigned mechanic provides direct (on-site during maintenance) supervision to other mechanics assisting with maintenance that may not have this level of experience or training;

2. All mechanics receive formal training on human factors and maintenance error reduction;

3. A policy is written that grants the mechanic permission without fear of reprisal to decline performing any maintenance critical to flight safety that he has not been appropriately trained for, until an appropriately trained mechanic is available to directly supervise or assist;

4. There is a documented annual review of infection control, medical systems, and installations on the aircraft, Patient loading and unloading procedures for all mechanics;

5. At least one (1) technician is available for each service with formal training on the aircraft electrical system and formal training on the autopilot system; and

6. Training related to the interior modification of the aircraft:

a. Prepares the mechanic for inspection of the installation as well as the removal and reinstallation of special medical equipment; and

b. Includes supplemental training on service and maintenance of medical oxygen systems and a policy as to who maintains responsibility for refilling the medical oxygen systems;

C. Fixed Wing Pilot. The EMS Agency shall ensure the pilot-in-command (PIC) possesses the following qualifications:

1. Possesses the following flight hours:

a. Prior to assignment with an EMS Agency and if the aircraft is to be operated using a single PIC, with no Second in Command (SIC):

TYPE OR CLASS OF AIRCRAFT	TOTAL FLIGHT HOURS	MULTI-ENGINE HOURS	PIC HOURS	TYPE RATE HOURS
Single Engine Turbo-Prop	2500	N/A	1000	50
Multi-Engine Piston	2500	500	1000	50
Multi-Engine Turbo Prop	2500	500	1000	100

b. If the aircraft is to be operated with two (2) fully trained and qualified pilots:

TYPE OR CLASS OF AIRCRAFT	PIC TOTAL FLIGHT HOURS	MULTI-ENGINE HOURS	PIC HOURS	SIC TOTAL HOURS
Single Engine Turbo-Prop	2000	N/A	1000	500
Multi-Engine Piston	2000	500	1000	500
Multi-Engine Turbo Prop	2000	500	1000	800
Multi-Engine Turbo Prop	3000	500	1500	1000

2. The PIC is Airline Transport Pilot (ATP) rated within five (5) years of hire;

3. In aircraft that requires two (2) pilots, both pilots shall be type-rated for the make and model, and both pilots shall hold first class medical Certificates if the Certificate holder operates internationally. Both pilots shall have training on Crew Resource Management (CRM) or Multi-pilot Crew Coordination (MCC); and

4. When operating an Air Ambulance with two (2) pilots, the EMS Agency shall maintain policies procedures that address avoidance of a "green on green" situation, where a lower experienced PIC is paired with a lower experienced SIC. The EMS Agency shall ensure the two (2) pilots combined have completed a minimum combined flight experience of two hundred fifty (250) hours in make and model.

D. Fixed-Wing Mechanic. The EMS Agency shall ensure:

1. The mechanic primarily assigned to a specific Air Ambulance possess a minimum of two (2) years of airplane experience as a certified airframe and power plant mechanic prior to assignment, or, in the case of a repair station, the Maintenance Repair Organization (MRO) shall hold a FAA issued Certificate under FAA 14 CFR Part 145, or the national equivalent, and hold the ratings and/or limitations within its Operations Specifications for the make/model upon which it is performing scheduled maintenance;

2. The primary mechanic performing scheduled maintenance to a specific Air Ambulance is factory-schooled or equivalent in an approved program on the type-specific airframe, the power plant, and all related systems within eighteen (18) months of employment by the operator;

3. All mechanics must receive formal training on human factors and maintenance error reduction;

4. If not working for a maintenance organization certified under FAA 14CFR Part 145 or national equivalent, the EMS Agency implements a written policy that grants the mechanic permission, without fear of reprisal, to decline from performing any maintenance critical to flight safety that he or she has not been appropriately trained for, until an appropriately trained mechanic is available to directly supervise;

5. There is an annual review of infection control, medical systems, and installations on the aircraft, Patient loading and unloading procedures for all mechanics;

6. There will be at least one (1) technician or MRO available for each service with formal training on the aircraft electrical system and formal training on avionics; and

7. Training related to the interior modifications of the aircraft:

a. Training must prepare the mechanic for inspection of the installation as well as the removal and reinstallation of special medical equipment; and

b. There is supplemental training on service and maintenance of medical oxygen systems and a policy as to who maintains responsibility for refilling the medical oxygen system.

E. The EMS Agency shall ensure that each Patient is evaluated prior to a flight for the purpose of determining that appropriate Air Ambulance, flight and medical crew, and equipment are provided to meet the Patient's needs.

F. The EMS Agency shall ensure that all medical crew members are adequately trained to perform in flight duties prior to functioning in an inflight capacity.

G. Aircraft Medical Crew. The EMS Agency shall ensure:

1. Each Advanced Life Support Air Ambulance is staffed with at least one (1) currently certified Paramedic or Flight Nurse as may be required by the Patient's condition;

2. Each crew member wears a flame retardant uniform with reflective striping; and

3. Each crew member displays, upon request, a legible photo identification with first name and certification level (for example, pilot, RN, or other) while Patient care is anticipated to be rendered.

H. Orientation Program. The EMS Agency shall ensure:

1. All medical flight crew members complete a base level flight orientation program supervised by the EMS Agency's Medical Control Physician; and

2. The flight orientation program is documented and of a duration and substance to cover all Patient care procedures, including altitude physiology, and flight crew requirements.

2204. Medical Supplies and Equipment. (II)

A. Delivering Oxygen. The EMS Agency shall ensure that oxygen is installed according to federal aviation regulations (FAA Part 135.91). The EMS Agency shall ensure that medical transport personnel determine how oxygen is functioning by use of pressure gauges mounted in the Patient care area. The EMS Agency shall ensure:

1. Each gas outlet shall be clearly identified;
2. "No Smoking" sign shall be included;
3. Oxygen flow must be stoppable at or near the oxygen source from inside the aircraft or Ambulance;
4. The following indicators shall be accessible to medical transport personnel while en route;
 - a. Quantity of oxygen remaining; and
 - b. Measurement of liter flow.
5. Adequate amounts of oxygen for anticipated liter flow and length of transport with an emergency reserve must be available for every mission; and
6. When the Air Ambulance is in motion, all oxygen cylinders shall be affixed to a wall or floor with crash stable, quick release fittings.

B. Sanitation. The EMS Agency shall ensure that the floor, sides, ceiling, and equipment in the Patient cabin of the Air Ambulance are a nonporous surface capable of being cleaned and disinfected in accordance with Section 1700.

C. Each EMS Agency shall maintain on each Air Ambulance all medical equipment pursuant to Section 2100.

2205. Medication and Fluids for Advanced Life Support Air Ambulances. (II)

A. The EMS Agency shall ensure medications and fluids approved by the Department for possession and administration by Paramedics and specified by the Medical Control Physician are carried on the Air Ambulance. The EMS Agency shall ensure that medications not included on the approved medication list for Paramedics are only carried on board the Air Ambulance if the EMS Agency has a written Protocol that includes delineation of administration only by a registered nurse or physician.

B. The EMS Agency shall ensure on each Air Ambulance:

1. All Medications are easily accessible;
2. Controlled substances are in a double locked system and kept in a manner consistent with state and federal controlled substances laws and regulations;
3. Storage of medications allows for protection from extreme temperature changes within the U.S. Pharmacopeia guidelines, if environment deems it necessary; and
4. If there is a refrigerator on the Air Ambulance for medications, a temperature monitoring and tracking policy is established and implemented, and the refrigerator is used and labeled "for medication use only."

2206. Rescue Exception. (II)

The EMS Agency may utilize an aircraft or SRV without a Permit for occasional non-routine missions, such as the rescue and transportation of victims or Patients who may or may not be ill or injured from structures, depressions, water, cliffs, swamps or isolated scenes when the rescuers or EMS Agency present at the scene determines the preferred method of rescue and transportation incident thereto due to the nature of the entrapment, condition of the victim, existence of an immediate life threatening condition, roughness of terrain, time element and/or other pertinent factors. The EMS Agency shall ensure:

A. After the initial rescue, an EMT-basic, AEMT, or Paramedic accompanies the victim or Patient en route with the necessary and appropriate EMS supplies and equipment needed for the en route care of the specific injuries or illness involved;

B. The aircraft or SRV is of adequate size and configuration to effectively make the rescue and to accommodate the victim or Patient, Attendant(s), and equipment;

C. Reasonable space is available inside the aircraft or SRV for continued victim or Patient comfort and care;

D. A permitted Air Ambulance or Ambulance is not available within a reasonable distance response time; and

E. Provided the Patient is transferred to a higher level of EMS ground transportation for stabilization and transport if such ground unit is available at a reasonably safe landing area.

SECTION 2300—[RESERVED]

SECTION 2400—[RESERVED]

SECTION 2500—[RESERVED]

SECTION 2600—[RESERVED]

SECTION 2700—SEVERABILITY

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of this regulation, and they shall remain in effect as if such invalid portions were not originally a part of this regulation.

SECTION 2800—GENERAL

Conditions that have not been addressed in this regulation shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Added eff March 18, 1975. Amended eff May 22, 1981; eff February 16, 1988; State Register Volume 19, Issue No. 7, eff July 28, 1995; State Register Volume 21, Issue No. 6, Part 2, eff June 27, 1997; State Register Volume 30, Issue No. 6, eff June 23, 2006; State Register Volume 40, Issue No. 6, Doc. No. 4610, eff June 24, 2016; SCSR 46-5 Doc. No. 5055, eff May 27, 2022.

¹ So in original.

61-8. Immunization Requirements for School and Childcare Attendance.

(Statutory Authority: S.C. Code Sections 44-29-40(A) and 44-29-180 (2002 & Supp. 2012)).

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II. EXEMPTIONS.

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IV. COMPLIANCE.

I. REQUIREMENTS FOR SCHOOL AND CHILDCARE ATTENDANCE.

A. No child or person shall be admitted to or retained in any public, private, or parochial school, grades kindergarten through twelve (K-12), or any public or private childcare facility as defined in Code Section 63-13-20 without a valid South Carolina Certificate of Immunization. To be valid, the South Carolina Certificate of Immunization must be signed by a licensed physician or his/her authorized representative. Exemptions to this requirement are authorized in Section II of this regulation.

B. A South Carolina Certificate of Immunization must be presented to school or childcare officials on admission and as required to document any subsequent immunizations required by the Department. School and childcare officials shall keep a copy of the Certificate with the child's or person's record.

C. The standard to obtain a South Carolina Certificate of Immunization shall be compliance with the schedule of required immunizations for school and childcare attendance published by the Department. The schedule of required immunizations shall apply to any child attending school or

childcare after the effective dates indicated in the schedule unless otherwise stipulated by the Department.

D. Blank forms for the South Carolina Certificate of Immunization will be provided to licensed physicians and their authorized representatives by the Department. The Certificate of Immunization may also be generated for signature using the statewide immunization registry.

E. Registered family childcare homes are exempt from requirements of this regulation.

F. "Childcare facility" and "childcare" in this regulation have the meaning given in Code Section 63-13-20 and are intended to include the terms child care, childcare facility, day care facility, child day care facility, day care, and family day care homes, as used in Code Section 44-29-180.

II. EXEMPTIONS.

A. Students may be exempt from the immunization requirements of this regulation for the following reasons:

1. Medical Exemption.

A Medical Exemption, may be granted when a licensed physician has determined, for medical reasons, that a particular vaccine(s) required by this regulation is not advisable for the child. The exemption is granted when the physician or his/her authorized representative completes and signs the South Carolina Certificate of Immunization containing the Medical Exemption. The physician must indicate whether the exemption is permanent or temporary. If the exemption is temporary, an updated South Carolina Certificate of Immunization showing proof of immunization must be presented to the school or childcare by the end of the exemption period.

2. Religious Exemption.

A South Carolina Certificate of Religious Exemption may be granted to any student whose parent, guardian, or person in loco parentis signs the appropriate section of the South Carolina Certificate of Religious Exemption stating that one or more immunizations conflicts with their religious beliefs. The Certificate of Religious Exemption form may only be obtained from the local health department.

3. Special Exemption.

A. A South Carolina Certificate of Special Exemption, signed by the school principal, authorized representative, or childcare director may be issued to transfer students while awaiting arrival of medical records from their former area of residence or to other students who have been unable to secure immunizations or documentation of immunizations already received. At the expiration of this special exemption, the student must present a valid South Carolina Certificate of Immunization, or a valid South Carolina Certificate of Medical Exemption, or a valid South Carolina Certificate of Religious Exemption. Completion of the Medical Exemption section of the Certificate of Immunization satisfies the requirement for the South Carolina Certificate of Medical Exemption.

B. Blank forms for the South Carolina Certificate of Special Exemption will be provided by the Department to school and childcare administrators.

III. REPORTING REQUIREMENTS.

Forty five (45) calendar days after the beginning of each school year, school principals must submit to the local health department, on forms provided by the Department, the numbers of students admitted to school with South Carolina Medical Exemptions, South Carolina Certificates of Religious Exemption, and South Carolina Certificates of Special Exemption as provided in Section II of this regulation.

IV. COMPLIANCE.

Representatives of the Department will audit school and childcare records to insure compliance with this regulation.

HISTORY: Amended by State Register Volume 16, Issue No. 4, eff April 24, 1992; State Register Volume 38, Issue No. 6, Doc. No. 4434, eff June 27, 2014; State Register Volume 38, Issue No. 7, Doc. No. 4434, eff July 25, 2014 (errata).

61-9

WATER POLLUTION CONTROL PERMITS

(Statutory Authority: §§ 48-1-10 et seq. and §§ 48-14-10 et seq.)

Editor's Note

Authority: 33 U.S.C. 1251, et seq.; section 54(c)(2) of the Clean Water Act of 1977, (Pub.L.95-217) sections 204(b)(1)(C), 208(b)(2)(C)(iii), 301(b)(1)(A)(ii), 301(b)(2)(A)(ii), 301(b)(2)(C), 301(h)(5), 301(i)(2), 304(e), 304(g), 307, 308, 309, 402(b), 405 and 501(a) of the Federal Water Pollution Control Act (Pub. L.92-500) as amended by the Clean Water Act of 1977 and the Water Quality Act of 1987 (Pub. L.100-4); secs. 2002 and 3018(d) of the Solid Waste Disposal Act as amended; 40 CFR 403, 43 FR 27746, June 26, 1978; Effective August 25, 1978; Amended by 44 FR 32854, June 7, 1979; Effective August 13, 1979; 45 FR 72945, November 3, 1980; Revised by 46 FR 6439, January 28, 1981; Amended by 47 FR 4521, February 1, 1982; 47 FR 42688, September 28, 1982; 48 FR 2776, January 21, 1983; 49 FR 5132, February 10, 1984; 49 FR 21037, May 17, 1984; 49 FR 28059, July 10, 1984; 40 FR 31221, August 3, 1984; 50 FR 38811, September 25, 1985; 51 FR 16030, April 30, 1986; 51 FR 20430, June 4, 1986; Corrected by 51 FR 23759, July 1, 1986; Amended by 51 FR 36372, October 9, 1986; 52 FR 1600, January 14, 1987; 52 FR 42435, November 5, 1987; 53 FR 40610, October 17, 1988; 54 FR 254, January 4, 1989; 55 FR 142, July 24, 1990; 62 FR 38406, July 17, 1997; 64 FR 42554, August 4, 1999.

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- 61-9.505. Land Application Permits and State Permits.

61-9.3. Cross-Media Electronic Reporting.

Refer to 40 CFR Part 3, which is hereby adopted by reference.

HISTORY: Added by SCSR 43-11 Doc. No. 4888, eff November 22, 2019.

61-9.122. THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM.

(Statutory Authority: 1976 Code Sections 48-1-10 et seq. and Sections 48-14-10 et seq.)

Editor's Note

The following constitutes the history for 61-9.122, 122.1 through Appendix J.

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001; State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003; State Register Volume 27, Issue No. 12, eff December 26, 2003; State Register Volume 29, Issue No. 2, eff February 25, 2005; State Register Volume 32, Issue No. 5, eff May 23, 2008; State Register Volume 34, Issue No. 11, eff November 26, 2010.

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PART A
DEFINITIONS AND GENERAL PROGRAM REQUIREMENTS

122.1. Purpose and scope.

(a) Coverage

(1) The regulatory provisions contained in R.61-9.122 and 124 implement the National Pollutant Discharge Elimination System (NPDES) Program under sections 318, 402, and 405 of the Clean Water Act (CWA) (Public Law 92-500, as amended by Pub. L. 95-217, Pub. L. 95-576, Pub. L. 96-483, Pub. L. 97-117, and Pub. L. 100-4; 33 U.S.C. 1251 et seq.) and the South Carolina Pollution Control Act, S.C. Code Ann. 48-1-10, et seq.

(2) These provisions cover basic Department permitting requirements (122) and procedures for Department processing of permit applications and appeals (124).

(3) These provisions also establish the requirements for public participation in State permit issuance and enforcement and related variance proceedings.

(4) The NPDES permit program has separate, additional provisions that are used by the Department to determine what requirements must be placed in permits, if issued. These provisions are located at S.C. R61-9.125, 129, 133, and 503, and 40 CFR 136, 40 CFR subchapter N (parts 400 through 471) and 40 CFR 125.80-89 (Federal Register December 18, 2001 amended June 19, 2003), which are hereby adopted by reference.

(b) Scope of the NPDES permit requirement.

(1) The NPDES program requires permits for the discharge of “pollutants” from any “point source” into “waters of the State” and into “waters of the United States.” The terms “pollutant”, “point source”, “waters of the State”, and “waters of the United States” are defined in section 122.2.

(2) The permit program established under this part also applies to owners or operators of any treatment works treating domestic sewage, whether or not the treatment works is otherwise required to obtain an NPDES permit, unless all requirements implementing section 405(d) of the CWA applicable to the treatment works treating domestic sewage are included in a permit issued under the appropriate provisions of subtitle C of the Solid Waste Disposal Act, Part C of the Safe Drinking Water Act, the Marine Protection, Research, and Sanctuaries Act of 1972, or the Clean Air Act, or under a Land Application or State permit issued by the Department under R.61-9.505, as adequate to assure compliance with section 405 of the CWA.

(3) The Department may designate any person subject to the standards for sewage sludge use and disposal as a “treatment works treating domestic sewage” as defined in section 122.2, where it finds that a permit is necessary to protect public health and the environment from the adverse effects of sewage sludge or to ensure compliance with the technical standards for sludge use and disposal developed under CWA section 405(d). Any person designated as a “treatment works treating domestic sewage” shall submit an application for a permit under section 122.21 within 180 days of being notified by the Department that a permit is required. The Department’s decision to designate a person as a “treatment works treating domestic sewage” under this paragraph shall be stated in the fact sheet for the permit.

(4) The following are point sources requiring NPDES permits for discharges:

- (i) Concentrated animal feeding operations as defined in section 122.23;
- (ii) Concentrated aquatic animal production facilities as defined in section 122.24;
- (iii) Discharges into aquaculture projects as set forth in section 122.25;
- (iv) Discharges of storm water as set forth in sections 122.26 and 122.30 through 36; and,
- (v) Silvicultural point sources as defined in section 122.27.

(c) The Department may incorporate the requirements (either directly or by reference), for permits for the Use and Disposal of Sewage Sludge (see R.61-9.503), or the Use and Disposal of

Industrial Sludge (see R.61-9.504) into NPDES permit(s) that may be issued to the applicant. A separate Land Application permit (see R.61-9.505) may be issued by the Department for the activities covered under R.61-9.503 or R.61-9.504, unless an NPDES permit is required for the activity.

(d) Relation to other requirements.

(1) Permit application forms. Applicants for permits must submit their applications on permit application forms designated by the Department. The basic information required in the general form (Form 1) and the additional information required by NPDES applications (Forms 2 a through e) are listed in section 122.21.

(2) Technical Regulations. The NPDES permit program has separate additional regulations. These separate regulations are used by the Department to determine what requirements must be placed in permits if they are issued. These separate regulations are located at R.61-9.125, 129, 133, and 403; 40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 460); R.61-9.503, R.61-9.504 and R.61-9.505.

(e) Public participation. This part of the regulation (R.61-9.122) establishes the requirements for public participation in NPDES permit issuance and enforcement and related variance proceedings.

(f) [Reserved]

(g) Authority.

(1) Section 48-1-90(a), S.C. Code of Laws (1976), provides that "it shall be unlawful for any person, directly or indirectly, to throw, drain, run, allow to seep, or otherwise discharge into the environment of the State organic or inorganic matter, including sewage, industrial wastes and other wastes, except as in compliance with a permit issued by the Department." Section 301(a) of CWA provides that "Except as in compliance with this section and sections 302, 306, 307, 318, 402, and 404 of this Act, the discharge of any pollutant by any person shall be unlawful."

(2) Section 48-1-100(a), S.C. Code of Laws (1976), provides that "if, after appropriate public comment procedures, as defined by Department regulations, the Department finds that the discharge from the proposed outlet ... will not be in contravention of provisions of Chapter 1, Title 48, S.C. Code of Laws, a permit to construct and a permit to discharge must be issued to the applicant." Section 402(a)(1) of CWA provides in part that "The [Department] may, after opportunity for public hearing, issue a permit for the discharge of any pollutant, or combination of pollutants, ... upon condition that such discharge will meet either all applicable requirements under sections 301, 302, 306, 307, 308, and 403 of this Act, or prior to the taking of necessary implementing actions relating to all such requirements, such conditions as the [Department] determines are necessary to carry out the provisions of this Act."

(3) Section 318(a) of CWA provides that "The [Department] is authorized, after public hearings, to permit the discharge of a specific pollutant or pollutants under controlled conditions associated with an approved aquaculture project under Federal or State supervision pursuant to section 402 of this Act."

(4) Section 405 of CWA provides, in part, that "Where the disposal of sewage sludge resulting from the operation of a treatment works as defined in section 212 of this Act (including the removal of in-place sewage sludge from one location and its deposit at another location) would result in any pollutant from such sewage sludge entering the [waters of the State], such disposal is prohibited except in accordance with a permit issued by the [Department] under section 402 of this Act."

(5) Section 405(d)(4) of the CWA requires the Department, prior to promulgation of standards for sewage sludge use and disposal, to "impose conditions in permits issued to publicly owned treatment works under section 402 of this Act, or take such other measures as the [Department] deems appropriate to protect public health and the environment from any adverse effects which may occur from toxic pollutants in sewage sludge."

(6) Section 405(f) of CWA provides that NPDES permits must include requirements implementing the standards for sludge use and disposal (40 CFR Part 503) "unless such requirements have been included in a permit issued under the appropriate provisions of subtitle C of the Solid Waste Disposal Act, part C of the Safe Drinking Water Act, the Marine Protection, Research, and Sanctuaries Act of 1972, or the Clean Air Act, or under State [NPDES] permit programs approved

by the Administrator....” Section 405(f) also authorizes the Department to issue permits with requirements for sludge use or disposal that assure compliance with 40 CFR Part 503 to any treatment works treating domestic sewage that is not subject to NPDES (i.e., has no point source discharge) and has not been issued a permit that includes applicable 40 CFR Part 503 standards under the other permit programs listed in section 405(f)(1) of the CWA.

(7) Sections 402(b), 318(b) and (c), and 405(c) and (f) of CWA authorize EPA approval of State NPDES permit programs for discharges from point sources, discharges to aquaculture projects, and use and disposal of sewage sludge.

(8) Section 304(i) of CWA provides that the Administrator shall promulgate guidelines establishing uniform application forms and other minimum requirements for the acquisition of information from dischargers in approved States and establishing minimum procedural and other elements of approved State NPDES programs.

(9) Section 48-1-40 authorizes the Department “after public hearing as herein provided, [to] adopt standards and determine what qualities of water ... shall indicate a polluted condition and these standards shall be promulgated and made a part of the rules and regulations of the Department.” Section 48-1-50(22) authorizes the Department to “[r]equire the owner or operator of any ... disposal system to establish and maintain such operational records; make reports; install, use, and maintain monitoring equipment or methods; sample and analyze ... discharges in accordance with established methods, at locations, intervals, and procedures as the Department shall prescribe; and provide such other information as the Department reasonably may require.” Section 48-1-50(23) authorizes the Department to “[a]dopt ... effluent control regulations, standards and limitations that are applicable to the entire State, that are applicable only within specified areas or zones of the State, or that are applicable only when a specified class of pollutant is present.” Section 501(a) of CWA provides that “The [Department] is authorized to prescribe such regulations as are necessary to carry out [its] functions under this Act.”

(10) Section 48-1-100(a) requires an opportunity for public comment before issuance of permits to discharge. Section 101(e) of CWA provides that “Public participation in the development, revision, and enforcement of any regulation, standard, effluent limitation, plan, or program established by the Administrator or any State under this Act shall be provided for, encouraged, and assisted by the Administrator and the States. The Administrator, in cooperation with the States, shall develop and publish regulations specifying minimum guidelines for public participation in such processes.”

122.2. Definitions.

(a) The following definitions apply to this regulation, R.61-9.124, R.61-9.125, R.61-9.129, R.61-9.133, and R.61-9.403. Terms not defined in this section have the meaning given by the Clean Water Act (CWA) or the Pollution Control Act (PCA).

(b) Definitions:

“Administrator” means the Administrator of the Environmental Protection Agency or any employee of the Agency to whom the Administrator may by order delegate the authority to carry out his functions under section 307(a) of the CWA, or any person who shall by operation of law be authorized to carry out such functions.

Note: “Animal feeding operation” is defined at section 122.23.

“Applicable standards and limitations” means all State, interstate, and federal standards and limitations to which a discharge, a sewage sludge use or disposal practice, or a related activity is subject under the CWA, including effluent limitations, water quality standards, standards of performance, toxic effluent standards or prohibitions, best management practices, pretreatment standards, and standards for sewage sludge use or disposal under section 301, 302, 303, 304, 306, 307, 308, 403 or 405 of CWA.

“Applicant” means a person applying to the Department for a State or NPDES permit to discharge wastes into the waters of the State or to operate a treatment works.

“Application” means the uniform NPDES application form, including subsequent additions, revisions, or modifications thereof promulgated by the Administrator of EPA, and adopted for use by the Board or a State permit application form.

Note: "Aquaculture project" is defined at section 122.25.

"Average monthly discharge limitation" means the highest allowable average of daily discharges over a calendar month, calculated as the sum of all daily discharges measured during a calendar month divided by the number of daily discharges measured during that month.

"Average weekly discharge limitation" means the highest allowable average of daily discharges over a calendar week, calculated as the sum of all daily discharges measured during a calendar week divided by the number of daily discharges measured during that week.

"Best management practices" (BMP) means schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution of waters of the State. BMPs also include treatment requirements, operating procedures and practices to control plant site runoff, spillage or leaks, sludge or waste disposal, or drainage from raw material storage.

"BMP" means best management practices.

"Board" means the Board of Health and Environmental Control for the State of South Carolina and shall be inclusive of any agent designated by the Board to perform any function.

Note: "Bypass" is defined at section 122.41(m).

"CFR" means the Code of Federal Regulations, as amended.

"Class I sludge management facility" means any POTW identified under R.61-9.403.8(a), as being required to have an approved pretreatment program and any other treatment works treating domestic sewage classified as a Class I sludge management facility by the Regional Administrator in conjunction with the Department because of the potential for its sludge use or disposal practices to adversely affect public health and the environment.

"Code" means the South Carolina Code of 1976, as amended.

"Commissioner" means the Commissioner of the S.C. Department of Health and Environmental Control, or his designated representative.

Note: "Concentrated animal feeding operation" is defined at section 122.23.

Note: "Concentrated aquatic animal feeding operation" is defined at section 122.24.

"Contiguous zone" means the entire zone established by the United States under Article 24 of the Convention on the Territorial Sea and the Contiguous Zone.

"Continuous discharge" means a discharge which occurs without interruption throughout the operating hours of the facility, except for infrequent shutdowns for maintenance, process changes, or other similar activities.

"CWA" means the Clean Water Act (formerly referred to as the Federal Water Pollution Control Act or Federal Water Pollution Control Act Amendments of 1972) Pub. L. 92-500, as amended by Pub. L. 95-217, Pub. L. 95-576, Pub. L. 96-483, and Pub. L. 97-117, 33 U.S.C. 1251 et seq. Specific references to sections within the CWA will be according to Pub. L. 92-500 notation.

"CWA and regulations" means the Clean Water Act (CWA) and applicable regulations promulgated thereunder and includes State NPDES program requirements.

"Daily discharge" means the discharge of a pollutant measured during a calendar day or any 24-hour period that reasonably represents the calendar day for purposes of sampling. For pollutants with limitations expressed in units of mass, the daily discharge is calculated as the total mass of the pollutant discharged over the day. For pollutants with limitations expressed in other units of measurement, the daily discharge is calculated as the average measurement of the pollutant over the day.

"Department" means the S.C. Department of Health and Environmental Control and shall also be inclusive of those persons within the Department authorized by the Board to administer the NPDES program or take any action in behalf of the Board.

"Direct discharge" means the discharge of a pollutant.

"Discharge" means any discharge or discharge of any sewage, industrial wastes or other wastes into any of the waters of the State, whether treated or not.

"Discharge of a pollutant"

(1) means:

(i) Any addition of any pollutant or combination of pollutants to waters of the State from any point source, or

(ii) Any addition of any pollutant or combination of pollutants to the waters of the contiguous zone or the ocean from any point source other than a vessel or other floating craft which is being used as a means of transportation.

(2) includes additions of pollutants into waters of the State from: surface runoff which is collected or channeled by man; discharges through pipes, sewers, or other conveyances owned by a State, municipality, or other person which do not lead to a treatment works; and discharges through pipes, sewers, or other conveyances, leading into privately owned treatment works. This term does not include an addition of pollutants by any indirect discharger.

“Discharge Monitoring Report” (DMR) means the EPA uniform national form, including any subsequent additions, revisions, or modifications for the reporting of self-monitoring results by permittees, and modified to substitute the State Agency name, address, logo, and other similar information, as appropriate, in place of EPA’s.

“Discharger” means any person who discharges any treated or untreated sewage, industrial wastes, or other wastes into any of the waters of the State.

“DMR” means Discharge Monitoring Report.

“Draft Permit” means a document prepared by the staff of the Department, in accordance with R.61–9.124.6, prior to public notice of an application for a permit by a discharger. This document indicates the Department’s tentative decision to issue or deny, modify, revoke and reissue, terminate, or reissue a permit to discharge. It contains proposed effluent standards and limitations, proposed compliance schedules and other proposed conditions or restrictions deemed necessary by the Department for a discharge. A notice of intent to terminate a permit, and a notice of intent to deny a permit, as discussed in R.61–9.124.5, are types of draft permits. A denial of a request for modification, revocation and reissuance, or termination, as discussed in R.61–9.124.5, is not a draft permit. A “proposed permit” is not a draft permit.

“Effluent limitation” means any restriction imposed by the Department on quantities, discharge rates, and concentrations of pollutants which are discharged from point sources into waters of the State, the waters of the contiguous zone, or the ocean.

“Effluent limitations guidelines” means: A regulation published by the Administrator under section 304(b) of CWA to adopt or revise effluent limitations.

“Effluent standards and limitations” means restrictions or prohibitions of chemical, physical, biological, and other constituents which are discharged from point sources into State waters, including but not limited to, effluent limitations, standards of performance, toxic effluent standards and prohibitions, pretreatment standards and schedules of compliance.

“Environmental Protection Agency” (EPA) means the United States Environmental Protection Agency.

“EPA” means the United States Environmental Protection Agency.

“Facility or activity” means any NPDES point source or any other facility or activity (including land or appurtenances thereto) that is subject to regulation under the NPDES program.

“Fact sheet” means a description of a discharge available to the public prepared by the Department staff pursuant to the guidelines, which includes, but is not limited to, information on the location of the discharge, rate of frequency of the discharge, components of the discharge, proposed requirements of the Department regarding the discharge, the location and identification of uses of the receiving waters, water quality standards and procedures for formulation of final requirements on the discharge by the Department.

“Federal Act” means the Federal Water Pollution Control Act (CWA), as amended.

“General permit” means an NPDES permit issued under section 122.28 authorizing a category of discharges or activities under the PCA and CWA within a geographical area.

“Hazardous substance” means any substance designated under 40 CFR Part 116 pursuant to section 311 of CWA.

“Indian country” means:

(1) All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation;

(2) All dependent Indian communities within the borders of the United States whether within the originally or subsequently acquired territory thereof, and whether within or without the limits of a state; and

(3) All Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.

“Indirect discharger” means a non-domestic discharge introducing pollutants to a publicly owned treatment works.

“Industry” means a private person, corporation, firm, plant or establishment which discharges sewage, industrial wastes or other wastes into the waters of the State.

“Interstate agency” means an agency of two or more States established by or under an agreement or compact approved by the Congress, or any other agency of two or more States having substantial powers or duties pertaining to the control of pollution as determined and approved by the Administrator under the CWA and regulations.

“Mailing list” means a list of persons requesting notification and information on public hearings, permits and other NPDES forms.

“Major Facility” means any NPDES facility or activity classified as such by the Regional Administrator in conjunction with the Department.

“Management agency” means an area-wide waste treatment management agency designated by the governor pursuant to Section 208(a) of the Federal Act.

“Maximum daily discharge limitation” means the highest allowable daily discharge.

“Minor discharge” means a discharge of wastewater which has a total volume of less than 50,000 gallons on every day of the year, does not closely affect the waters of another state and is not identified by the Department, the Regional Administrator or by the Administrator of EPA in regulations issued by him pursuant to Section 307(a) of the Federal Act, as a discharge which is not a minor discharge, except that in the case of a discharge of less than 50,000 gallons on any day of the year which represents 1 or 2 or more discharges from a single person which in total exceeds 50,000 gallons on any day of the year, then no discharge from the facility is a minor discharge.

Note: “Municipal separate storm sewer system” is defined at sections 122.26 (b).

“Municipality” means a city, town, borough, county, parish, district, association, or other public body created by or under State law and having jurisdiction over disposal of sewage, industrial wastes, or other wastes, or an Indian tribe or an authorized Indian tribal organization, or a designated and approved management agency under section 208 of CWA.

“National Pollutant Discharge Elimination System” means the national program for issuing, modifying, revoking and reissuing, terminating, monitoring and enforcing permits, and imposing and enforcing pretreatment requirements, under sections 307, 402, 318, and 405 of CWA.

“New discharger”

(1) means any building, structure, facility, or installation:

(i) From which there is or may be a discharge of pollutants.

(ii) That did not commence the discharge of pollutants at a particular site prior to August 13, 1979;

(iii) Which is not a new source, and

(iv) Which has never received a finally effective NPDES permit for discharges at that site.

(2) includes an indirect discharger which commences discharging into waters of the State after August 13, 1979. It also includes any existing mobile point source (other than an offshore or coastal oil and gas exploratory drilling rig or a coastal oil and gas developmental drilling rig) such as a seafood processing rig, seafood processing vessel, or aggregate plant, that begins discharging at a site for which it does not have a permit; and any offshore or coastal mobile oil and gas

exploratory drilling rig or coastal mobile oil and gas developmental drilling rig that commences the discharge of pollutants after August 13, 1979, at a site under Department's permitting jurisdiction for which it is not covered by an individual or general permit and which is located in an area determined by the Department in the issuance of a final permit to be an area of biological concern. In determining whether an area is an area of biological concern, the Department shall consider the factors specified in section 122(a)(1) through (10). An offshore or coastal mobile exploratory drilling rig or coastal mobile developmental drilling rig will be considered a new discharger only for the duration of its discharge in an area of biological concern.

"New source" means any building, structure, facility, or installation from which there is or may be a discharge of pollutants, the construction of which commenced:

(1) After promulgation of standards of performance under section 306 of CWA which are applicable to such source, or

(2) After proposal of standards of performance in accordance with section 306 of CWA which are applicable to such source, but only if the standards are promulgated in accordance with section 306 within 120 days of their proposal.

"NPDES" means National Pollutant Discharge Elimination System established by the CWA.

"NPDES form" means any issued permit or any uniform national form used by the Department developed for use in the NPDES, including a NPDES application, a Refuse Act permit application and a reporting form.

"NPDES permit" means a permit issued by the Department to a discharger pursuant to regulations adopted by the Board for all point source discharges into surface waters, and shall constitute a final determination of the Board.

"Non-compliance list" means a list of dischargers, prepared by the Department pursuant to this regulation and the guidelines for transmittal to the Regional Administrator, who fail or refuse to comply with a compliance schedule in a NPDES permit issued pursuant to the State law.

"Owner or operator" means the owner or operator of any facility or activity subject to regulation under the NPDES program.

"Permit" means an authorization, license, or equivalent control document issued by the Department to implement the requirements of this regulation, 40 CFR Parts 123, and R.61-9.124. Permit includes an NPDES general permit (section 122.28). Permit does not include any permit which has not yet been the subject of final agency action, such as a draft permit or a proposed permit.

"Person" means any individual, public or private corporation, political subdivision, association, partnership, corporation, municipality, State or Federal agency, industry, copartnership, firm, trust, estate, any other legal entity whatsoever, or an agent or employee thereof.

"Pesticide discharges to waters of the State from pesticide application" means the discharges that result from the application of biological pesticides, and the application of chemical pesticides that leave a residue, from point sources to waters of the United States. In the context of this definition of pesticide discharges to waters of the United States from pesticide application, this does not include agricultural storm water discharges and return flows from irrigated agriculture, which are excluded by law (33 U.S.C. 1342(l); 33 U.S.C. 1362(14)).

"Pesticide residue" for the purpose of determining whether an NPDES permit is needed for discharges to waters of the State from pesticide application, means that portion of a pesticide application that is discharged from a point source to waters of the United States and no longer provides pesticidal benefits. It also includes any degradates of the pesticide.

"Point source" means any discernible, confined, and discrete conveyance, including but not limited to, any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, vessel, or other floating craft from which pollutants are or may be discharged. This term does not include return flows from irrigated agriculture.

"Point source discharge" means a discharge which is released to the waters of the State by a discernible, confined and discrete conveyance, including but not limited to a pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, vessel, or other floating craft from which waste is or may be discharged.

"Pollutant"

(1) means dredged spoil, solid waste, incinerator residue, filter backwash, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials (except those regulated under the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.)), heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water.

(2) does not mean:

(i) Sewage from vessels; or

(ii) Water, gas, or other material which is injected into a well to facilitate production of oil or gas, or water derived in association with oil and gas production and disposed of in a well, if the well used either to facilitate production or for disposal purposes is approved by authority of the State in which the well is located, and if the State determines that the injection or disposal will not result in the degradation of ground or surface water resources.

“Pollution Control Act” (PCA) means the South Carolina Pollution Control Act (PCA), S.C. Code Ann. section 48-1-10 et seq. (1976).

“POTW” means publicly owned treatment works.

“Primary industry category” means any industry category listed in the NRDC settlement agreement (Natural Resources Defense Council et al., v. Train, 8 E.R.C. 2120 (D.D.C. 1976), modified 12 E.R.C. 1833 (D.D.C. 1979)); also listed in Appendix A of this regulation.

“Privately owned treatment works” means any device or system which both is used to treat wastes from any facility whose operator is not the operator of the treatment works and is not a POTW.

“Process wastewater” means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, byproduct, or waste product.

“Proposed permit” means a State NPDES permit prepared after the close of the public comment period (and, when applicable, any public hearing and administrative appeals) which is sent to EPA for review before final issuance by the State. A “proposed permit” is not a draft permit.

“Publicly owned treatment works” or POTW means a treatment works as defined by section 212 of the Clean Water Act, which is owned by a state or municipality (as defined by section 502[4] of the CWA). This definition includes any devices and systems used in the storage, treatment, recycling and reclamation of municipal sewage or industrial wastes of a liquid nature. It also includes sewers, pipes and other conveyances only if they convey wastewater to a POTW Treatment Plant. The term also means the municipality, as defined in section 502(4) of the CWA, which has jurisdiction over the Indirect Discharges to and the discharge from such a treatment works.

“Recommencing discharger” means a source which recommences discharge after terminating operations.

“Refuse Act permit application” means an application for a permit issued under authority of Section 13 of the United States Rivers and Harbors Act of March 3, 1899.

“Regional Administrator” means the Regional Administrator of Region IV of the Environmental Protection Agency or the authorized representative of the Regional Administrator.

“Reporting form” means the uniform NPDES reporting form, including subsequent additions, revisions or modifications thereof, adopted by the Department for use in administering this regulation, or a State form prescribed by the Department for use in administering this regulation, for reporting data and information to the Department by a discharger on monitoring and other conditions of permits.

“Satellite sewer system” means a sewer system that is owned or operated by one person that discharges to a system that is owned or operated by a different person. Satellite sewer systems depend on a separate person for final wastewater treatment and discharge and include systems approved under R.61-9.505.8.

“Schedule of compliance” means a schedule of remedial measures included in a “permit”, including an enforceable sequence of interim requirements (for example, actions, operations, or milestone events) leading to compliance with the CWA and regulations.

“Secondary industry category” means any industry category which is not a primary industry category.

“Secretary” means the Secretary of the Army, acting through the Chief of Engineers.

“Septage” means the liquid and solid material pumped from septic tank, cesspool or similar domestic sewage treatment system, or a holding tank when the system is cleaned or maintained.

“Sewage from vessels” means human body wastes and the wastes from toilets and other receptacles intended to receive or retain body wastes that are discharged from vessels and regulated under section 312 of CWA.

“Sewage Sludge” means any solid, semi-solid, or liquid residue removed during the treatment of municipal waste water or domestic sewage. Sewage sludge includes, but is not limited to, solids removed during primary, secondary, or advanced waste water treatment, scum, septage, portable toilet pumpings, type III marine sanitation device pumpings (33 CFR Part 159), and sewage sludge products. Sewage sludge does not include grit or screenings or ash generated during the incineration of sewage sludge.

“Sewage sludge use or disposal practice” means the collection, storage, treatment, transportation, processing, monitoring, use or disposal of sewage sludge.

“Sewer system” means any system of wastewater collection lines, sewers, interceptors and pump stations, except for service connections, as defined by R.61-67. In this part, a sewer system includes “sewage system” as defined by the Pollution Control Act.

Note: “Silvicultural point source” is defined at section 122.27.

“Site” means the land or water area where any facility or activity is physically located or conducted, including adjacent land used in connection with the facility or activity.

“Sludge-only facility” means any “treatment works treating domestic sewage” whose methods of sewage sludge use or disposal are subject to regulations promulgated pursuant to section 405(d) of the CWA and is required to obtain a permit under section 122.1(b)(2).

“Standards for sewage sludge use or disposal” means the regulations promulgated pursuant to section 405(d) of the CWA which govern minimum requirements for sludge quality, management practices, and monitoring and reporting applicable to sewage sludge or the use or disposal of sewage sludge by any person.

“State” means the State of South Carolina.

“State/EPA Agreement” means an agreement between the Regional Administrator and the State which coordinates EPA and State activities, responsibilities and programs including those under the CWA programs.

“State Law” means the S.C. Pollution Control Act (PCA), specifically 48-1-10 through 48-1-350 of the South Carolina Code of 1976, and any subsequent amendments thereto.

“State permit” See R-61-9.505.2 for definition.

Note: “Storm water” is defined at section 122.26(b)(13).

Note: “Storm water discharge associated with industrial activity” is defined at section 122.26(b)(14).

“Total dissolved solids” (TDS) means the total dissolved (filterable) solids as determined by use of the method specified in 40 CFR Part 136.

“Toxic pollutant” means any pollutant listed as toxic under section 307(a)(1) or, in the case of sludge use or disposal practices, any pollutant identified in regulations implementing section 405(d) of the CWA.

“Trade secret” means the whole or any portion or phase of any manufacturing proprietary process or method, not patented, which is secret, useful in compounding an article of trade having a commercial value, and the secrecy of which the owner has taken reasonable measures to prevent from becoming available to persons other than those selected by the owner to have access thereto to limited purpose. It shall not be construed for purpose of this regulation to include any information relative to the quantity and character of waste products or their constituents discharged into waters of the State.

“Treatment works” means any plant, disposal field, lagoon, constructed drainage ditch or surface water intercepting ditch, incinerator, area devoted to sanitary landfills or other works not specifically mentioned herein, installed for the purpose of treating, neutralizing, stabilizing or disposing of sewage, industrial waste or other wastes.

“Treatment works treating domestic sewage” (TWTDS) means a POTW or any other sewage sludge or waste water treatment devices or system, regardless of ownership (including federal facilities), used in the storage, treatment, recycling, and reclamation of municipal or domestic sewage, including land dedicated for the disposal of sewage sludge. This definition does not include septic tanks or similar devices. For purposes of this definition, domestic sewage includes waste and waste water from humans or household operations that are discharged to or otherwise enter a treatment works. In States where there is no approved State sludge management program under section 405(f) of the CWA, the Regional Administrator may designate any person subject to the standards for sewage sludge use and disposal in 40 CFR Part 503 as a treatment works treating domestic sewage, where he or she finds that there is a potential for adverse effects on public health and the environment from poor sludge quality or poor sludge handling use or disposal practices or where he or she finds that such designation is necessary to ensure that such person is in compliance with 40 CFR Part 503.

“TWTDS” means treatment works treating domestic sewage.

Note: “Upset” is defined at section 122.41(n).

“Variance” means any mechanism or provision under section 301 or 316 of CWA, PCA, or R.61–9.125, or in the applicable effluent limitations guidelines which allows modification to or waiver of the generally applicable effluent limitation requirements or time deadlines of CWA. This includes provisions which allow the establishment of alternative limitations based on fundamentally different factors or on section 301(c), 301(g), 301(h), 301(i), or 316(a) of CWA.

“Vessel” means any contrivance used or capable of being used for navigation upon water, whether or not capable of self-propulsion, including foreign and domestic vessels engaged in commerce upon the waters of this State, passenger or other cargo carrying vessels, privately owned recreational watercraft or any other floating craft.

“Waste” shall be synonymous with sewage, industrial waste, and other wastes.

“Waters of the State” means lakes, bays, sounds, ponds, impounding reservoirs, springs, wells, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Atlantic Ocean within the territorial limits of the State, and all other bodies of surface or underground water, natural or artificial, public or private, inland or coastal, fresh or salt, which are wholly or partially within or bordering the State or within its jurisdiction.

“Waters of the United States” or “waters of the U.S.”;

(1) All waters which are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters which are subject to the ebb and flow of the tide;

(2) All interstate waters, including interstate “wetlands;”

(3) All other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sand flats, “wetlands,” sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds the use, degradation, or destruction of which would affect or could affect interstate or foreign commerce including any such waters:

(i) Which are or could be used by interstate or foreign travelers for recreational or other purposes;

(ii) From which fish or shellfish are or could be taken and sold in interstate or foreign commerce; or

(iii) Which are used or could be used for industrial purposes by industries in interstate commerce;

(4) All impoundments of waters otherwise defined as waters of the United States under this definition;

(5) Tributaries of waters identified in paragraphs (1) through (4) of this definition;

- (6) The territorial sea; and
- (7) Wetlands adjacent to waters (other than waters which are themselves wetlands) identified in paragraphs (1) through (6) of this definition.
- (8) Waste treatment systems, including treatment ponds or lagoons designed to meet the requirements of CWA are not waters of the United States.

“Wetlands” means those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas.

“Whole effluent toxicity” means the aggregate toxic effect of an effluent measured directly by a toxicity test.

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

122.3. Exclusions.

The following discharges do not require NPDES permits:

(a) Any discharge of sewage from vessels, effluent from properly functioning marine engines, laundry, shower, and galley sink wastes, or any other discharge incidental to the normal operation of a vessel. This exclusion does not apply to rubbish, trash, garbage, or other such materials discharged overboard; nor to other discharges when the vessel is operating in a capacity other than as a means of transportation such as when used as an energy or mining facility, a storage facility or a seafood processing facility, or when secured to a storage facility or a seafood processing facility, or when secured to the bed of the ocean, contiguous zone or waters of the State for the purpose of mineral or oil exploration or development.

(b) Discharges of dredged or fill material into waters of the United States which are regulated under section 404 of CWA.

(c) The introduction of sewage, industrial wastes or other pollutants into publicly owned treatment works by indirect dischargers. Plans or agreements to switch to this method of disposal in the future do not relieve dischargers of the obligation to have and comply with permits until all discharges of pollutants to waters of the State are eliminated. (See also section 122.47(b)). This exclusion does not apply to the introduction of pollutants to privately owned treatment works or to other discharges through pipes, sewers, or other conveyances owned by a State, municipality, or other party not leading to treatment works.

(d) Any discharge in compliance with the instructions of an On-Scene Coordinator pursuant to 40 CFR Part 1510 (The National Oil and Hazardous Substances Pollution Plan) or 33 CFR 153.10(e) (Pollution by Oil and Hazardous Substances).

(e) Any introduction of pollutants from non point-source agricultural and silvicultural activities, including storm water runoff from orchards, cultivated crops, pastures, range lands, and forest lands, but not discharges from concentrated animal feeding operations as defined in section 122.23, discharges from concentrated aquatic animal production facilities defined in section 122.24, discharges to aquaculture projects as defined in section 122.25, and discharges from silvicultural point sources as defined in section 122.27.

(f) Return flows from irrigated agriculture.

(g) Discharges into a privately owned treatment works, except as the Department may otherwise require under section 122.44(m).

122.4. Prohibitions.

No permit may be issued:

(a) When the conditions of the permit do not provide for compliance with the applicable requirements of CWA, State regulations, or regulations promulgated under CWA;

(b) When the applicant is required to obtain a State or other appropriate certification under section 401 of CWA and R.61-9.124.53 and that certification has not been obtained or waived;

(c) By the Department where the Regional Administrator has objected to issuance of the permit under 40 CFR Part 123.44;

(d) When the imposition of conditions cannot ensure compliance with the applicable water quality requirements of all affected States;

(e) When, in the judgment of the Secretary, anchorage and navigation in or on any of the waters of the United States would be substantially impaired by the discharge;

(f) For the discharge of any radiological, chemical, or biological warfare agent or high-level radioactive waste;

(g)(1) For any discharge inconsistent with a plan or plan amendment approved under section 208(b) of CWA, unless the Department finds such variance necessary to protect the public health, safety, and welfare;

(2) In reissuance of a permit which requires connection to a regional sewer system or other treatment facilities under the water quality management plan under section 208 of the CWA, once the permittee is notified by the Department that the regional sewer system is operational.

(h) For any discharge to the territorial sea, the waters of the contiguous zone, or the oceans in the following circumstances;

(1) Before the promulgation of guidelines under section 403(c) of CWA (for determining degradation of the waters of the territorial seas, the contiguous zone, and the oceans) unless the Department determines permit issuance to be in the public interest; or

(2) After promulgation of guidelines under section 403(c) of CWA, when insufficient information exists to make a reasonable judgment whether the discharge complies with them.

(i) To a new source or a new discharger, if the discharge from its construction or operation will cause or contribute to the violation of water quality standards. The owner or operator of a new source or new discharger proposing to discharge into a water segment which does not meet applicable water quality standards or is not expected to meet those standards even after the application of the effluent limitations required by sections 301(b)(1)(A) and 301(b)(1)(B) of CWA, and for which the State or interstate agency has performed a pollutants load allocation for the pollutant to be discharged, must demonstrate, before the close of the public comment period, that:

(1) There are sufficient remaining pollutant load allocations to allow for the discharge; and

(2) The existing dischargers into that segment are subject to compliance schedules designed to bring the segment into compliance with applicable water quality standards. The Department may waive the submission of information by the new source or new discharger required by paragraph

(i) of this section if the Department determines that the Department already has adequate information to evaluate the request. An explanation of the development of limitations to meet the criteria of this paragraph (i)(2) is to be included in the fact sheet to the permit under section 124.56(b)(1).

122.5. Effect of a permit.

(a)(1) Except for any toxic effluent standards and prohibitions imposed under section 307 of the CWA and “standards for sewage sludge use or disposal” under 405(d) of the CWA, compliance with a permit during its term constitutes compliance, for purposes of enforcement, with the Pollution Control Act and with sections 301, 302, 306, 307, 318, 403, and 405(a)-(b) of CWA. However, a permit may be modified, revoked and reissued, or terminated during its term for cause as set forth in section 122.62 and section 122.64.

(2) Compliance with a permit condition which implements a particular “standard for sewage sludge use or disposal” shall be an affirmative defense in any enforcement action brought for a violation of that “standard for sewage sludge use or disposal” pursuant to sections 405(e) and 309 of the CWA.

(b) The issuance of a permit does not convey any property rights of any sort, or any exclusive privilege.

(c) The issuance of a permit does not authorize any injury to persons or property or invasion of other private rights, or any infringement of State or local law or regulations.

122.6. Continuation of expiring permits.

(a) The conditions of an expired permit continue in force under S.C. Code section 1–23–370(b) until the effective date of a new permit (see R.61–9.124.15), except when the permit requires connection to a

regional sewer system or other treatment facilities under the water quality management plan under section 208 of the CWA and the permittee has been notified by the Department that the regional sewer system is operational, if:

- (1) The permittee has submitted a timely application under section 122.21 which is a complete (under section 122.21(e)) application for a new permit; and
 - (2) The Department, through no fault of the permittee does not issue a new permit with an effective date under R.61-9.124.15 on or before the expiration date of the previous permit (for example, when issuance is impracticable due to time or resource constraints); or
 - (3) The permittee has submitted a timely application under section 122.21 which is a complete application for a new permit and makes a timely appeal of the new permit.
- (b) Effect. Permits continued under this section remain fully effective and enforceable.
- (c) Enforcement. When the permittee is not in compliance with the conditions of the expiring or expired permit the Department may choose to do any or all of the following:
- (1) Initiate enforcement action based upon the permit which has been continued;
 - (2) Issue a notice of intent to deny the new permit under section 124.6. If the permit is denied, the owner or operator would then be required to cease the activities authorized by the continued permit or be subject to enforcement action for operating without a permit;
 - (3) Issue a new permit under R.61-9.124 with appropriate conditions; or
 - (4) Take other actions authorized by these regulations.

122.7. Confidentiality of information.

- (a) [Reserved]
- (b) Claims of confidentiality for the following information will be denied:
 - (1) The name and address of any permit applicant or permittee;
 - (2) Permit applications, permits, and effluent data.
- (c) Information required by NPDES application forms provided by the Department under section 122.21 may not be claimed confidential. This includes information submitted on the forms themselves and any attachments used to supply information required by the forms.

PART B

PERMIT APPLICATION AND SPECIAL NPDES PROGRAM REQUIREMENTS

122.21. Application for a permit.

- (a) Duty to apply.
 - (1) Any person who discharges or proposes to discharge pollutants or who owns or operates a "sludge-only facility" whose sewage sludge use or disposal practice is regulated by R.61-9.503 and who does not have an effective permit, except persons covered by general permits under section 122.28, excluded under section 122.3, or a user of a privately owned treatment works, unless the Department requires otherwise under section 122.44(m), must submit a complete application to the Department in accordance with this section and R.61-9.124. All concentrated animal feeding operations have a duty to seek coverage under an NPDES permit, as described in section 122.23(d).
 - (2) Application Forms:
 - (i) All applicants for State-issued permits must submit applications on EPA permit application forms. More than one application form may be required from a facility depending on the number and types of discharges or outfalls found there. Applications for State-issued permits must be submitted as follows:
 - (A) All applicants, other than POTWs, TWTDS, vessels, and pesticide applicators must submit Form 1.
 - (B) Applicants for new and existing POTWs must submit the information contained in paragraph (j) of this section using Form 2A or other form provided by the Department.
 - (C) Applicants for concentrated animal feeding operations or aquatic animal production facilities must submit Form 2B.

(D) Applicants for existing industrial facilities (including manufacturing facilities, commercial facilities, mining activities, and silvicultural activities), must submit Form 2C.

(E) Applicants for new industrial facilities that discharge process wastewater must submit Form 2D.

(F) Applicants for new and existing industrial facilities that discharge only nonprocess wastewater must submit Form 2E.

(G) Applicants for new and existing facilities whose discharge is composed entirely of storm water associated with industrial activity must submit Form 2F, unless exempted by Section 122.26(c)(1)(ii). If the discharge is composed of storm water and non-storm water, the applicant must also submit Forms 2C, 2D, and/or 2E, as appropriate (in addition to Form 2F).

(H) Applicants for new and existing TWTDS, subject to paragraph (c)(2)(i) of this section must submit the application information required by paragraph (q) of this section, using Form 2S or other form provided by the Department.

(ii) The application information required by paragraph (a)(2)(i) of this section may be electronically submitted if such method of submittal is approved by the Department.

(iii) Applicants can obtain copies of these forms by contacting the Department.

(3) Applicants for State-issued permits must use State forms which must require at a minimum the information listed in the appropriate paragraphs of this section.

(4) A person discharging or proposing to discharge wastes into the waters of the State shall promptly make application for and obtain a valid NPDES Permit and, if required, a valid State Construction Permit.

(b) [Reserved]

(c) Time to apply.

(1) Any person proposing a new discharge shall submit an application at least 180 days before the date on which the discharge is to commence, unless permission for a later date has been granted by the Department. Facilities proposing a new discharge of storm water associated with industrial activity shall submit an application 180 days before that facility commences industrial activity which may result in a discharge of storm water associated with that industrial activity. Facilities described under section 122.26(b)(14)(x) or (b)(15)(i) shall submit applications at least 90 days before the date on which construction is to commence. Different submittal dates may be required under the terms of applicable general permits. Persons proposing a new discharge are encouraged to submit their applications well in advance of the 90 or 180-day requirements to avoid delay. See also paragraph (k) of this section and section 122.26(c)(1)(i)(G) and (c)(1)(ii).

(2) Permits under section 405(f) of CWA. All "treatment works treating domestic sewage" (TWTDS) whose sewage sludge use or disposal practices are regulated by part 503 of this chapter must submit permit applications according to the applicable schedule in paragraphs (c)(2)(i) or (ii) of this section.

(i) A TWTDS with a currently effective NPDES permit must submit a permit application at the time of its next NPDES permit renewal application. Such information must be submitted in accordance with paragraph (d) of this section.

(ii) Any other TWTDS not addressed under paragraphs (c)(2)(i) of this section must submit the information listed in paragraphs (c)(2)(ii)(A) through (E) of this section to the Department within 1 year after publication of a standard applicable to its sewage sludge use or disposal practice(s), using Form 2S or another form provided by the Department. The Department will determine when such TWTDS must submit a full permit application.

(A) The TWTDS's name, mailing address, location, and status as federal, State, private, public or other entity;

(B) The applicant's name, address, telephone number, and ownership status;

(C) A description of the sewage sludge use or disposal practices. Unless the sewage sludge meets the requirements of paragraph (q)(8)(iv) of this section, the description must include the name and address of any facility where sewage sludge is sent for treatment or disposal, and the location of any land application sites;

(D) Annual amount of sewage sludge generated, treated, used or disposed (estimated dry weight basis); and

(E) The most recent data the TWTDS may have on the quality of the sewage sludge.

(iii) Notwithstanding paragraphs (c)(2)(i) or (ii) of this section, the Department may require permit applications from any TWTDS at any time if the Department determines that a permit is necessary to protect public health and the environment from any potential adverse effects that may occur from toxic pollutants in sewage sludge.

(iv) Any TWTDS that commences operations after promulgation of an applicable “standard for sewage sludge use or disposal” must submit an application to the Department at least 180 days prior to the date proposed for commencing operations.

(3) [Reserved]

(d) Duty to reapply.

(1) Any POTW with a current effective permit shall submit a new application at least 180 days before the expiration date of the existing permit, unless permission for a later date has been granted by the Department. (The Department shall not grant permission for applications to be submitted later than the expiration date of the existing permit).

(2) All other permittees with currently effective permits shall submit a new application 180 days before the existing permit expires, except that the Department may grant permission to submit an application later than the deadline for submission otherwise applicable, but no later than the permit expiration date; and

(3) [Reserved]

(e) Completeness.

(1) The Department shall not issue a permit before receiving a complete application for a permit except for NPDES general permits. An application for a permit is complete when the Department receives an application form and any supplemental information which are completed to its satisfaction. The completeness of any application for a permit shall be judged independently of the status of any other permit application or permit for the same facility or activity.

(2) A permit application shall not be considered complete if a permitting authority has waived application requirements under paragraphs (j) or (q) of this section and EPA has disapproved the waiver application. If a waiver request has been submitted to EPA more than two hundred ten (210) days prior to permit expiration and EPA has not disapproved the waiver application one hundred eighty-one (181) days prior to permit expiration, the permit application lacking the information subject to the waiver application shall be considered complete.

(3) Except as specified in 122.21(e)(3)(ii), a permit application shall not be considered complete unless all required quantitative data are collected in accordance with sufficiently sensitive analytical methods approved under 40 CFR Part 136 or required under 40 CFR chapter I, subchapter N or O.

(i) For the purposes of this requirement, a method approved under 40 CFR Part 136 or required under 40 CFR chapter I, subchapter N or O is “sufficiently sensitive” when:

(A) The method minimum level (ML) is at or below the level of the applicable water quality criterion for the measured pollutant or pollutant parameter; or

(B) The method ML is above the applicable water quality criterion, but the amount of the pollutant or pollutant parameter in a facility’s discharge is high enough that the method detects and quantifies the level of the pollutant or pollutant parameter in the discharge; or

(C) The method has the lowest ML of the analytical methods approved under 40 CFR Part 136 or required under 40 CFR chapter I, subchapter N or O for the measured pollutant or pollutant parameter.

Note to paragraph (e)(3)(i):

Consistent with 40 CFR Part 136, applicants have the option of providing matrix or sample specific minimum levels rather than the published levels. Further, where an applicant can demonstrate that, despite a good faith effort to use a method that would otherwise meet the definition of “sufficiently sensitive,” the analytical results are not consistent with the QA/QC specifications for that method, then the Department may determine that the method is not performing adequately and the applicant

should select a different method from the remaining EPA-approved methods that is sufficiently sensitive consistent with 40 CFR 122.21(e)(3)(i). Where no other EPA-approved methods exist, the applicant should select a method consistent with 40 CFR 122.21(e)(3)(ii).

(ii) When there is no analytical method that has been approved under 40 CFR Part 136, required under 40 CFR chapter I, subchapter N or O, and is not otherwise required by the Department, the applicant may use any suitable method but shall provide a description of the method. When selecting a suitable method, other factors such as a method's precision, accuracy, or resolution may be considered when assessing the performance of the method.

(4) The Department, at its discretion, or upon request of the Regional Administrator, may request of an applicant any additional information deemed necessary to complete or correct deficiencies in a Refuse Act permit application, before processing the application or issuing or denying the issuance of a permit.

(5) The Department may take enforcement action as prescribed by the State law or this regulation against any person who fails to file a complete application, if deficiencies are not corrected or complete information is not supplied within sixty (60) days to the Department following its request.

(f) Information requirements. All applicants for NPDES permits, other than POTW and other TWTDS, vessels, and pesticide applicators, must provide the following information to the Department, using the application form provided by the Department. Additional information required of applicants is set forth in paragraphs (g) through (k) of this section.

(1) The activities conducted by the applicant which require it to obtain an NPDES permit.

(2) Name, mailing address, and location of the facility for which the application is submitted.

(3) Up to four SIC codes and up to four NAICS codes which best reflect the principal products or services provided by the facility.

(4) The operator's name, address, telephone number, electronic mail address, ownership status, and status as Federal, State, private, public, or other entity.

(5) Whether the facility is located on Indian lands.

(6) A listing of all permits or construction approvals received or applied for under any of the following programs:

(i) Hazardous Waste Management program under RCRA.

(ii) UIC program under SDWA.

(iii) NPDES program under CWA.

(iv) Prevention of Significant Deterioration (PSD) program under the Clean Air Act.

(v) Nonattainment program under the Clean Air Act.

(vi) National Emission Standards for Hazardous Pollutants (NESHAPS) preconstruction approval under the Clean Air Act.

(vii) Ocean dumping permits under the Marine Protection Research and Sanctuaries Act.

(viii) Dredge or fill permits under section 404 of CWA.

(ix) Other relevant environmental permits, including State permits.

(7) A topographic map (or other map if a topographic map is unavailable) extending one mile beyond the property boundaries of the source, depicting the facility and each of its intake and discharge structures; each of its hazardous waste treatment, storage, or disposal facilities; each well where fluids from the facility are injected underground; and those wells, springs, other surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant in the map area.

(8) A brief description of the nature of the business, activity, or type project.

(9) An indication of whether the facility uses cooling water and the source of the cooling water.

(10) An indication of whether the facility is requesting any of the variances at Section 122.21(m) if known at the time of application.

(g) Application requirements for existing manufacturing, commercial, mining, and silvicultural dischargers. Existing manufacturing, commercial, mining, and silvicultural dischargers applying for

NPDES permits, except for those facilities subject to the requirements of section 122.21(h), shall provide the following information to the Department, using application forms provided by the Department.

(1) Outfall location. The latitude and longitude to the nearest 15 seconds and the name of the receiving water.

(2) Line Drawing. A line drawing of the water flow through the facility with a water balance, showing operations contributing wastewater to the effluent and treatment units. Similar processes, operations, or production areas may be indicated as a single unit, labeled to correspond to the more detailed identification under paragraph (g)(3) of this section. The water balance must show approximate average flows at intake and discharge points and between units, including treatment units. If a water balance cannot be determined (for example, for certain mining activities), the applicant may provide instead a pictorial description of the nature and amount of any sources of water and any collection and treatment measures.

(3) Average flows and treatment. A narrative identification of each type of process, operation, or production area which contributes wastewater to the effluent for each outfall, including process wastewater, cooling water, and stormwater runoff; the average flow which each process contributes; and a description of the treatment the wastewater receives, including the ultimate disposal of any solid or fluid wastes other than by discharge. Processes, operations or production areas may be described in general terms (for example, "dye-making reactor", "distillation tower." For a privately owned treatment works, this information shall include the identity of each user of the treatment works. The average flow of point sources composed of storm water may be estimated. The basis for the rainfall event and the method of estimation must be indicated.

(4) Intermittent flows. If any of the discharges described in paragraph (g)(3) of this section are intermittent or seasonal, a description of the frequency, duration and flow rate of each discharge occurrence (except for stormwater runoff, spillage or leaks).

(5) Maximum production. If an effluent guideline promulgated under section 304 of CWA applies to the applicant and is expressed in terms of production (or other measure of operation), a reasonable measure of the applicant's actual production reported in the units used in the applicable effluent guideline. The reported measure must reflect the actual production of the facility as required by section 122.45(b)(2).

(6) Improvements. If the applicant is subject to any present requirements or compliance schedules for construction, upgrading or operation of waste treatment equipment, an identification of the abatement requirement, a description of the abatement project, and a listing of the required and projected final compliance dates.

(7) Effluent characteristics.

(i) Information on the discharge of pollutants specified in this paragraph (g)(7) (except information on storm water discharges which is to be provided as specified in section 122.26). When "quantitative data" for a pollutant are required, the applicant must collect a sample of effluent and analyze it for the pollutant in accordance with analytical methods approved under 40 CFR Part 136. When no analytical method is approved the applicant may use any suitable method but must provide a description of the method. When an applicant has two or more outfalls with substantially identical effluents, the Department may allow the applicant to test only one outfall and report that the quantitative data also apply to the substantially identical outfalls. The requirements in paragraphs (g)(7)(vi) and (vii) of this section that an applicant must provide quantitative data for certain pollutants known or believed to be present do not apply to pollutants present in a discharge solely as the result of their presence in intake water; however, an applicant must report such pollutants as present. Grab samples must be used for pH, temperature, cyanide, total phenols, residual chlorine, oil and grease, fecal coliform, and fecal streptococcus. For all other pollutants, 24-hour composite samples must be used. However, a minimum of one grab sample may be taken for effluents from holding ponds or other impoundments with a retention period greater than 24 hours. In addition for discharges other than storm water discharges, the Department may waive composite sampling for any outfall for which the applicant demonstrates that the use of an automatic sampler is infeasible and that the minimum of four (4) grab samples will be a representative sample of the effluent being discharged.

(ii) Storm water discharges. For storm water discharges, all samples shall be collected from the discharge resulting from a storm event that is greater than 0.1 inch and at least 72 hours from the previously measurable (greater than 0.1 inch rainfall) storm event. Where feasible, the variance in the duration of the event and the total rainfall of the event should not exceed 50 percent from the average or median rainfall event in that area. For all applicants, a flow-weighted composite shall be taken for either the entire discharge or for the first three hours of the discharge. The flow-weighted composite sample for a storm water discharge may be taken with a continuous sampler or as a combination of a minimum of three sample aliquots taken in each hour of discharge for the entire discharge or for the first three hours of the discharge, with each aliquot being separated by a minimum period of fifteen minutes (applicants submitting permit applications for storm water discharges under section 122.26(d) may collect flow weighted composite samples using different protocols with respect to the time duration between the collection of sample aliquots, subject to the approval of the Department). However, a minimum of one grab sample may be taken for storm water discharges from holding ponds or other impoundments with a retention period greater than 24 hours. For a flow-weighted composite sample, only one analysis of the composite of aliquots is required. For storm water discharge samples taken from discharges associated with industrial activities, quantitative data must be reported for the grab sample taken during the first thirty minutes (or as soon thereafter as practicable) of the discharge for all pollutants specified in section 122.26(c)(1). For all storm water permit applicants taking flow-weighted composites, quantitative data must be reported for all pollutants specified in section 122.26 except pH, temperature, cyanide, total phenols, residual chlorine, oil and grease, fecal coliform, and fecal streptococcus. The Department may allow or establish appropriate site-specific sampling procedures or requirements, including sampling locations, the season in which the sampling takes place, the minimum duration between the previous measurable storm event and the storm event sampled, the minimum or maximum level of precipitation required for an appropriate storm event, the form of precipitation sampled (snow melt or rain fall), protocols for collecting samples under 40 CFR Part 136, and additional time for submitting data on a case-by-case basis. An applicant is expected to "know or have reason to believe" that a pollutant is present in an effluent based on an evaluation of the expected use, production, or storage of the pollutant, or on any previous analyses for the pollutant. (For example, any pesticide manufactured by a facility may be expected to be present in contaminated storm water runoff from the facility.)

(iii) Reporting requirements. Every applicant must report quantitative data for every outfall for the following pollutants:

- (A) Biochemical oxygen demand, 5-day (BOD₅)
- (B) Chemical oxygen demand
- (C) Total organic carbon
- (D) Total suspended solids
- (E) Ammonia (as N)
- (F) Temperature (both winter and summer)
- (G) pH

(iv) The Department may waive the reporting requirements for individual point sources or for a particular industry category for one or more of the pollutants listed in paragraph (g)(7)(iii) of this section if the applicant has demonstrated that such a waiver is appropriate because information adequate to support issuance of a permit can be obtained with less stringent requirements.

(v) Each applicant with processes in one or more primary industry category (see appendix A to this regulation) contributing to a discharge must report quantitative data for the following pollutants in each outfall containing process wastewater:

(A) The organic toxic pollutants in the fractions designated in Table I of Appendix D for the applicant's industrial category or categories unless the applicant qualifies as a small business under paragraph (g)(8) of this section. Table II of Appendix D lists the organic toxic pollutants in each fraction. The fractions result from the sample preparation required by the analytical procedure which uses gas chromatography/mass spectrometry. A determination that an applicant falls within a particular industrial category for the purposes of selecting fractions for testing

is not conclusive as to the applicant's inclusion in that category for any other purposes. [See Notes 2, 3, and 4 of 40 CFR 122.21.]

(B) The pollutants listed in Table III of Appendix D (the toxic metals, cyanide, and total phenols).

(vi)(A) Each applicant must indicate whether it knows or has reason to believe that any of the pollutants in Table IV of appendix D of this part (certain conventional and nonconventional pollutants) is discharged from each outfall. If an applicable effluent limitations guideline either directly limits the pollutant or, by its express terms, indirectly limits the pollutant through limitations on an indicator, the applicant must report quantitative data. For every pollutant discharged which is not so limited in an effluent limitations guideline, the applicant must either report quantitative data or briefly describe the reasons the pollutant is expected to be discharged.

(B) Each applicant must indicate whether it knows or has reason to believe that any of the pollutants listed in Table II or Table III of appendix D of this part (the toxic pollutants and total phenols) for which quantitative data are not otherwise required under paragraph (g)(7)(v) of this section is discharged from each outfall. For every pollutant expected to be discharged in concentrations of 10 ppb or greater the applicant must report quantitative data. For acrolein, acrylonitrile, 2,4 dinitrophenol, and 2-methyl-4,6 dinitrophenol, where any of these four pollutants are expected to be discharged in concentrations of 100 ppb or greater the applicant must report quantitative data. For every pollutant expected to be discharged in concentrations less than 10 ppb, or in the case of acrolein, acrylonitrile, 2,4 dinitrophenol, and 2-methyl-4,6 dinitrophenol, in concentrations less than 100 ppb, the applicant must either submit quantitative data or briefly describe the reasons the pollutant is expected to be discharged. An applicant qualifying as a small business under paragraph (g)(8) of this section is not required to analyze for pollutants listed in Table II of Appendix D (the organic toxic pollutants).

(vii) Each applicant must indicate whether it knows or has reason to believe that any of the pollutants in Table V of appendix D (certain hazardous substances and asbestos) are discharged from each outfall. For every pollutant expected to be discharged, the applicant must briefly describe the reasons the pollutant is expected to be discharged, and report any quantitative data it has for any pollutant.

(viii) Each applicant must report qualitative data, generated using a screening procedure not calibrated with analytical standards, for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) if it:

(A) Uses or manufactures 2,4,5-trichlorophenoxy acetic acid (2,4,5,-T); 2-(2,4,5-trichlorophenoxy) propanoic acid (Silvex, 2,4,5,-TP); 2-(2,4,5-trichlorophenoxy) ethyl, 2,2-dichloropropionate (Erbon); O,O-dimethyl O-(2,4,5-trichlorophenyl) phosphorothioate (Ronnel); 2,4,5-trichlorophenol (TCP); or hexachlorophene (HCP); or

(B) Knows or has reason to believe that TCDD is or may be present in an effluent.

(ix) Where quantitative data are required in paragraphs (g)(7)(i) through (viii) of this section, existing data may be used, if available, in lieu of sampling done solely for the purpose of the application, provided that: All data requirements are met; sampling was performed, collected, and analyzed no more than four and one-half (4.5) years prior to submission; all data are representative of the discharge; and all available representative data are considered in the values reported.

(8) Small business exemption. An applicant which qualifies as a small business under one of the following criteria is exempt from the requirements in paragraph (g)(7) (v)(A) or (g)(7)(vi)(A) of this section to submit quantitative data for the pollutants listed in Table II of Appendix D (the organic toxic pollutants):

(i) For coal mines, a probable total annual production of less than 100,000 tons per year.

(ii) For all other applicants, gross total annual sales averaging less than \$100,000 per year (in second quarter 1980 dollars).

(9) Used or manufactured toxics. A listing of any toxic pollutant which the applicant currently uses or manufactures as an intermediate or final product or byproduct. The Department may waive or modify this requirement for any applicant if the applicant demonstrates that it would be unduly burdensome to identify each toxic pollutant and the Department has adequate information to issue the permit.

(10) [Reserved]

(11) Biological toxicity tests. An identification of any biological toxicity tests which the applicant knows or has reason to believe have been made within the last 3 years on any of the applicant's discharges or on a receiving water in relation to a discharge.

(12) Contract analyses. If a contract laboratory or consulting firm performed any of the analyses required by paragraph (g)(7) of this section, the identity of each laboratory or firm and the analyses performed.

(13) Additional information. In addition to the information reported on the application form, applicants shall provide to the Department upon request such other information as the Department may reasonably require to assess the discharges of the facility and to determine whether to issue an NPDES permit. The additional information may include additional quantitative data and bioassays to assess the relative toxicity of discharges to aquatic life and requirements to determine the cause of the toxicity.

(h) Application requirements for manufacturing, commercial, mining and silvicultural facilities which discharge only non-process wastewater. Except for stormwater discharges, all manufacturing, commercial, mining and silvicultural dischargers applying for NPDES permits which discharge only non-process wastewater not regulated by an effluent limitations guideline or new source performance standard shall provide the following information to the Department, using application forms provided by the Department.

(1) Outfall location. Outfall number, latitude and longitude to the nearest 15 seconds, and the name of the receiving water.

(2) Discharge date (for new dischargers). Date of expected commencement of discharge.

(3) Type of waste. An identification of the general type of waste discharged, or expected to be discharged upon commencement of operations, including sanitary wastes, restaurant or cafeteria wastes, or noncontact cooling water. An identification of cooling water additives (if any) that are used or expected to be used upon commencement of operations, along with their composition if existing composition is available.

(4) Effluent characteristics.

(i) Quantitative data for the pollutants or parameters listed below, unless testing is waived by the Department. The quantitative data may be data collected over the past 365 days, if they remain representative of current operations, and must include maximum daily value, average daily value, and number of measurements taken. The applicant must collect and analyze samples in accordance with 40 CFR Part 136. Grab samples must be used for pH, temperature, oil and grease, total residual chlorine, and fecal coliform. For all other pollutants, 24-hour composite samples must be used. New dischargers must include estimates for the pollutants or parameters listed below instead of actual sampling data, along with the source of each estimate. All levels must be reported or estimated as concentration and as total mass, except for flow, pH, and temperature.

(A) Biochemical Oxygen Demand (BOD₅).

(B) Total Suspended Solids (TSS).

(C) Fecal Coliform (if believed present or if sanitary waste is or will be discharged).

(D) Total Residual Chlorine (if chlorine is used).

(E) Oil and Grease.

(F) Chemical Oxygen Demand (COD) (only if non-contact cooling water is or will be discharged).

(G) Total Organic Carbon (TOC) (only if non-contact cooling water is or will be discharged).

(H) Ammonia (as N).

(I) Discharge Flow.

(J) pH.

(K) Temperature (Winter and Summer).

(ii) The Department may waive the testing and reporting requirements for any of the pollutants or flow listed in paragraph (h)(4)(i) of this section if the applicant submits a request for such a

waiver before or with his application which demonstrates that information adequate to support issuance of a permit can be obtained through less stringent requirements.

(iii) If the applicant is a new discharger, he must complete and submit Item IV of Form 2e (see section 122.21(h)(4)) by providing quantitative data in accordance with that section no later than two years after commencement of discharge. However, the applicant need not complete those portions of Item IV requiring tests which he has already performed and reported under the discharge monitoring requirements of his NPDES permit.

(iv) The requirements of parts i and iii of this section that an applicant must provide quantitative data or estimates of certain pollutants do not apply to pollutants present in a discharge solely as a result of their presence in intake water. However, an applicant must report such pollutants as present. Net credit may be provided for the presence of pollutants in intake water if the requirements of section 122.45(g) are met.

(5) Flow. A description of the frequency of flow and duration of any seasonal or intermittent discharge (except for stormwater runoff, leaks, or spills).

(6) Treatment system. A brief description of any system used or to be used.

(7) Optional information. Any additional information the applicant wishes to be considered, such as influent data for the purpose of obtaining "net" credits pursuant to section 122.45(g).

(8) Certification. Signature of certifying official under section 122.22.

(i) Application requirements for new and existing concentrated animal feeding operations and aquatic animal production facilities. New and existing concentrated animal feeding operations (defined in section 122.23) and concentrated aquatic animal production facilities (defined in section 122.24) shall provide the following information to the Department, using the application form provided by the Department:

(1) For concentrated animal feeding operations:

(i) The name of the owner or operator;

(ii) The facility location and mailing addresses;

(iii) Latitude and longitude of the production area (entrance to production area);

(iv) A topographic map of the geographic area in which the CAFO is located showing the specific location of the production area, in lieu of the requirements of paragraph (f)(7) of this section;

(v) Specific information about the number and type of animals, whether in open confinement or housed under roof (beef cattle, broilers, layers, swine weighing 55 pounds or more, swine weighing less than 55 pounds, mature dairy cows, dairy heifers, veal calves, sheep and lambs, horses, ducks, turkeys, other);

(vi) The type of containment and storage (anaerobic lagoon, roofed storage shed, storage ponds, under-floor pits, above ground storage tanks, below ground storage tanks, concrete pad, impervious soil pad, other) and total capacity for manure, litter, and process wastewater storage (tons/gallons);

(vii) The total number of acres under control of the applicant available for land application of manure, litter, or process wastewater;

(viii) Estimated amounts of manure, litter, and process wastewater generated per year (tons/gallons);

(ix) Estimated amounts of manure, litter, and process wastewater transferred to other persons per year (tons/gallons); and

(x) For CAFO that must seek coverage under a permit after December 31, 2006, certification that a nutrient management plan has been completed and will be implemented upon the date of permit coverage.

(2) For concentrated aquatic animal production facilities:

(i) The maximum daily and average monthly flow from each outfall.

(ii) The number of ponds, raceways, and similar structures.

(iii) The name of the receiving water and the source of intake water.

(iv) For each species of aquatic animals, the total yearly and maximum harvestable weight.

(v) The calendar month of maximum feeding and the total mass of food fed during that month.

(j) Application requirements for new and existing POTWs. Unless otherwise indicated, all POTW and other dischargers designated by the Department must provide, at a minimum, the information in this paragraph to the Department, using Form 2A or another application form provided by the Department. Permit applicants must submit all information available at the time of permit application. The information may be provided by referencing information previously submitted to the Department. The Department may waive any requirement of this paragraph if he or she has access to substantially identical information. The Department may also waive any requirement of this paragraph that is not of material concern for a specific permit, if approved by the Regional Administrator. The waiver request to the Regional Administrator must include the State's justification for the waiver. A Regional Administrator's disapproval of a State's proposed waiver does not constitute final Agency action, but does provide notice to the State and permit applicant(s) that EPA may object to any State-issued permit issued in the absence of the required information.

(1) Basic application information. All applicants must provide the following information:

(i) Facility information. Name, mailing address, and location of the facility for which the application is submitted;

(ii) Applicant information. Name, mailing address, telephone number, and electronic mail address of the applicant, and indication as to whether the applicant is the facility's owner, operator, or both;

(iii) Existing environmental permits. Identification of all environmental permits or construction approvals received or applied for (including dates) under any of the following programs:

(A) Hazardous Waste Management program under the Resource Conservation and Recovery Act (RCRA), Subpart C;

(B) Underground Injection Control program under the Safe Drinking Water Act (SDWA);

(C) NPDES program under Clean Water Act (CWA);

(D) Prevention of Significant Deterioration (PSD) program under the Clean Air Act;

(E) Nonattainment program under the Clean Air Act;

(F) National Emission Standards for Hazardous Air Pollutants (NESHAPS) preconstruction approval under the Clean Air Act;

(G) Ocean dumping permits under the Marine Protection, Research, and Sanctuaries Act;

(H) Dredge or fill permits under section 404 of the CWA; and

(I) Other relevant environmental permits, including State permits.

(iv) Population. The name and population of each municipal entity served by the facility, including unincorporated connector districts. Indicate whether each municipal entity owns or maintains the collection system and whether the collection system is separate sanitary or combined storm and sanitary, if known;

(v) Indian country. Information concerning whether the facility is located in Indian country and whether the facility discharges to a receiving stream that flows through Indian country;

(vi) Flow rate. The facility's design flow rate (the wastewater flow rate the plant was built to handle), annual average daily flow rate, and maximum daily flow rate for each of the previous 3 years;

(vii) Collection system. Identification of type(s) of collection system(s) used by the treatment works (i.e., separate sanitary sewers or combined storm and sanitary sewers) and an estimate of the percent of sewer line that each type comprises; and

(viii) Outfalls and other discharge or disposal methods. The following information for outfalls to waters of the State and/or of the United States and other discharge or disposal methods:

(A) For effluent discharges to waters of the State and/or of the United States, the total number and types of outfalls (e.g., treated effluent, combined sewer overflows, bypasses, constructed emergency overflows);

(B) For wastewater discharged to surface impoundments:

- (1) The location of each surface impoundment;
 - (2) The average daily volume discharged to each surface impoundment; and
 - (3) Whether the discharge is continuous or intermittent;
- (C) For wastewater applied to the land:
- (1) The location of each land application site;
 - (2) The size of each land application site, in acres;
 - (3) The average daily volume applied to each land application site, in gallons per day; and
 - (4) Whether land application is continuous or intermittent;
- (D) For effluent sent to another facility for treatment prior to discharge:
- (1) The means by which the effluent is transported;
 - (2) The name, mailing address, contact person, phone number, and electronic mail address of the organization transporting the discharge, if the transport is provided by a party other than the applicant;
 - (3) The name, mailing address, contact person, phone number, electronic mail address, and NPDES permit number (if any) of the receiving facility; and
 - (4) The average daily flow rate from this facility into the receiving facility, in millions of gallons per day; and
- (E) For wastewater disposed of in a manner not included in paragraphs (j)(1)(viii)(A) through (D) of this section (e.g., underground percolation, underground injection):
- (1) A description of the disposal method, including the location and size of each disposal site, if applicable;
 - (2) The annual average daily volume disposed of by this method, in gallons per day; and
 - (3) Whether disposal through this method is continuous or intermittent;
- (ix) An indication of whether the applicant is operating under or requesting to operate under a variance as specified at Section 122.21(n), if known at the time of application.
- (2) Additional Information. All applicants with a design flow greater than or equal to 0.1 mgd must provide the following information:
- (i) Inflow and infiltration. The current average daily volume of inflow and infiltration, in gallons per day, and steps the facility is taking to minimize inflow and infiltration;
 - (ii) Topographic map. A topographic map (or other map if a topographic map is unavailable) extending at least one mile beyond property boundaries of the treatment plant, including all unit processes, and showing:
 - (A) Treatment plant area and unit processes;
 - (B) The major pipes or other structures through which wastewater enters the treatment plant and the pipes or other structures through which treated wastewater is discharged from the treatment plant. Include outfalls from bypass piping, if applicable;
 - (C) Each well where fluids from the treatment plant are injected underground;
 - (D) Wells, springs, and other surface water bodies listed in public records or otherwise known to the applicant within 1/4 mile of the treatment works' property boundaries;
 - (E) Sewage sludge management facilities (including on-site treatment, storage, and disposal sites); and
 - (F) Location at which waste classified as hazardous under RCRA enters the treatment plant by truck, rail, or dedicated pipe;
 - (iii) Process flow diagram or schematic.
 - (A) A diagram showing the processes of the treatment plant, including all bypass piping and all backup power sources or redundancy in the system. This includes a water balance showing all treatment units, including disinfection, and showing daily average flow rates at influent and discharge points, and approximate daily flow rates between treatment units; and

- (B) A narrative description of the diagram; and
- (iv) Scheduled improvements, schedules of implementation. The following information regarding scheduled improvements:
 - (A) The outfall number of each outfall affected;
 - (B) A narrative description of each required improvement;
 - (C) Scheduled or actual dates of completion for the following:
 - (1) Commencement of construction;
 - (2) Completion of construction;
 - (3) Commencement of discharge; and
 - (4) Attainment of operational level;
 - (D) A description of permits and clearances concerning other Federal and/or State requirements;
- (3) Information on effluent discharges. Each applicant must provide the following information for each outfall, including bypass points, through which effluent is discharged, as applicable:
 - (i) Description of outfall. The following information about each outfall:
 - (A) Outfall number;
 - (B) State, county, and city or town in which outfall is located;
 - (C) Latitude and longitude, to the nearest second;
 - (D) Distance from shore and depth below surface;
 - (E) Average daily flow rate, in million gallons per day;
 - (F) The following information for each outfall with a seasonal or periodic discharge:
 - (1) Number of times per year the discharge occurs;
 - (2) Duration of each discharge;
 - (3) Flow of each discharge; and
 - (4) Months in which discharge occurs; and
 - (G) Whether the outfall is equipped with a diffuser and the type (e.g., high-rate) of diffuser used;
 - (ii) Description of receiving waters. The following information (if known) for each outfall through which effluent is discharged to waters of the state and or of the United States:
 - (A) Name of receiving water;
 - (B) Name of watershed/river/stream system and United States Soil Conservation Service 14-digit watershed code;
 - (C) Name of State Management/River Basin and United States Geological Survey 8-digit hydrologic cataloging unit code; and
 - (D) Critical flow of receiving stream and total hardness of receiving stream at critical low flow (if applicable);
 - (iii) Description of treatment. The following information describing the treatment provided for discharges from each outfall to waters of state and/or the United States:
 - (A) The highest level of treatment (e.g., primary, equivalent to secondary, secondary, advanced, other) that is provided for the discharge for each outfall and:
 - (1) Design biochemical oxygen demand (BOD₅ or CBOD₅) removal (percent);
 - (2) Design total suspended solids (TSS) removal (percent); and, where applicable;
 - (3) Design phosphorus (P) removal (percent);
 - (4) Design nitrogen (N) removal (percent); and
 - (5) Any other removals that an advanced treatment system is designed to achieve.
 - (B) A description of the type of disinfection used, and whether the treatment plant dechlorinates (if disinfection is accomplished through chlorination);

(4) Effluent monitoring for specific parameters.

(i) As provided in paragraphs (j)(4)(ii) through (x) of this section, all applicants must submit to the Department effluent monitoring information for samples taken from each outfall through which effluent is discharged to waters of the State, except for CSOs. The Department may allow applicants to submit sampling data for only one outfall on a case-by-case basis, where the applicant has two or more outfalls with substantially identical effluent. The Department may also allow applicants to composite samples from one or more outfalls that discharge into the same mixing zone. For POTWs applying prior to commencement of discharge, data shall be submitted no later than twenty-four (24) months after the commencement of discharge;

(ii) All applicants must sample and analyze for the pollutants listed in Appendix J, Table 1A of this part;

(iii) All applicants with a design flow greater than or equal to 0.1 mgd must sample and analyze for the pollutants listed in Appendix J, Table 1 of R.61–9.122. Facilities that do not use chlorine for disinfection, do not use chlorine elsewhere in the treatment process, and have no reasonable potential to discharge chlorine in their effluent may delete chlorine from Table 1;

(iv) The following applicants must sample and analyze for the pollutants listed in Appendix J, Table 2 of R.61–9.122, and for any other pollutants for which the State or EPA have established water quality standards applicable to the receiving waters:

(A) All POTW with a design flow rate equal to or greater than one million gallons per day;

(B) All POTW with approved pretreatment programs or POTW required to develop a pretreatment program;

(C) Other POTW, as required by the Department;

(v) The Department should require sampling for additional pollutants, as appropriate, on a case-by-case basis.

(vi) Applicants must provide data from a minimum of three samples taken within four and one-half years prior to the date of the permit application. Samples must be representative of the seasonal variation in the discharge from each outfall. Existing data may be used, if available, in lieu of sampling done solely for the purpose of this application. The Department should require additional samples, as appropriate, on a case-by-case basis.

(vii) All existing data for pollutants specified in paragraphs (j)(4)(ii) through (v) of this section that is collected within four and one-half years of the application must be included in the pollutant data summary submitted by the applicant. If, however, the applicant samples for a specific pollutant on a monthly or more frequent basis, it is only necessary, for such pollutant, to summarize all data collected within one year of the application.

(viii) Applicants must collect samples of effluent and analyze such samples for pollutants in accordance with analytical methods approved under 40 CFR part 136 unless an alternative is specified in the existing NPDES permit. Grab samples must be used for pH, temperature, cyanide, total phenols, residual chlorine, oil and grease, and fecal coliform. For all other pollutants, 24-hour composite samples must be used. For a composite sample, only one analysis of the composite of aliquots is required.

(ix) The effluent monitoring data provided must include at least the following information for each parameter:

(A) Maximum daily discharge, expressed as concentration or mass, based upon actual sample values;

(B) Average daily discharge for all samples, expressed as concentration or mass, and the number of samples used to obtain this value;

(C) The analytical method used; and

(D) The threshold level (i.e., method detection limit, minimum level, or other designated method endpoints) for the analytical method used.

(x) Unless otherwise required by the Department, metals must be reported as total recoverable.

(5) Effluent monitoring for whole effluent toxicity.

(i) All applicants must provide an identification of any whole effluent toxicity tests conducted during the four and one-half years prior to the date of the application on any of the applicant's discharges or on any receiving water near the discharge. For POTWs applying prior to commencement of discharge, data shall be submitted no later than twenty-four (24) months after the commencement of discharge.

(ii) As provided in paragraphs (j)(5)(iii)-(ix) of this section, the following applicants must submit to the Department the results of valid whole effluent toxicity tests for acute or chronic toxicity for samples taken from each outfall through which effluent is discharged to surface waters, except for combined sewer overflows:

(A) All POTW with design flow rates greater than or equal to one million gallons per day;

(B) All POTW with approved pretreatment programs or POTW required to develop a pretreatment program;

(C) Other POTW, as required by the Department, based on consideration of the following factors:

(1) The variability of the pollutants or pollutant parameters in the POTW effluent (based on chemical-specific information, the type of treatment plant, and types of industrial contributors);

(2) The ratio of effluent flow to receiving stream flow;

(3) Existing controls on point or non-point sources, including total maximum daily load calculations for the receiving stream segment and the relative contribution of the POTW;

(4) Receiving stream characteristics, including possible or known water quality impairment, and whether the POTW discharges to a coastal water or a water designated as an outstanding natural resource water; or

(5) Other considerations (including, but not limited to, the history of toxic impacts and compliance problems at the POTW) that the Department determines could cause or contribute to adverse water quality impacts.

(iii) Where the POTW has two or more outfalls with substantially identical effluent discharging to the same receiving stream segment, the Department may allow applicants to submit whole effluent toxicity data for only one outfall on a case-by-case basis. The Department may also allow applicants to composite samples from one or more outfalls that discharge into the same mixing zone.

(iv) Each applicant required to perform whole effluent toxicity testing pursuant to paragraph (j)(5)(ii) of this section must provide:

(A) Results of a minimum of four quarterly tests for a year, from the year preceding the permit application; or

(B) Results from four tests performed at least annually in the four and one half year period prior to the application, provided the results show no appreciable toxicity using a safety factor determined by the permitting authority.

(v) Applicants must conduct tests with multiple species (no less than two species; e.g., fish, invertebrate, plant), and test for acute or chronic toxicity, depending on the range of receiving water dilution. EPA recommends that applicants conduct acute or chronic testing based on the following dilutions:

(A) Acute toxicity testing if the dilution of the effluent is greater than 1000:1 at the edge of the mixing zone;

(B) Acute or chronic toxicity testing if the dilution of the effluent is between 100:1 and 1000:1 at the edge of the mixing zone. Acute testing may be more appropriate at the higher end of this range (1000:1), and chronic testing may be more appropriate at the lower end of this range (100:1); and

(C) Chronic testing if the dilution of the effluent is less than 100:1 at the edge of the mixing zone.

(vi) Each applicant required to perform whole effluent toxicity testing pursuant to paragraph (j)(5)(ii) of this section must provide the number of chronic or acute whole effluent toxicity tests that have been conducted since the last permit reissuance.

(vii) Applicants must provide the results using the form provided by the Department, or test summaries if available and comprehensive, for each whole effluent toxicity test conducted pursuant to paragraph (j)(5)(ii) of this section for which such information has not been reported previously to the Department.

(viii) Whole effluent toxicity testing conducted pursuant to paragraph (j)(5)(ii) of this section must be conducted using methods approved under 40 CFR part 136.

(ix) For whole effluent toxicity data submitted to the Department within four and one-half years prior to the date of the application, applicants must provide the dates on which the data were submitted and a summary of the results.

(x) Each POTW required to perform whole effluent toxicity testing pursuant to paragraph (j)(5)(ii) of this section must provide any information on the cause of toxicity and written details of any toxicity reduction evaluation conducted, if any whole effluent toxicity test conducted within the past four and one-half years revealed toxicity.

(6) Industrial discharges. Applicants must submit the following information about industrial discharges to the POTW:

(i) Number of significant industrial users (SIU) and non-significant categorical industrial users (NSCIUs), as defined at 40 CFR 403.3(v), including SIUs and NSCIUs that truck or haul waste, discharging to the POTW; and

(ii) POTW with one or more SIU shall provide the following information for each SIU, as defined at R.61-9.403.3(o), that discharges to the POTW:

(A) Name and mailing address;

(B) Description of all industrial processes that affect or contribute to the SIU's discharge;

(C) Principal products and raw materials of the SIU that affect or contribute to the SIU's discharge;

(D) Average daily volume of wastewater discharged, indicating the amount attributable to process flow and non-process flow;

(E) Whether the SIU is subject to local limits;

(F) Whether the SIU is subject to categorical standards, and if so, under which category(ies) and subcategory(ies); and

(G) Whether any problems at the POTW (e.g., upsets, pass through, interference) have been attributed to the SIU in the past four and one-half years.

(iii) The information required in paragraphs (j)(6)(i) and (ii) of this section may be waived by the Department for POTW with pretreatment programs if the applicant has submitted either of the following that contain information substantially identical to that required in paragraphs (j)(6)(i) and (ii) of this section.

(A) An annual report submitted within one year of the application; or

(B) A pretreatment program;

(7) Discharges from hazardous waste generators and from waste cleanup or remediation sites. POTW receiving Resource Conservation and Recovery Act (RCRA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), or RCRA Corrective Action wastes or wastes generated at another type of cleanup or remediation site must provide the following information:

(i) If the POTW receives, or has been notified that it will receive, by truck, rail, or dedicated pipe any wastes that are regulated as RCRA hazardous wastes pursuant to 40 CFR Part 261, the applicant must report the following:

(A) The method by which the waste is received (i.e., whether by truck, rail, or dedicated pipe) and

(B) The hazardous waste number and amount received annually of each hazardous waste;

(ii) If the POTW receives, or has been notified that it will receive, wastewaters that originate from remedial activities, including those undertaken pursuant to CERCLA and sections 3004(u) or 3008(h) of RCRA, the applicant must report the following:

(A) The identity and description of the site(s) or facility(ies) at which the wastewater originates;

(B) The identities of the wastewater's hazardous constituents, as listed in Appendix VIII of 40 CFR part 261, if known; and

(C) The extent of treatment, if any, the wastewater receives or will receive before entering the POTW.

(iii) Applicants are exempt from the requirements of paragraph (j)(7)(ii) of this section if they receive no more than fifteen kilograms per month of hazardous wastes, unless the wastes are acute hazardous wastes as specified in 40 CFR 261.30(d) and 261.33(e).

(8) Combined sewer overflows. Each applicant with combined sewer systems must provide the following information:

(i) Combined sewer system information. The following information regarding the combined sewer system:

(A) System map. A map indicating the location of the following:

(1) All CSO discharge points;

(2) Sensitive use areas potentially affected by CSO (e.g., beaches, drinking water supplies, shellfish beds, sensitive aquatic ecosystems, and outstanding national resource waters); and

(3) Waters supporting threatened and endangered species potentially affected by CSO; and

(B) System diagram. A diagram of the combined sewer collection system that includes the following information:

(1) The location of major sewer trunk lines, both combined and separate sanitary;

(2) The locations of points where separate sanitary sewers feed into the combined sewer system;

(3) In-line and off-line storage structures;

(4) The locations of flow-regulating devices; and

(5) The locations of pump stations.

(ii) Information on CSO outfalls. The following information for each CSO discharge point covered by the permit application:

(A) Description of outfall. The following information on each outfall:

(1) Outfall number;

(2) State, county, and city or town in which outfall is located;

(3) Latitude and longitude, to the nearest second;

(4) Distance from shore and depth below surface;

(5) Whether the applicant monitored any of the following in the past year for this CSO:

(i) Rainfall;

(ii) CSO flow volume;

(iii) CSO pollutant concentrations;

(iv) Receiving water quality;

(v) CSO frequency; and

(6) The number of storm events monitored in the past year;

(B) CSO events. The following information about CSO overflows from each outfall:

(1) The number of events in the past year;

(2) The average duration per event, if available;

(3) The average volume per CSO event, if available; and

(4) The minimum rainfall that caused a CSO event, if available, in the last year.

(C) Description of receiving waters. The following information about receiving waters:

(1) Name of receiving water;

(2) Name of watershed/stream system and the United States Soil Conservation Service watershed (14-digit) code (if known); and

(3) Name of State Management/River Basin and the United States Geological Survey hydrologic cataloging unit (8-digit) code (if known); and

(D) CSO operations. A description of any known water quality impacts on the receiving water caused by the CSO (e.g., permanent or intermittent beach closings, permanent or intermittent shellfish bed closings, fish kills, fish advisories, other recreational loss, or exceedance of any applicable State water quality standard);

(9) Contractors. All applicants must provide the name, mailing address, telephone number, electronic mail address, and responsibilities of all contractors responsible for any operational or maintenance aspects of the facility; and

(10) Signature. All applications must be signed by a certifying official in compliance with section 122.22.

(k) Application requirements for new sources and new discharges.

New manufacturing, commercial, mining, and silvicultural dischargers applying for NPDES permits (except for new discharges of facilities subject to the requirements of paragraph (h) of this section or new discharges of storm water associated with industrial activity which are subject to the requirements of section 122.26(c)(1) and this section (except as provided by section 122.26(c)(1)(ii)) shall provide the following information to the Department, using application forms provided by the Department.

(1) Expected outfall location. The latitude and longitude to the nearest 15 seconds and the name of the receiving water.

(2) Discharge dates. The expected date of commencement of discharge.

(3) Flows, sources of pollution, and treatment technologies.

(i) Expected treatment of wastewater. Description of the treatment that the wastewater will receive, along with all operations contributing wastewater to the effluent, average flow contributed by each operation, and the ultimate disposal of any solid or liquid wastes not discharged.

(ii) Line drawing. A line drawing of the water flow through the facility with a water balance as described in section 122.21(g)(2).

(iii) Intermittent flows. If any of the expected discharges will be intermittent or seasonal, a description of the frequency, duration and maximum daily flow rate of each discharge occurrence (except for storm water runoff, spillage, or leaks).

(4) Production. If a new source performance standard promulgated under section 306 of CWA or an effluent limitation guideline applies to the applicant and is expressed in terms of production (or other measure of operation), a reasonable measure of the applicant's expected actual production reported in the units used in the applicable effluent guideline or new source performance standard as required by section 122.45(b)(2) for each of the first three years. Alternative estimates may also be submitted if production is likely to vary.

(5) Effluent characteristics. The requirements in paragraphs (h)(4)(i), (ii), and (iii) of this section that an applicant must provide estimates of certain pollutants expected to be present do not apply to pollutants present in a discharge solely as a result of their presence in intake water; however, an applicant must report such pollutants as present. Net credits may be provided for the presence of pollutants in intake water if the requirements of section 122.45(g) are met. All levels (except for discharge flow, temperature, and pH) must be estimated as concentration and as total mass.

(i) Each applicant must report estimated daily maximum, daily average, and source of information for each outfall for the following pollutants or parameters. The Department may waive the reporting requirements for any of these pollutants and parameters if the applicant submits a request for such a waiver before or with his application which demonstrates that information adequate to support issuance of the permit can be obtained through less stringent reporting requirements.

- (A) Biochemical Oxygen Demand (BOD).
- (B) Chemical Oxygen Demand (COD).
- (C) Total Organic Carbon (TOC).
- (D) Total Suspended Solids (TSS).
- (E) Flow.
- (F) Ammonia (as N).
- (G) Temperature (winter and summer).
- (H) pH.

(ii) Each applicant must report estimated daily maximum, daily average, and source of information for each outfall for the following pollutants, if the applicant knows or has reason to believe they will be present or if they are limited by an effluent limitation guideline or new source performance standard either directly or indirectly through limitations on an indicator pollutant: all pollutants in Table IV of Appendix D (certain conventional and nonconventional pollutants).

(iii) Each applicant must report estimated daily maximum, daily average and source of information for the following pollutants if he knows or has reason to believe that they will be present in the discharges from any outfall:

(A) The pollutants listed in Table III of Appendix D (the toxic metals, in the discharge from any outfall; total cyanide, and total phenols);

(B) The organic toxic pollutants in Table II of Appendix D (except bis chloromethyl ether, dichlorofluoromethane and trichlorofluoromethane). This requirement is waived for applicants with expected gross sales of less than \$100,000 per year for the next three years, and for coal mines with expected average production of less than 100,000 tons of coal per year.

(iv) The applicant is required to report that 2,3,7,8 Tetrachlorodibenzo-P-Dioxin (TCDD) may be discharged if he uses or manufactures one of the following compounds, or if he knows or has reason to believe that TCDD will or may be present in the effluent:

- (A) 2,4,5-trichlorophenoxy acetic acid (2,4,5-T) (CAS #93-76-5);
- (B) 2-(2,4,5-trichlorophenoxy)propanoic acid (Silvex, 2,4,5-TP) (CAS #93-72-1);
- (C) 2-(2,4,5-trichlorophenoxy) ethyl 2,2-dichloropropionate (Erbon) (CAS #136-25-4);
- (D) O,O-dimethyl O-(2,4,5-trichlorophenyl) phosphorothioate (Ronnel) (CAS #299-84-3);
- (E) 2,4,5-trichlorophenol (TCP) (CAS #95-95-4); or
- (F) Hexachlorophene (HCP) (CAS #70-30-4);

(v) Each applicant must report any pollutants listed in Table V of Appendix D (certain hazardous substances) if he believes they will be present in any outfall (no quantitative estimates are required unless they are already available).

(vi) No later than twenty-four (24) months after the commencement of discharge from the proposed facility, the applicant is required to complete and submit Items V and VI of NPDES application Form 2C (see section 122.21(g)). However, the applicant need not complete those portions of Item V requiring tests which have already been performed and reported under the discharge monitoring requirements of the NPDES permit.

(6) Engineering Report. Each applicant must report the existence of any technical evaluation concerning his wastewater treatment, along with the name and location of similar plants of which he has knowledge.

(7) Other information. Any optional information the permittee wishes to have considered.

(8) Certification. Signature of certifying official under section 122.22.

(l) [Reserved]

(m) Variance requests by non-POTWs. A discharger which is not a publicly owned treatment works (POTW) may request a variance from otherwise applicable effluent limitations under any of the following statutory or regulatory provisions within the times specified in this paragraph:

- (1) Fundamentally different factors.

(i) A request for a variance based on the presence of “fundamentally different factors” from those on which the effluent limitations guideline was based shall be filed as follows:

(A) For a request from best practicable control technology currently available (BPT) by the close of the public comment period under R.61-9.124.10.

(B) For a request from best available technology economically achievable (BAT) and/or best conventional pollutant control technology (BCT), by no later than:

(1) July 3, 1989, for a request based on an effluent limitation guideline promulgated before February 4, 1987, to the extent July 3, 1989 is not later than that provided under previously promulgated regulations; or

(2) 180 days after the date on which an effluent limitation guideline is published in the Federal Register for a request based on an effluent limitation guideline promulgated on or after February 4, 1987.

(ii) The request shall explain how the requirements of the applicable regulatory and/or statutory criteria have been met.

(2) Non-conventional pollutants. A request for a variance from the BAT requirements for CWA section 301(b)(2)(F) pollutants (commonly called “non-conventional” pollutants) pursuant to section 301(c) of CWA because of the economic capability of the owner or operator, or pursuant to section 301(g) of the CWA (provided, however, that a section 301(g) variance may only be requested for ammonia; chlorine; color; iron; total phenols (4AAP) (when determined by the Department to be a pollutant covered by section 301(b)(2)(F)) and any other pollutant which the Administrator lists under section 301(g)(4) of the CWA) must be made as follows:

(i) For those requests for a variance from an effluent limitation based upon an effluent limitation guideline by:

(A) Submitting an initial request to the Regional Administrator as well as to the Department, stating the name of the discharger, the permit number, the outfall number(s), the applicable effluent guideline, and whether the discharger is requesting a section 301(c) or section 301(g) modification or both. This request must have been filed not later than:

(1) September 25, 1978, for a pollutant which is controlled by a BAT effluent limitation guideline promulgated before December 27, 1977; or

(2) 270 days after promulgation of an applicable effluent limitation guideline for guidelines promulgated after December 27, 1977, and

(B) Submitting a completed request no later than the close of the public comment period under section 124.10 demonstrating that the requirements of section 124.13 and the applicable requirements of R.61-9.125 have been met.

(C) Notwithstanding this provision, the complete application for a request under section 301(g) shall be filed 180 days before EPA must make a decision.

(ii) For those requests for a variance from effluent limitations not based on effluent limitation guidelines, the request need only comply with paragraph (m)(2)(i)(B) of this section and need not be preceded by an initial request under paragraph (m)(2)(i)(A) of this section.

(3) [Reserved]

(4) [Reserved]

(5) Water quality related effluent limitations. A modification under section 302(b)(2) of requirements under section 302(a) for achieving water quality related effluent limitations may be requested no later than the close of the public comment period under R.61-9.124.10 on the permit from which the modification is sought.

(6) Thermal discharges. A variance under CWA section 316(a) for the thermal component of any discharge must be filed with a timely application for a permit under this section, except that if thermal effluent limitations are established under CWA Section 402(a)(1) or are based on water quality standards, the request for a variance may be filed by the close of the public comment period under R.61-9.124.10. A copy of the request as required under R.61-9.125, Part H, shall be sent simultaneously to the appropriate State or interstate certifying agency as required under R.61-9.125.

(See 40 CFR 124.66 for special procedures for thermal variances in accordance with section 316(a) of the CWA.)

(n) Variance requests by POTWs. A discharger which is a publicly owned treatment works (POTW) may request a variance from otherwise applicable effluent limitations under any of the following statutory provisions as specified in this paragraph:

(1) Discharges into marine waters. A request for a modification under CWA section 301(h) of requirements of CWA section 301(b)(1)(B) for discharges into marine waters must be filed in accordance with the requirements of R.61-9.125 Part G.

(2) [Reserved]

(3) Water quality based effluent limitation. A modification under CWA section 302(b)(2) of the requirements under section 302(a) for achieving water quality based effluent limitations shall be requested no later than the close of the public comment period under section 124.10 on the permit from which the modification is sought.

(o) Expedited variance procedures and time extensions.

(1) Notwithstanding the time requirements in paragraphs (m) and (n) of this section, the Department may notify a permit applicant before a draft permit is issued under section 124.6 that the draft permit will likely contain limitations which are eligible for variances. In the notice the Department may require the applicant as a condition of consideration of any potential variance request to submit a request, explaining how the requirements of R.61-9.125 applicable to the variance have been met and may require its submission within a specified reasonable time after receipt of the notice. The notice may be sent before the permit application has been submitted. The draft or final permit may contain the alternative limitations which may become effective upon final grant of the variance.

(2) A discharger who cannot file a timely complete request required under paragraph (m)(2)(i)(B) or (m)(2)(ii) of this section may request an extension. The extension may be granted or denied at the discretion of the Department. Extensions shall be no more than 6 months in duration.

(p) Record keeping. Except for information required by paragraph (q) of this section, which shall be retained for a period of at least five years from the date the application is signed (or longer as required by R.61-9.503 or R.61-9.504), applicants shall keep records of all data used to complete permit applications and any supplemental information submitted under this section for a period of at least 3 years from the date the application is signed.

(q) Sewage sludge management. All TWTDS subject to paragraph (c)(2)(i) of this section must provide the information in this paragraph to the Department, using Form 2S or another application form approved by the Department. New applicants must submit all information available at the time of permit application. The information may be provided by referencing information previously submitted to the Department. The Department may waive any requirement of this paragraph if he or she has access to substantially identical information. The Department may also waive any requirement of this paragraph that is not of material concern for a specific permit, if approved by the Regional Administrator. The waiver request to the Regional Administrator must include the State's justification for the waiver. A Regional Administrator's disapproval of a State's proposed waiver does not constitute final Agency action, but does provide notice to the State and permit applicant(s) that EPA may object to any State-issued permit issued in the absence of the required information.

(1) Facility information. All applicants must submit the following information:

- (i) The name, mailing address, and location of the TWTDS for which the application is submitted;
- (ii) Whether the facility is a Class I Sludge Management Facility;
- (iii) The design flow rate (in million gallons per day);
- (iv) The total population served; and
- (v) The status of the TWTDS as Federal, State, private, public, or other entity.

(2) Applicant information. All applicants must submit the following information:

- (i) The name, mailing address, telephone number, and electronic mail address of the applicant; and
- (ii) Indication whether the applicant is the owner, operator, or both.

(3) Permit information. All applicants must submit the facility's NPDES permit number, if applicable, and a listing of all other Federal, State, and local permits or construction approvals received or applied for under any of the following programs:

- (i) Hazardous Waste Management program under the Resource Conservation and Recovery Act (RCRA);
- (ii) UIC program under the Safe Drinking Water Act (SDWA);
- (iii) NPDES program under the Clean Water Act (CWA);
- (iv) Prevention of Significant Deterioration (PSD) program under the Clean Air Act;
- (v) Nonattainment program under the Clean Air Act;
- (vi) National Emission Standards for Hazardous Air Pollutants (NESHAPS) preconstruction approval under the Clean Air Act;
- (vii) Dredge or fill permits under section 404 of CWA;
- (viii) Other relevant environmental permits, including State or local permits.

(4) Indian country. All applicants must identify any generation, treatment, storage, land application, or disposal of sewage sludge that occurs in Indian country.

(5) Topographic map. All applicants must submit a topographic map (or other map if a topographic map is unavailable) extending one mile beyond property boundaries of the facility and showing the following information:

- (i) All sewage sludge management facilities, including on-site treatment, storage, and disposal sites and
- (ii) Wells, springs, and other surface water bodies that are within 1/4 mile of the property boundaries and listed in public records or otherwise known to the applicant.

(6) Sewage sludge handling. All applicants must submit a line drawing and/or a narrative description that identifies all sewage sludge management practices employed during the term of the permit, including all units used for collecting, dewatering, storing, or treating sewage sludge, the destination(s) of all liquids and solids leaving each such unit, and all processes used for pathogen reduction and vector attraction reduction.

(7) Sewage sludge quality. The applicant must submit sewage sludge monitoring data for the pollutants for which limits in sewage sludge have been established in R.61-9.503 for the applicant's use or disposal practices on the date of permit application.

- (i) The Department may require sampling for additional pollutants, as appropriate, on a case-by-case basis.
- (ii) Applicants must provide data from a minimum of three samples taken within four and one-half years prior to the date of the permit application. Samples must be representative of the sewage sludge and should be taken at least one month apart. Existing data may be used in lieu of sampling done solely for the purpose of this application.

(iii) Applicants must collect and analyze samples in accordance with analytical methods approved under SW-846 unless an alternative has been specified in an existing sewage sludge permit.

(iv) The monitoring data provided must include at least the following information for each parameter:

- (A) Average monthly concentration for all samples (mg/kg dry weight), based upon actual sample values;
- (B) The analytical method used; and
- (C) The method detection level.

(8) Preparation of sewage sludge. If the applicant is a "person who prepares" sewage sludge, as defined at R.61-9.503.9(r), the applicant must provide the following information:

- (i) If the applicant's facility generates sewage sludge, the total dry metric tons per 365-day period generated at the facility;
- (ii) If the applicant's facility receives sewage sludge from another facility, the following information for each facility from which sewage sludge is received:

- (A) The name, mailing address, and location of the other facility;
 - (B) The total dry metric tons per 365-day period received from the other facility; and
 - (C) A description of any treatment processes occurring at the other facility, including blending activities and treatment to reduce pathogens or vector attraction characteristics.
- (iii) If the applicant's facility changes the quality of sewage sludge through blending, treatment, or other activities, the following information:
- (A) Whether the Class A pathogen reduction requirements in R.61–9.503.32(a) or the Class B pathogen reduction requirements in R.61–9.503.32(b) are met, and a description of any treatment processes used to reduce pathogens in sewage sludge;
 - (B) Whether any of the vector attraction reduction options of R.61–9.503.33(b)(1) through (b)(8) are met, and a description of any treatment processes used to reduce vector attraction properties in sewage sludge; and
 - (C) A description of any other blending, treatment, or other activities that change the quality of sewage sludge.
- (iv) If sewage sludge from the applicant's facility meets the ceiling concentrations in R.61–9.503.13(b)(1), the pollutant concentrations in section 503.13(b)(3), the Class A pathogen requirements in section 503.32(a), and one of the vector attraction reduction requirements in section 503.33(b)(1) through (b)(8), and if the sewage sludge is applied to the land, the applicant must provide the total dry metric tons per 365-day period of sewage sludge subject to this paragraph that is applied to the land.
- (v) If sewage sludge from the applicant's facility is sold or given away in a bag or other container for application to the land, and the sewage sludge is not subject to paragraph (q)(8)(iv) of this section, the applicant must provide the following information:
- (A) The total dry metric tons per 365-day period of sewage sludge subject to this paragraph that is sold or given away in a bag or other container for application to the land and
 - (B) A copy of all labels or notices that accompany the sewage sludge being sold or given away.
- (vi) If sewage sludge from the applicant's facility is provided to another "person who prepares," as defined at R.61–9.503.9(r), and the sewage sludge is not subject to paragraph (q)(8)(iv) of this section, the applicant must provide the following information for each facility receiving the sewage sludge:
- (A) The name, mailing address, and electronic mail address of the receiving facility;
 - (B) The total dry metric tons per 365-day period of sewage sludge subject to this paragraph that the applicant provides to the receiving facility;
 - (C) A description of any treatment processes occurring at the receiving facility, including blending activities and treatment to reduce pathogens or vector attraction characteristic;
 - (D) A copy of the notice and necessary information that the applicant is required to provide the receiving facility under R.61–9.503.12(g); and
 - (E) If the receiving facility places sewage sludge in bags or containers for sale or give-away to application to the land, a copy of any labels or notices that accompany the sewage sludge.
- (9) Land application of bulk sewage sludge. If sewage sludge from the applicant's facility is applied to the land in bulk form, and is not subject to paragraphs (q)(8)(iv), (v), or (vi) of this section, the applicant must provide the following information:
- (i) The total dry metric tons per 365-day period of sewage sludge subject to this paragraph that is applied to the land;
 - (ii) If any land application sites are located in States other than the State where the sewage sludge is prepared, a description of how the applicant will notify the permitting authority for the State(s) where the land application sites are located;
 - (iii) The following information for each land application site that has been identified at the time of permit application:
 - (A) The name (if any), and location for the land application site;
 - (B) The site's latitude and longitude to the nearest second, and method of determination;

(C) A topographic map (or other map if a topographic map is unavailable) that shows the site's location;

(D) The name, mailing address, telephone number, and electronic mail address of the site owner, if different from the applicant;

(E) The name, mailing address, telephone number, and electronic mail address of the person who applies sewage sludge to the site, if different from the applicant;

(F) Whether the site is agricultural land, forest, a public contact site, or a reclamation site, as such site types are defined under R.61-9.503.11;

(G) The type of vegetation grown on the site, if known, and the nitrogen requirement for this vegetation;

(H) Whether either of the vector attraction reduction options of R.61-9.503.33(b)(9) or (b)(10) is met at the site, and a description of any procedures employed at the time of use to reduce vector attraction properties in sewage sludge; and

(I) Other information that describes how the site will be managed, as specified by the permitting authority.

(iv) The following information for each land application site that has been identified at the time of permit application, if the applicant intends to apply bulk sewage sludge subject to the cumulative pollutant loading rates in R.61-9.503.13(b)(2) to the site:

(A) Whether the applicant has contacted the permitting authority in the State where the bulk sewage sludge subject to section 503.13(b)(2) will be applied, to ascertain whether bulk sewage sludge subject to section 503.13(b)(2) has been applied to the site on or since July 20, 1993, and if so, the name of the permitting authority and the name, phone number, and electronic mail address if available, of a contact person at the permitting authority;

(B) Identification of facilities other than the applicant's facility that have sent, or are sending, sewage sludge subject to the cumulative pollutant loading rates in section 503.13(b)(2) to the site since July 20, 1993, if, based on the inquiry in paragraph (q)(iv)(A), bulk sewage sludge subject to cumulative pollutant loading rates in section 503.13(b)(2) has been applied to the site since July 20, 1993;

(v) If not all land application sites have been identified at the time of permit application, the applicant must submit a land application plan that, at a minimum:

(A) Describes the geographical area covered by the plan;

(B) Identifies the site selection criteria;

(C) Describes how the site(s) will be managed;

(D) Provides for advance notice to the Department of specific land application sites and reasonable time for the permit authority to object prior to land application of the sewage sludge; and

(E) Provides for advance public notice of land application sites in the manner prescribed by State and local law. When State or local law does not require advance public notice, it must be provided in a manner reasonably calculated to apprise the general public of the planned land application.

(10) Surface disposal. If sewage sludge from the applicant's facility is placed on a surface disposal site, the applicant must provide the following information:

(i) The total dry metric tons of sewage sludge from the applicant's facility that is placed on surface disposal sites per 365-day period;

(ii) The following information for each surface disposal site receiving sewage sludge from the applicant's facility that the applicant does not own or operate:

(A) The site name or number, contact person, mailing address, telephone number, and electronic mail address for the surface disposal site and

(B) The total dry metric tons from the applicant's facility per 365-day period placed on the surface disposal site;

(iii) The following information for each active sewage sludge unit at each surface disposal site that the applicant owns or operates:

- (A) The name or number and the location of the active sewage sludge unit;
- (B) The unit's latitude and longitude to the nearest second, and method of determination;
- (C) If not already provided, a topographic map (or other map if a topographic map is unavailable) that shows the unit's location;
- (D) The total dry metric tons placed on the active sewage sludge unit per 365-day period;
- (E) The total dry metric tons placed on the active sewage sludge unit over the life of the unit;
- (F) A description of any liner for the active sewage sludge unit, including whether it has a maximum permeability of 1×10^{-7} cm/sec;
- (G) A description of any leachate collection system for the active sewage sludge unit, including the method used for leachate disposal, and any Federal, State, and local permit number(s) for leachate disposal;
- (H) If the active sewage sludge unit is less than 150 meters from the property line of the surface disposal site, the actual distance from the unit boundary to the site property line;
- (I) The remaining capacity (dry metric tons) for the active sewage sludge unit;
- (J) The date on which the active sewage sludge unit is expected to close, if such a date has been identified;
- (K) The following information for any other facility that sends sewage sludge to the active sewage sludge unit:

(1) The name, contact person, mailing address, and electronic mail address of the facility and

(2) Available information regarding the quality of the sewage sludge received from the facility, including any treatment at the facility to reduce pathogens or vector attraction characteristics;

(L) Whether any of the vector attraction reduction options of R.61-9.503.33(b)(9) through (b)(11) is met at the active sewage sludge unit, and a description of any procedures employed at the time of disposal to reduce vector attraction properties in sewage sludge;

(M) The following information, as applicable to any ground water monitoring occurring at the active sewage sludge unit:

(1) A description of any ground water monitoring occurring at the active sewage sludge unit;

(2) Any available ground-water monitoring data, with a description of the well locations and approximate depth to ground water;

(3) A copy of any ground-water monitoring plan that has been prepared for the active sewage sludge unit;

(4) A copy of any certification that has been obtained from a qualified ground-water scientist that the aquifer has not been contaminated; and

(N) If site-specific pollutant limits are being sought for the sewage sludge placed on this active sewage sludge unit, information to support such a request.

(11) Incineration. If sewage sludge from the applicant's facility is fired in a sewage sludge incinerator, the applicant must provide the following information:

(i) The total dry metric tons of sewage sludge from the applicant's facility that is fired in sewage sludge incinerators per 365-day period;

(ii) The following information for each sewage sludge incinerator firing the applicant's sewage sludge that the applicant does not own or operate:

(A) The name and/or number, contact person, mailing address, telephone number, and electronic mail address of the sewage sludge incinerator and

(B) The total dry metric tons from the applicant's facility per 365-day period fired in the sewage sludge incinerator;

(iii) The following information for each sewage sludge incinerator that the applicant owns or operates:

- (A) The name and/or number and the location of the sewage sludge incinerator;
 - (B) The incinerator's latitude and longitude to the nearest second, and method of determination;
 - (C) The total dry metric tons per 365-day period fired in the sewage sludge incinerator;
 - (D) Information, test data, and documentation of ongoing operating parameters indicating that compliance with the National Emission Standard for Beryllium in 40 CFR part 61 will be achieved;
 - (E) Information, test data, and documentation of ongoing operating parameters indicating that compliance with the National Emission Standard for Mercury in 40 CFR part 61 will be achieved;
 - (F) The dispersion factor for the sewage sludge incinerator, as well as modeling results and supporting documentation;
 - (G) The control efficiency for parameters regulated in R.61-9.503.43, as well as performance test results and supporting documentation;
 - (H) Information used to calculate the risk specific concentration (RSC) for chromium, including the results of incinerator stack tests for hexavalent and total chromium concentrations, if the applicant is requesting a chromium limit based on a site-specific RSC value;
 - (I) Whether the applicant monitors total hydrocarbons (THC) or carbon monoxide (CO) in the exit gas for the sewage sludge incinerator;
 - (J) The type of sewage sludge incinerator;
 - (K) The maximum performance test combustion temperature, as obtained during the performance test of the sewage sludge incinerator to determine pollutant control efficiencies;
 - (L) The following information on the sewage sludge feed rate used during the performance test:
 - (1) Sewage sludge feed rate in dry metric tons per day;
 - (2) Identification of whether the feed rate submitted is average use or maximum design; and
 - (3) A description of how the feed rate was calculated;
 - (M) The incinerator stack height in meters for each stack, including identification of whether actual or creditable stack height was used;
 - (N) The operating parameters for the sewage sludge incinerator air pollution control device(s), as obtained during the performance test of the sewage sludge incinerator to determine pollutant control efficiencies;
 - (O) Identification of the monitoring equipment in place, including (but not limited to) equipment to monitor the following:
 - (1) Total hydrocarbons or Carbon Monoxide;
 - (2) Percent oxygen;
 - (3) Percent moisture; and
 - (4) Combustion temperature; and
 - (P) A list of all air pollution control equipment used with this sewage sludge incinerator.
- (12) Disposal in a municipal solid waste landfill. If sewage sludge from the applicant's facility is sent to a municipal solid waste landfill (MSWLF), the applicant must provide the following information for each MSWLF to which sewage sludge is sent:
- (i) The name, contact person, mailing address, electronic mail address, location, and all applicable permit numbers of the MSWLF;
 - (ii) The total dry metric tons per 365-day period sent from this facility to the MSWLF;
 - (iii) A determination of whether the sewage sludge meets applicable requirements for disposal of sewage sludge in a MSWLF, including the results of the paint filter liquids test and any additional requirements that apply on a site-specific basis; and
 - (iv) Information, if known, indicating whether the MSWLF complies with criteria set forth in 40 CFR part 258.

(13) Contractors. All applicants must provide the name, mailing address, telephone number, electronic mail address, and responsibilities of all contractors responsible for any operational or maintenance aspects of the facility related to sewage sludge generation, treatment, use, or disposal.

(14) Other information. At the request of the Department, the applicant must provide any other information necessary to determine the appropriate standards for permitting under R.61-9.503, and must provide any other information necessary to assess the sewage sludge use and disposal practices, determine whether to issue a permit, or identify appropriate permit requirements.

(15) Signature. All applications must be signed by a certifying official in compliance with section 122.22.

HISTORY: Amended by SCSR 43-11 Doc. No. 4888, eff November 22, 2019.

122.22. Signatories to permit applications and reports.

(a) Applications. All permit applications shall be signed as follows:

(1) For a corporation: by a responsible corporate officer. For the purpose of this section, a responsible corporate officer means:

(i) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or

(ii) The manager of one or more manufacturing, production, or operating facilities, provided, the manager is authorized to make management decisions which govern the operation of the regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiating and directing other comprehensive measures to assure long term environmental compliance with environmental laws and regulations; the manager can ensure that the necessary systems are established or actions taken to gather complete and accurate information for permit application requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

(2) For a partnership or sole proprietorship: by a general partner or the proprietor, respectively; or

(3) For a municipality, State, Federal, or other public agency or public facility: By either a principal executive officer, mayor, or other duly authorized employee or ranking elected official. For purposes of this section, a principal executive officer of a Federal agency includes:

(i) The chief executive officer of the agency, or

(ii) A senior executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., Regional Administrator, Region IV, EPA).

(b) All reports required by permits, and other information requested by the Department, shall be signed by a person described in paragraph (a) of this section, or by a duly authorized representative of that person. A person is a duly authorized representative only if:

(1) The authorization is made in writing by a person described in paragraph (a) of this section;

(2) The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity such as the position of plant manager, operator of a well or a well field, superintendent, position of equivalent responsibility, or an individual or position having overall responsibility for environmental matters for the company. (A duly authorized representative may thus be either a named individual or any individual occupying a named position.) and,

(3) The written authorization is submitted to the Department.

(c) Changes to authorization. If an authorization under paragraph (b) of this section is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements of paragraph (b) of this section must be submitted to the Department prior to or together with any reports, information, or applications to be signed by an authorized representative.

(d) Certification. Any person signing a document under paragraph (a) or (b) of this section shall make the following certification: "I certify under penalty of law that this document and all attachments

were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.”

(e) Electronic Reporting. If documents described in paragraph (a) or (b) of this section are submitted electronically by or on behalf of the NPDES-regulated facility, any person providing the electronic signature for such documents shall meet all relevant requirements of this section, and shall ensure that all of the relevant requirements of 40 CFR Part 3 (including, in all cases, subpart D to Part 3) (Cross-Media Electronic Reporting) and 40 CFR Part 127 (NPDES Electronic Reporting Requirements) are met for that submission.

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

122.23. Concentrated animal feeding operations.

(a) Scope. Concentrated animal feeding operations (CAFOs), as defined in paragraph (b) of this section or designated in accordance with paragraph (c) of this section, are point sources, subject to NPDES permitting requirements as provided in this section. Once an animal feeding operation is defined as a CAFO for at least one type of animal, the NPDES requirements for CAFOs apply with respect to all animals in confinement at the operation and all manure, litter, and process wastewater generated by those animals or the production of those animals, regardless of the type of animal.

(b) Definitions applicable to this section:

(1) “Animal feeding operation (AFO)” means a lot or facility (other than an aquatic animal production facility) where the following conditions are met:

(i) Animals (other than aquatic animals) have been, are, or will be stabled or confined and fed or maintained for a total of forty-five (45) days or more in any twelve (12)-month period, and

(ii) Crops, vegetation, forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility.

(2) “Concentrated animal feeding operation (CAFO)” means an AFO that is defined as a Large CAFO or as a Medium CAFO by the terms of this paragraph, or that is designated as a CAFO in accordance with paragraph (c) of this section. Two or more AFOs under common ownership are considered to be a single AFO for the purposes of determining the number of animals at an operation, if they adjoin each other or if they use a common area or system for the disposal of wastes.

(3) The term “land application area” means land under the control of an AFO owner or operator, whether it is owned, rented, or leased, to which manure, litter, or process wastewater from the production area is or may be applied.

(4) “Large concentrated animal feeding operation (Large CAFO).” An AFO is defined as a Large CAFO if it stables or confines as many as or more than the numbers of animals specified in any of the following categories:

- (i) 700 mature dairy cows, whether milked or dry;
- (ii) 1,000 veal calves;
- (iii) 1,000 cattle other than mature dairy cows or veal calves. The term cattle includes but is not limited to heifers, steers, bulls, and cow/calf pairs;
- (iv) 2,500 swine, each weighing fifty-five pounds (55 lbs) or more;
- (v) 10,000 swine, each weighing less than fifty-five pounds (55 lbs);
- (vi) 500 horses;
- (vii) 10,000 sheep or lambs;
- (viii) 55,000 turkeys;
- (ix) 30,000 laying hens or broilers, if the AFO uses a liquid manure handling system;

- (x) 125,000 chickens (other than laying hens), if the AFO uses other than a liquid manure handling system;
- (xi) 82,000 laying hens, if the AFO uses other than a liquid manure handling system;
- (xii) 30,000 ducks, if the AFO uses other than a liquid manure handling system; or
- (xiii) 5,000 ducks, if the AFO uses a liquid manure handling system.

(5) The term “manure” is defined to include manure, bedding, compost, and raw materials or other materials commingled with manure or set aside for disposal.

(6) “Medium concentrated animal feeding operation (Medium CAFO).” The term Medium CAFO includes any AFO with the type and number of animals that fall within any of the ranges listed in paragraph (b)(6)(i) of this section and which has been defined or designated as a CAFO. An AFO is defined as a Medium CAFO if:

(i) The type and number of animals that it stables or confines falls within any of the following ranges:

- (A) 200 to 699 mature dairy cows, whether milked or dry;
- (B) 300 to 999 veal calves;
- (C) 300 to 999 cattle other than mature dairy cows or veal calves. The term cattle includes, but is not limited to, heifers, steers, bulls, and cow/calf pairs;
- (D) 750 to 2,499 swine each weighing fifty-five pounds (55 lbs) or more;
- (E) 3,000 to 9,999 swine each weighing less than fifty-five pounds (55 lbs);
- (F) 150 to 499 horses;
- (G) 3,000 to 9,999 sheep or lambs;
- (H) 16,500 to 54,999 turkeys;
- (I) 9,000 to 29,999 laying hens or broilers, if the AFO uses a liquid manure handling system;
- (J) 37,500 to 124,999 chickens (other than laying hens), if the AFO uses other than a liquid manure handling system;
- (K) 25,000 to 81,999 laying hens, if the AFO uses other than a liquid manure handling system;
- (L) 10,000 to 29,999 ducks, if the AFO uses other than a liquid manure handling system; or
- (M) 1,500 to 4,999 ducks, if the AFO uses a liquid manure handling system; and

(ii) Either one of the following conditions is met:

(A) Pollutants are discharged into waters of the United States through a man-made ditch, flushing system, or other similar man-made device; or

(B) Pollutants are discharged directly into waters of the United States which originate outside of and pass over, across, or through the facility or otherwise come into direct contact with the animals confined in the operation.

(7) “Process wastewater” means water directly or indirectly used in the operation of the AFO for any or all of the following: spillage or overflow from animal or poultry watering systems; washing, cleaning, or flushing pens, barns, manure pits, or other AFO facilities; direct contact swimming, washing, or spray cooling of animals; or dust control. Process wastewater also includes any water which comes into contact with any raw materials, products, or byproducts including manure, litter, feed, milk, eggs, or bedding.

(8) “Production area” means that part of an AFO that includes the animal confinement area, the manure storage area, the raw materials storage area, and the waste containment areas. The animal confinement area includes but is not limited to open lots, housed lots, feedlots, confinement houses, stall barns, free stall barns, milkrooms, milking centers, cowyards, barnyards, medication pens, walkers, animal walkways, and stables. The manure storage area includes but is not limited to lagoons, runoff ponds, storage sheds, stockpiles, under-house or pit storages, liquid impoundments, static piles, and composting piles. The raw materials storage area includes but is not limited to feed silos, silage bunkers, and bedding materials. The waste containment area includes but is not limited to settling basins, and areas within berms and diversions which separate uncontaminated storm

water. Also included in the definition of production area is any egg washing or egg processing facility, and any area used in the storage, handling, treatment, or disposal of mortalities.

(9) "Small concentrated animal feeding operation (Small CAFO)." An AFO that is designated as a CAFO and is not a Medium CAFO.

(c) How may an AFO be designated as a CAFO? The appropriate authority (i.e., the Department or Regional Administrator, or both, as specified in paragraph (c)(1) of this section) may designate any AFO as a CAFO upon determining that it is a significant contributor of pollutants to waters of the United States.

(1) Who may designate? Designations may be made by the Department. The Regional Administrator may also designate CAFOs but only where the Regional Administrator has determined that one or more pollutants in the AFO's discharge contributes to an impairment in a downstream or adjacent state or Indian country water that is impaired for that pollutant.

(2) In making this designation, the Department or the Regional Administrator shall consider the following factors:

(i) The size of the AFO and the amount of wastes reaching waters of the United States;

(ii) The location of the AFO relative to waters of the United States;

(iii) The means of conveyance of animal wastes and process wastewaters into waters of the United States;

(iv) The slope, vegetation, rainfall, and other factors affecting the likelihood or frequency of discharge of animal wastes, manure, and process wastewaters into waters of the United States; and

(v) Other relevant factors.

(3) No AFO shall be designated under this paragraph unless the Department or the Regional Administrator has conducted an on-site inspection of the operation and determined that the operation should and could be regulated under the permit program. In addition, no AFO with numbers of animals below those established in paragraph (b)(6) of this section may be designated as a CAFO unless:

(i) Pollutants are discharged into waters of the United States through a manmade ditch, flushing system, or other similar man-made device; or

(ii) Pollutants are discharged directly into waters of the United States which originate outside of the facility and pass over, across, or through the facility or otherwise come into direct contact with the animals confined in the operation.

(d) NPDES permit authorization -

(1) Permit Requirement. A CAFO must not discharge unless the discharge is authorized by an NPDES permit. In order to obtain authorization under an NPDES permit, the CAFO owner or operator must either apply for an individual NPDES permit or submit a notice of intent for coverage under an NPDES general permit.

(2) Information to submit with permit application or notice of intent. An application for an individual permit must include the information specified in section 122.21. A notice of intent for a general permit must include the information specified in sections 122.21 and 122.28.

(3) Information to submit with permit application. A permit application for an individual permit must include the information specified in section 122.21. A notice of intent for a general permit must include the information specified in sections 122.21 and 122.28.

(e) Land application discharges from a CAFO are subject to NPDES requirements. The discharge of manure, litter, or process wastewater to waters of the United States from a CAFO as a result of the application of that manure, litter, or process wastewater by the CAFO to land areas under its control is a discharge from that CAFO subject to NPDES permit requirements, except where it is an agricultural stormwater discharge as provided in 33 U.S.C. 1362(14). For purposes of this paragraph, where the manure, litter, or process wastewater has been applied in accordance with site-specific nutrient management practices that ensure appropriate agricultural utilization of the nutrients in the manure, litter, or process wastewater, as specified in section 122.42(e)(1)(vi) through (ix), a precipitation-related discharge of manure, litter, or process wastewater from land areas under the control of a CAFO is an agricultural stormwater discharge.

(1) For unpermitted Large CAFOs, a precipitation-related discharge of manure, litter, or process wastewater from land areas under the control of a CAFO shall be considered an agricultural stormwater discharge only where the manure, litter, or process wastewater has been land applied in accordance with site-specific nutrient management practices that ensure appropriate agricultural utilization of the nutrients in the manure, litter, or process wastewater, as specified in section 122.42(e)(1)(vi) through (ix).

(2) Unpermitted Large CAFOs must maintain documentation specified in section 122.42(e)(1)(ix) either on site or at a nearby office, or otherwise make such documentation readily available to the Department or Regional Administrator upon request.

(f) By when must the owner or operator of a CAFO have an NPDES permit if it discharges? A CAFO must be covered by a permit at the time that it discharges.

(g) [Reserved]

(h) Procedures for CAFOs seeking coverage under a general permit.

(1) CAFO owners or operators must submit a notice of intent when seeking authorization to discharge under a general permit in accordance with section 122.28(b). The Department must review notices of intent submitted by CAFO owners or operators to ensure that the notice of intent includes the information required by section 122.21(i)(1), including a nutrient management plan that meets the requirements of section 122.42(e) and applicable effluent limitations and standards, including those specified in 40 CFR part 412. When additional information is necessary to complete the notice of intent or clarify, modify, or supplement previously submitted material, the Department may request such information from the owner or operator. If the Department makes a preliminary determination that the notice of intent meets the requirements of sections 122.21(i)(1) and 122.42(e), the Department must notify the public of the Department's proposal to grant coverage under the permit to the CAFO and make available for public review and comment the notice of intent submitted by the CAFO, including the CAFO's nutrient management plan, and the draft terms of the nutrient management plan to be incorporated into the permit. The process for submitting public comments and hearing requests, and the hearing process if a request for a hearing is granted, must follow the procedures applicable to draft permits set forth in 40 CFR 124.11 through 124.13. The Department may establish, either by regulation or in the general permit, an appropriate period of time for the public to comment and request a hearing that differs from the time period specified in 40 CFR 124.10. The Department must respond to significant comments received during the comment period, as provided in 40 CFR 124.17, and, if necessary, require the CAFO owner or operator to revise the nutrient management plan in order to be granted permit coverage. When the Department authorizes coverage for the CAFO owner or operator under the general permit, the terms of the nutrient management plan shall become incorporated as terms and conditions of the permit for the CAFO. The Department shall notify the CAFO owner or operator and inform the public that coverage has been authorized and of the terms of the nutrient management plan incorporated as terms and conditions of the permit applicable to the CAFO.

(2) For EPA-issued permits only. The Regional Administrator shall notify each person who has submitted written comments on the proposal to grant coverage and the draft terms of the nutrient management plan or requested notice of the final permit decision. Such notification shall include notice that coverage has been authorized and of the terms of the nutrient management plan incorporated as terms and conditions of the permit applicable to the CAFO.

(3) Nothing in this paragraph (h) shall affect the authority of the Department to require an individual permit under section 122.28(b)(3).

HISTORY: Amended by SCSR 47-5 Doc. No. 5137, eff May 26, 2023.

122.24. Concentrated aquatic animal production facilities.

(a) Permit requirement. Concentrated aquatic animal production facilities, as defined in this section, are point sources subject to the NPDES permit program.

(b) Definition. "Concentrated aquatic animal production facility" means a hatchery, fish farm, or other facility which meets the criteria in Appendix C of this regulation, or which the Department designates under paragraph (c) of this section.

(c) Case-by-case designation of concentrated aquatic animal production facilities.

(1) The Department may designate any warm or cold water aquatic animal production facility as a concentrated aquatic animal production facility upon determining that it is a significant contributor of pollution to waters of the State. In making this designation the Department shall consider the following factors:

- (i) The location and quality of the receiving waters of the State;
- (ii) The holding, feeding, and production capacities of the facility;
- (iii) The quantity and nature of the pollutants reaching waters of the State; and
- (iv) Other relevant factors.

(2) A permit application shall not be required from a concentrated aquatic animal production facility designated under this paragraph until the Department has conducted on-site inspection of the facility and has determined that the facility should and could be regulated under the permit program.

122.25. Aquaculture projects.

(a) Permit requirement. Discharges into aquaculture projects, as defined in this section, are subject to the NPDES permit program through section 318 of CWA, and in accordance with R.61-9.125 Part B.

(b) Definitions.

(1) "Aquaculture project" means a defined managed water area which uses discharges of pollutants into that designated area for the maintenance or production of harvestable freshwater, estuarine, or marine plants or animals.

(2) "Designated project area" means the portions of the waters of the State within which the permittee or permit applicant plans to confine the cultivated species, using a method or plan or operation (including, but not limited to, physical confinement) which, on the basis of reliable scientific evidence, is expected to ensure that specific individual organisms comprising an aquaculture crop will enjoy increased growth attributable to the discharge of pollutants, and be harvested within a defined geographic area.

122.26. Storm water discharges.

(a) Permit requirement.

(1) Prior to October 1, 1992, a permit shall not be required for a discharge composed entirely of storm water, except:

- (i) A discharge with respect to which a permit has been issued prior to February 4, 1987;
- (ii) A discharge associated with industrial activity (see section 122.26(a)(4));
- (iii) A discharge from a large municipal separate storm sewer system;
- (iv) A discharge from a medium municipal separate storm sewer system;

(v) A discharge which the Department or the EPA Regional Administrator determines to contribute to a violation of a water quality standard or is a significant contributor of pollutants to waters of the State. This designation may include a discharge from any conveyance or system of conveyances used for collecting and conveying storm water runoff or a system of discharges from municipal separate storm sewers, except for those discharges from conveyances which do not require a permit under paragraph (a)(2) of this section or agricultural storm water runoff which is exempted from the definition of point source at section 122.2. The Department may designate discharges from municipal separate storm sewers on a system-wide or jurisdiction-wide basis. In making this determination the Department may consider the following factors:

- (A) The location of the discharge with respect to waters of the State as defined at section 122.2;
- (B) The size of the discharge;
- (C) The quantity and nature of the pollutants discharged to waters of the State; and
- (D) Other relevant factors.

(2) The Department may not require a permit for discharges of storm water runoff from mining operations or oil and gas exploration, production, processing or treatment operations or transmis-

sion facilities, composed entirely of flows which are from conveyances or systems of conveyances (including but not limited to pipes, conduits, ditches, and channels) used for collecting and conveying precipitation runoff and which are not contaminated by contact with or that has not come into contact with, any overburden, raw material, intermediate products, finished product, byproduct or waste products located on the site of such operations.

(3) Large and medium municipal separate storm sewer systems.

(i) Permits must be obtained for all discharges from large and medium municipal separate storm sewer systems.

(ii) The Department may either issue one system-wide permit covering all discharges from municipal separate storm sewers within a large or medium municipal storm sewer system or issue distinct permits for appropriate categories of discharges within a large or medium municipal separate storm sewer system including, but not limited to: all discharges owned or operated by the same municipality; located within the same jurisdiction; all discharges within a system that discharge to the same watershed; discharges within a system that are similar in nature; or for individual discharges from municipal separate storm sewers within the system.

(iii) The operator of a discharge from a municipal separate storm sewer which is part of a large or medium municipal separate storm sewer system must either:

(A) Participate in a permit application (to be a permittee or a co-permittee) with one or more other operators of discharges from the large or medium municipal storm sewer system which covers all, or a portion of all, discharges from the municipal separate storm sewer system;

(B) Submit a distinct permit application which only covers discharges from the municipal separate storm sewers for which the operator is responsible; or

(C) A regional authority may be responsible for submitting a permit application under the following guidelines:

(1) The regional authority together with co-applicants shall have authority over a storm water management program that is in existence, or shall be in existence at the time part 1 of the application is due:

(2) The permit applicant or co-applicants shall establish their ability to make a timely submission of part 1 and part 2 of the municipal application;

(3) Each of the operators of municipal separate storm sewers within the systems described in paragraphs (b)(4)(i), (ii) and (iii) or (b)(7)(i), (ii), and (iii) of this section, that are under the purview of the designated regional authority, shall comply with the application requirements of paragraph (d) of this section.

(iv) One permit application may be submitted for all or a portion of all municipal separate storm sewers within adjacent or interconnected large or medium municipal separate storm sewer systems. The Department may issue one system-wide permit covering all, or a portion of all municipal separate storm sewers in adjacent or interconnected large or medium municipal separate storm sewer systems.

(v) Permits for all or a portion of all discharges from large or medium municipal separate storm sewer systems that are issued on a system-wide, jurisdiction-wide, watershed or other basis may specify different conditions relating to different discharges covered by the permit, including different management programs for different drainage areas which contribute storm water to the system.

(vi) Co-permittees need only comply with permit conditions relating to discharges from the municipal separate storm sewers for which they are operators.

(4) Discharges through large and medium municipal separate storm sewer systems. In addition to meeting the requirements of paragraph (c) of this section, an operator of a storm water discharge associated with industrial activity which discharges through a large or medium municipal separate storm sewer system shall submit to the operator of the municipal separate storm sewer system receiving the discharge no later than May 15, 1991, or 180 days prior to commencing such discharge: the name of the facility; a contact person and phone number; the location of the discharge; a description, including Standard Industrial Classification, which best reflects the principal products or services provided by each facility; and any existing NPDES permit number.

(5) Other municipal separate storm sewers. The Department may issue permits for municipal separate storm sewers that are designated under paragraph (a)(1)(v) of this section on a system-wide basis, jurisdiction-wide basis, watershed basis or other appropriate basis, or may issue permits for individual discharges.

(6) Non-municipal separate storm sewers. For storm water discharges associated with industrial activity from point sources which discharge through a non-municipal or non-publicly owned separate storm sewer system, the Department, in its discretion, may issue: a single NPDES permit, with each discharger a co-permittee to a permit issued to the operator of the portion of the system that discharges into waters of the State; or, individual permits to each discharger of storm water associated with industrial activity through the non-municipal conveyance system.

(i) All storm water discharges associated with industrial activity that discharge through a storm water discharge system that is not a municipal separate storm sewer must be covered by an individual permit, or a permit issued to the operator of the portion of the system that discharges to waters of the State, with each discharger to the non-municipal conveyance a co-permittee to that permit.

(ii) Where there is more than one operator of a single system of such conveyances, all operators of such conveyances, all operators of storm water discharges associated with industrial activity must submit applications.

(iii) Any permit covering more than one operator shall identify the effluent limitations or other permit conditions, if any, that apply to each operator.

(7) Combined sewer systems. Conveyances that discharge storm water runoff combined with municipal sewage are point sources that must obtain NPDES permits in accordance with the procedures of section 122.21 and are not subject to the provisions of this section.

(8) Whether a discharge from a municipal separate storm sewer is or is not subject to regulation under this section shall have no bearing on whether the owner or operator of the discharge is eligible for funding under Title II, Title III or Title IV of the Clean Water Act. See 40 CFR Part 35, subpart I, Appendix A(b)H.2.j.

(9) (i) On and after October 1, 1994, for discharges composed entirely of storm water, that are not required by paragraph (a)(1) of this section to obtain a permit, operators shall be required to obtain a NPDES permit only if:

(A) The discharge is from a small MS4 required to be regulated pursuant to section 122.32;

(B) The discharge is a storm water discharge associated with small construction activity pursuant to paragraph (b)(15) of this section;

(C) Either the Department or the EPA Regional Administrator determines that storm water controls are needed for the discharge based on wasteload allocations that are part of "total maximum daily loads" (TMDLs) that address the pollutant(s) of concern; or

(D) Either the Department or the EPA Regional Administrator determines that the discharge, or category of discharges within a geographic area, contributes to a violation of a water quality standard or is a significant contributor of pollutants to waters of the United States.

(ii) Operators of small MS4s designated pursuant to paragraphs (a)(9)(i)(A), (a)(9)(i)(C), or (a)(9)(i)(D) of this section shall seek coverage under an NPDES permit in accordance with sections 122.33 through 122.35. Operators of non-municipal sources designated pursuant to paragraphs (a)(9)(i)(B), (a)(9)(i)(C), or (a)(9)(i)(D) of this section shall seek coverage under an NPDES permit in accordance with paragraph (c)(1) of this section.

(iii) Operators of storm water discharges designated pursuant to paragraph (a)(9)(i)(C) or (a)(9)(i)(D) of this section shall apply to the Department for a permit within 180 days of receipt of notice, unless permission for a later date is granted by the Department (see section 124.52[c] of this chapter).

(b) Definitions.

(1) "Co-permittee" means a permittee to an NPDES permit that is only responsible for permit conditions relating to the discharge for which it is operator.

Note: "General permit application" is defined at 122.28(b)(4).

(2) “Illicit discharge” means any discharge to a municipal separate storm sewer that is not composed entirely of storm water except discharges pursuant to an NPDES permit (other than the NPDES permit for discharges from the municipal separate storm sewer) and discharges resulting from fire fighting activities.

(3) “Incorporated place” means a city, town, township, or village that is incorporated under the laws of the State of South Carolina.

(4) “Large municipal separate storm sewer system” means all municipal separate storm sewers that are either:

(i) Located in an incorporated place with a population of 250,000 or more as determined by the 1990 Decennial Census by the Bureau of the Census (Appendix F of this part); or

(ii) Located in the counties listed in appendix H, except municipal separate storm sewers that are located in the incorporated places, townships or towns within such counties; or

(iii) Owned or operated by a municipality other than those described in paragraph (b)(4)(i) or (ii) of this section and that are designated by the Department as part of the large or medium municipal separate storm sewer system due to the interrelationship between the discharges of the designated storm sewer and the discharges from municipal separate storm sewers described under paragraph (b)(4)(i) or (ii) of this section. In making this determination the Department may consider the following factors:

(A) Physical interconnections between the municipal separate storm sewers;

(B) The location of discharges from the designated municipal separate storm sewer relative to discharges from municipal separate storm sewers described in paragraph (b)(4)(i) of this section;

(C) The quantity and nature of pollutants discharged to waters of the State;

(D) The nature of the receiving waters; and

(E) Other relevant factors; or

(iv) The Department may, upon petition, designate as a large municipal separate storm sewer system, municipal separate storm sewers located within the boundaries of a region defined by a storm water management regional authority based on a jurisdictional, watershed, or other appropriate basis that includes one or more of the systems described in paragraph (b)(4)(i), (ii), and (iii) of this section.

(5) “Major municipal separate storm sewer outfall” (or “major outfall”) means a municipal separate storm sewer outfall that discharges from a single pipe with an inside diameter of 36 inches or more or its equivalent (discharge from a single conveyance other than circular pipe which is associated with a drainage area of more than 50 acres); or for municipal separate storm sewers that receive storm water from lands zoned for industrial activity (based on comprehensive zoning plans or the equivalent), an outfall that discharges from a single pipe with an inside diameter of 12 inches or more or from its equivalent (discharge from other than a circular pipe associated with a drainage area of 2 acres or more).

(6) “Major outfall” means a major municipal separate storm sewer outfall.

(7) “Medium municipal” separate storm sewer system means all municipal separate storm sewers that are either:

(i) Located in an incorporated place with a population of 100,000 or more but less than 250,000, as determined by the 1990 Decennial Census by the Bureau of the Census (Appendix G); or

(ii) Located in the counties listed in appendix I, except municipal separate storm sewers that are located in the incorporated places, townships or towns within such counties; or

(iii) Owned or operated by a municipality other than those described in paragraph (b) (7)(i) or (ii) of this section and that are designated by the Department as part of the large or medium municipal separate storm sewer system due to the interrelationship between the discharges of the designated storm sewer and the discharges from municipal separate storm sewers described under paragraph (b)(7)(i) or (ii) of this section. In making this determination the Department may consider the following factors:

(A) Physical interconnections between the municipal separate storm sewers;

(B) The location of discharges from the designated municipal separate storm sewer relative to discharges from municipal separate storm sewers described in paragraph (b)(7)(i) of this section;

(C) The quantity and nature of pollutants discharged to waters of the State;

(D) The nature of the receiving waters; or

(E) Other relevant factors; or

(iv) The Department may, upon petition, designate as a medium municipal separate storm sewer system, municipal separate storm sewers located within the boundaries of a region defined by a storm water management regional authority based on a jurisdictional, watershed, or other appropriate basis that includes one or more of the systems described in paragraphs (b)(7)(i), (ii), and (iii) of this section.

(8) "Municipal separate storm sewer" means a conveyance or system of conveyances (including roads with drainage systems, municipal streets, catch basins, curbs, gutters, ditches, man-made channels, or storm drains):

(i) Owned or operated by a State, city, town, borough, county, parish, district, association, or other public body (created by or pursuant to State law) having jurisdiction over disposal of sewage, industrial wastes, storm water, or other wastes, including special districts under State law such as a sewer district, flood control district or drainage district, or similar entity, or an Indian tribe or an authorized Indian tribal organization, or a designated and approved management agency under section 208 of the CWA that discharges to waters of the State;

(ii) Designed or used for collecting or conveying storm water;

(iii) Which is not a combined sewer; and

(iv) Which is not part of a Publicly Owned Treatment Works (POTW) as defined at section 122.2.

Note: "Notice of Intent" is defined at 122.28(b)(4).

(9) "Outfall" means a point source as defined by section 122.2 at the point where a municipal separate storm sewer discharges to waters of the State and does not include open conveyances connecting two municipal separate storm sewers, or pipes, tunnels or other conveyances which connect segments of the same stream or other waters of the State and are used to convey waters of the State.

(10) "Overburden" means any material of any nature, consolidated or unconsolidated, that overlies a mineral deposit, excluding topsoil or similar naturally-occurring surface materials that are not disturbed by mining operations.

(11) "Runoff coefficient" means the fraction of total rainfall that will appear at a conveyance as runoff.

(12) "Significant materials" includes, but is not limited to: raw materials; fuels; materials such as solvents, detergents, and plastic pellets; finished materials such as metallic products; raw materials used in food processing or production; hazardous substances designated under section 101(14) of CERCLA; any chemical the facility is required to report pursuant to section 313 of Title III of SARA; fertilizers; pesticides; and waste products such as ashes, slag and sludge that have the potential to be released with storm water discharges.

(13) "Storm water" means storm water runoff, snow melt runoff and surface runoff and drainage.

(14) "Storm water discharge associated with industrial activity" means the discharge from any conveyance that is used for collecting and conveying storm water and that is directly related to manufacturing, processing or raw materials storage areas at an industrial plant. The term does not include discharges from facilities or activities excluded from the NPDES program under this regulation. For the categories of industries identified in this section, the term includes, but is not limited to, storm water discharges from industrial plant yards; immediate access roads and rail lines used or traveled by carriers of raw materials, manufactured products, waste material, or by-products used or created by the facility; material handling sites; refuse sites; sites used for the application or disposal of process waste waters (as defined at 40 CFR Part 401); sites used for the storage and maintenance of material handling equipment; sites used for residual treatment, storage, or disposal; shipping and receiving areas; manufacturing buildings; storage areas (including tank farms) for raw

materials and intermediate and final products; and areas where industrial activity has taken place in the past and significant materials remain and are exposed to storm water. For the purposes of this paragraph, material handling activities include storage, loading and unloading, transportation, or conveyance of any raw material, intermediate product, final product, by-product or waste product. The term excludes areas located on plant lands separate from the plant's industrial activities, such as office buildings and accompanying parking lots as long as the drainage from the excluded areas is not mixed with storm water drained from the above described areas. Industrial facilities (including industrial facilities that are federally, State, or municipally owned or operated that meet the description of the facilities listed in paragraphs (b)(14)(i) through (xi) of this section) include those facilities designated under the provisions of paragraph (a)(1)(v) of this section. The following categories of facilities are considered to be engaging in "industrial activity" for purposes of paragraph (b)(14):

(i) Facilities subject to storm water effluent limitations guidelines, new source performance standards, or toxic pollutant effluent standards under 40 CFR subchapter N (except facilities with toxic pollutant effluent standards which are exempted under category (xi) in paragraph (b)(14) of this section);

(ii) Facilities classified as Standard Industrial Classifications 24 (except 2434), 26 (except 265 and 267), 28 (except 283), 29, 311, 32 (except 323), 33, 3441, 373;

(iii) Facilities classified as Standard Industrial Classifications 10 through 14 (mineral industry) including active or inactive mining operations (except for areas of coal mining operations no longer meeting the definition of a reclamation area under 40 CFR 434.11(1) because the performance bond issued to the facility by the appropriate SMCRA authority has been released, or except for areas of non-coal mining operations which have been released from applicable State or Federal reclamation requirements after December 17, 1990) and oil and gas exploration, production, processing, or treatment operations, or transmission facilities that discharge storm water contaminated by contact with or that has come into contact with, any overburden, raw material, intermediate products, finished products, byproducts or waste products located on the site of such operations; (inactive mining operations are mining sites that are not being actively mined but which have an identifiable owner/operator; inactive mining sites do not include sites where mining claims are being maintained prior to disturbances associated with the extraction, beneficiation, or processing of mined materials, nor sites where minimal activities are undertaken for the sole purpose of maintaining a mining claim);

(iv) Hazardous waste treatment, storage, or disposal facilities, including those that are operating under interim status or a permit under subtitle C of RCRA;

(v) Landfills, land application sites, and open dumps that receive or have received any industrial wastes (waste that is received from any of the facilities described under this subsection) including those that are subject to regulation under subtitle D of RCRA;

(vi) Facilities involved in the recycling of materials, including metal scrapyards, battery reclaimers, salvage yards and automobile junkyards, including but limited to those classified as Standard Industrial Classification 5015 and 5093;

(vii) Steam electric power generating facilities, including coal handling sites;

(viii) Transportation facilities classified as Standard Industrial Classifications 40, 41, 42 (except 4221-25), 43, 44, 45, and 5171 which have vehicle maintenance shops, equipment cleaning operations, or airport deicing operations. Only those portions of the facility that are either involved in vehicle maintenance (including vehicle rehabilitation, mechanical repairs, painting, fueling, and lubrication), equipment cleaning operations, airport deicing operations, or which are otherwise identified under paragraphs (b)(14)(i)-(vii) or (ix)-(xi) of this section are associated with industrial activity;

(ix) Treatment works treating domestic sewage or any other sewage sludge or wastewater treatment device or system, used in the storage treatment, recycling, and reclamation of municipal or domestic sewage, including land dedicated to the disposal of sewage sludge that are located within the confines of the facility, with a design flow of 1.0 mgd or more, or required to have an approved pretreatment program under R.61-9.403. Not included are farm lands, domestic gardens or lands used for sludge management where sludge is beneficially reused and which are

not physically located in the confines of the facility, or areas that are in compliance with section 405 of the CWA;

(x) Construction activity including clearing, grading, and excavation, except operations that result in the disturbance of less than five acres of total land area. Construction activity also includes the disturbance of less than five acres of total land area that is a part of a larger common plan of development or sale if the larger common plan will ultimately disturb five acres or more;

(xi) Facilities under Standard Industrial Classifications 20, 21, 22, 23, 2434, 25, 265, 267, 27, 283, 285, 30, 31 (except 311), 323, 34 (except 3441), 35, 36, 37 (except 373), 38, 39, and 4221–25;

(15) Storm water discharge associated with small construction activity means the discharge of storm water from:

(i) Construction activities including clearing, grading, and excavating that result in land disturbance of equal to or greater than one acre and less than five acres and, in coastal counties within one-half (1/2) mile of a receiving water body (but not for single-family homes which are not part of a subdivision development), that result in any land disturbance less than five acres. Small construction activity also includes the disturbance of less than one acre of total land area that is part of a larger common plan of development or sale if the larger common plan will ultimately disturb equal to or greater than one and less than five acres. Small construction activity does not include routine maintenance that is performed to maintain the original line and grade, hydraulic capacity, or original purpose of the facility. The Department may waive the otherwise applicable requirements in a general permit for a storm water discharge from construction activities that disturb less than five acres where:

(A) The value of the rainfall erosivity factor (“R” in the Revised Universal Soil Loss Equation) is less than five during the period of construction activity. The rainfall erosivity factor is determined in accordance with Chapter 2 of Agriculture Handbook Number 703, Predicting Soil Erosion by Water: A Guide to Conservation Planning With the Revised Universal Soil Loss Equation (RUSLE), pages 21–64, dated January 1997. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from EPA’s Water Resource Center, Mail Code RC4100, 401 M St. S.W., Washington, DC 20460. A copy is also available for inspection at the U.S. EPA Water Docket, 401 M Street S.W., Washington, DC. 20460, or the Office of the Federal Register, 800 N. Capitol Street N.W. Suite 700, Washington, DC. An operator must certify to the Department that the construction activity will take place during a period when the value of the rainfall erosivity factor is less than five; or

(B) Storm water controls are not needed based on a “total maximum daily load” (TMDL) approved or established by EPA that addresses the pollutant(s) of concern or, for non-impaired waters that do not require TMDLs, an equivalent analysis that determines allocations for small construction sites for the pollutant(s) of concern or that determines that such allocations are not needed to protect water quality based on consideration of existing in-stream concentrations, expected growth in pollutant contributions from all sources, and a margin of safety. For the purpose of this paragraph, the pollutant(s) of concern include sediment or a parameter that addresses sediment (such as total suspended solids, turbidity or siltation) and any other pollutant that has been identified as a cause of impairment of any water body that will receive a discharge from the construction activity. The operator must certify to the Department that the construction activity will take place, and storm water discharges will occur, within the drainage area addressed by the TMDL or equivalent analysis.

(C) As of December 21, 2020, all certifications submitted in compliance with paragraphs (b)(15)(i)(A) and (B) of this section must be submitted electronically by the owner or operator to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, owners or operators may be required to report electronically if specified by a particular permit or if required to do so by State law.

(ii) Any other construction activity designated by the Department, or in States with approved NPDES programs either the Department or the EPA Regional Administrator, based on the

potential for contribution to a violation of a water quality standard or for significant contribution of pollutants to waters of the United States.

Exhibit 1 to Section 122.26(b)(15) - Summary of Coverage of "Storm Water Discharges Associated with Small Construction Activity" Under the NPDES Storm Water Program

Automatic Designation: Required Nationwide Coverage	Construction activities that result in a land disturbance of equal to or greater than one acre and less than five acres. Construction activities disturbing less than one acre if part of a larger common plan of development or sale with a planned disturbance of equal to or greater than one acre and less than five acres. (See Section 122.26(b)(15)(i).)
Potential Designation: Optional Evaluation and Designation by the NPDES Permitting Authority or EPA Regional Administrator.	Construction activities that result in a land disturbance of less than one acre based on the potential for contribution to a violation of a water quality standard or for significant contribution of pollutants. (See Section 122.26(b)(15)(ii).)
Potential Waiver: Waiver from Requirements as Determined by the NPDES Permitting Authority.	Any automatically designated construction activity where the operator certifies: (1) A rainfall erosivity factor of less than five or (2) that the activity will occur within an area where controls are not needed based on a TMDL or, for non-impaired waters that do not require a TMDL, an equivalent analysis for the pollutants of concern. (See Section 122.26(b)(15)(i).)

(16) Small municipal separate storm sewer system means all separate storm sewers that are:

(i) Owned or operated by the United States, a State, city, town, borough, county, parish, district, association, or other public body (created by or pursuant to State law) having jurisdiction over disposal of sewage, industrial wastes, storm water, or other wastes, including special districts under State law such as a sewer district, flood control district, or drainage district, or similar entity, or an Indian tribe or an authorized Indian tribal organization, or a designated and approved management agency under section 208 of the CWA that discharges to waters of the United States and

(ii) Not defined as "large" or "medium" municipal separate storm sewer systems pursuant to paragraphs (b)(4) and (b)(7) of this section, or designated under paragraph (a)(1)(v) of this section.

(iii) This term includes systems similar to separate storm sewer systems in municipalities, such as systems at military bases, large hospital or prison complexes, and highways and other thoroughfares. The term does not include separate storm sewers in very discrete areas, such as individual buildings.

(17) Small MS4 means a small municipal separate storm sewer system.

(18) Municipal separate storm sewer system means all separate storm sewers that are defined as "large" or "medium" or "small" municipal separate storm sewer systems pursuant to paragraphs (b)(4), (b)(7), and (b)(16) of this section, or designated under paragraph (a)(1)(v) of this section.

(19) MS4 means a municipal separate storm sewer system.

(20) Uncontrolled sanitary landfill means a landfill or open dump whether in operation or closed, that does not meet the requirements for runoff or runoff controls established pursuant to subtitle D of the Solid Waste Disposal Act.

(21) "Storm water point source" means a conveyance or system of conveyances (including but not limited to pipes, conduits, ditches and channels) primarily used for collecting and conveying storm water runoff and that:

- (i) Is located in an urbanized area as designated by the Bureau of the Census;
- (ii) Discharges from lands of facilities used for industrial or commercial activities; or
- (iii) Is referenced under section 122.26 (Storm Water Discharges).

(c) Application requirements for storm water discharges associated with industrial activity and storm water discharges associated with small construction activity;

(1) Individual application. Dischargers of storm water associated with industrial activity and with small construction activity are required to apply for an individual permit or seek coverage under a promulgated storm water general permit. Facilities that are required to obtain an individual permit, or any discharge of storm water which the Department is evaluating for designation (see R.61-9.124.52(c)) under paragraph (a)(1)(v) of this section and is not a municipal storm sewer, shall submit an NPDES application in accordance with the requirements of section 122.21 as modified and supplemented by the provisions of the remainder of this paragraph. Applicants for discharges composed entirely of storm water shall submit Form 1 and Form 2F. Applicants for discharges composed of storm water and non-storm water shall submit Form 1, Form 2C and Form 2F. Applicants for new sources or new discharges (as defined in section 122.2 of this regulation) composed of storm water and non-storm water shall submit Form 1, Form 2D, and Form 2F.

(i) Except as provided in section 122.26(c)(1)(ii)-(iv), the operator of a storm water discharge associated with industrial activity subject to this section shall provide:

(A) A site map showing topography (or indicating the outline of drainage areas served by the outfall(s) covered in the application if a topographic map is unavailable) of the facility including: each of its drainage and discharge structures; the drainage area of each storm water outfall; paved areas and buildings within the drainage area of each storm water outfall, each past or present area used for outdoor storage or disposal of significant materials; each existing structural control measure to reduce pollutants in storm water runoff, materials loading and access areas, areas where pesticides, herbicides, soil conditioners and fertilizers are applied, each of its hazardous waste treatment, storage or disposal facilities (including each area not required to have a RCRA permit which is used for accumulating hazardous waste under R.61-79.262.34); each well where fluids from the facility are injected underground; springs, and other surface water bodies which receive storm water discharges from the facility;

(B) An estimate of the area of impervious surfaces (including paved areas and building roofs) and the total area drained by each outfall (within a mile radius of the facility) and a narrative description of the following: Significant materials that in the three years prior to the submittal of this application have been treated, stored or disposed in a manner to allow exposure to storm water; method of treatment, storage or disposal of such materials; materials management practices employed, in the three years prior to the submittal of this application, to minimize contact by these materials with storm water runoff; materials loading and access areas; the location, manner and frequency in which pesticides, herbicides, soil conditioners and fertilizers are applied; the location and a description of existing structural and non-structural control measures to reduce pollutants in storm water runoff; and a description of the treatment the storm water receives, including the ultimate disposal of any solid or fluid wastes other than by discharge;

(C) A certification that all outfalls that should contain storm water discharges associated with industrial activity have been tested or evaluated for the presence of non-storm water discharges which are not covered by a NPDES permit; tests for such non-storm water discharges may include smoke tests, fluorometric dye tests, analysis of accurate schematics, as well as other appropriate tests. The certification shall include a description of the method used, the date of any testing, and the onsite drainage points that were directly observed during a test;

(D) Existing information regarding significant leaks or spills of toxic or hazardous pollutants at the facility that have taken place within the three years prior to the submittal of this application;

(E) Quantitative data based on samples collected during storm events and collected in accordance with section 122.21 of this regulation from all outfalls containing a storm water discharge associated with industrial activity for the following parameters:

(1) Any pollutant limited in an effluent guideline to which the facility is subject;

(2) Any pollutant listed in the facility's NPDES permit for its process wastewater (if the facility is operating under an existing NPDES permit);

(3) Oil and grease, pH, BOD₅, COD, TSS, total phosphorus, total Kjeldahl nitrogen, and nitrate plus nitrite nitrogen;

(4) Any information on the discharge required under section 122.21(g)(7) (vi) and (vii) of this regulation;

(5) Flow measurements or estimates of the flow rate, and the total amount of discharge for the storm event(s) sampled, and the method of flow measurement or estimation; and

(6) The date and duration (in hours) of the storm event(s) sampled, rainfall measurements or estimates of the storm event (in inches) which generated the sampled runoff and the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event (in hours);

(F) Operators of a discharge which is composed entirely of storm water are exempt from the requirements of section 122.21(g)(2), (g)(3), (g)(4), (g)(5), (g)(7)(iii), (g)(7)(iv), (g)(7)(v), (g)(7)(viii); and

(G) Operators of new sources or new discharges (as defined in section 122.2 of this regulation) which are composed in part or entirely of storm water must include estimates for the pollutants or parameters listed in paragraph (c)(1)(i)(E) of this section instead of actual sampling data, along with the source of each estimate. Operators of new sources or new discharges composed in part or entirely of storm water must provide quantitative data for the parameters listed in paragraph (c)(1)(i)(E) of this section within two years after commencement of discharge, unless such data has already been reported under the monitoring requirements of the NPDES permit for the discharge. Operators of a new source or new discharge which is composed entirely of storm water are exempt from the requirements of section 122.21(k)(3)(ii), (k)(3)(iii), and (k)(5).

(ii) An operator of an existing or new storm water discharge that is associated with industrial activity solely under paragraph (b)(14)(x) of this section or is associated with small construction activity solely under paragraph (b)(15) of this section, is exempt from the requirements of section 122.21(g) and paragraph (c)(1)(i) of this section.

(A) The location (including a map) and the nature of the construction activity;

(B) The total area of the site and the area of the site that is expected to undergo excavation during the life of the permit;

(C) Proposed measures, including best management practices, to control pollutants in storm water discharges during construction, including a brief description of applicable State and local erosion and sediment control requirements;

(D) Proposed measures to control pollutants in storm water discharges that will occur after construction operations have been completed, including a brief description of applicable State or local erosion and sediment control requirements;

(E) An estimate of the runoff coefficient of the site and the increase in impervious area after the construction addressed in the permit application is completed, the nature of fill material and existing data describing the soil or the quality of the discharge; and

(F) The name of the receiving water.

(iii) The operator of an existing or new discharge composed entirely of storm water from an oil or gas exploration, production, processing, or treatment operation, or transmission facility is not required to submit a permit application in accordance with paragraph (c)(1)(i) of this section, unless the facility:

(A) Has had a discharge of storm water resulting in the discharge of a reportable quantity for which notification is or was required pursuant to 40 CFR 117.21 or 40 CFR 302.6 at any time since November 16, 1987; or

(B) Has had a discharge of storm water resulting in the discharge of a reportable quantity for which notification is or was required pursuant to 40 CFR 110.6 at any time since November 16, 1987; or

(C) Contributes to a violation of a water quality standard.

(iv) The operator of an existing or new discharge composed entirely of storm water from a mining operation is not required to submit a permit application unless the discharge has come

into contact with any overburden, raw material, intermediate products, finished product, byproduct or waste products located on the site of such operations.

(v) Applicants shall provide such other information the Department may reasonably require under section 122.21(g)(13) of this regulation to determine whether to issue a permit and may require any facility subject to paragraph (c)(1)(ii) of this section to comply with paragraph (c)(1)(i) of this section.

(2) [Reserved]

(d) Application requirements for large and medium municipal separate storm sewer discharges. The operator of a discharge from a large or medium municipal separate storm sewer or a municipal separate storm sewer that is designated by the Department under paragraph (a)(1)(v) of this section, may submit a jurisdiction-wide or system-wide permit application. Where more than one public entity owns or operates a municipal separate storm sewer within a geographic area (including adjacent or interconnected municipal separate storm sewer systems), such operators may be a co-applicant to the same application. Permit applications for discharges from large and medium municipal storm sewers or municipal storm sewers designated under paragraph (a)(1)(v) of this section shall include:

(1) Part 1. Part 1 of the application shall consist of:

(i) General information. The applicant's name, address, telephone number of contact person, ownership status, and status as a State or local government entity.

(ii) Legal authority. A description of existing legal authority to control discharges to the municipal separate storm sewer system. When existing legal authority is not sufficient to meet the criteria provided in paragraph (d)(2)(i) of this section, the description shall list additional authorities as will be necessary to meet the criteria and shall include a schedule and commitment to seek such additional authority that will be needed to meet the criteria.

(iii) Source identification.

(A) A description of the historic use of ordinances, guidance or other controls which limited the discharge of non-storm water discharges to any Publicly Owned Treatment Works serving the same area as the municipal separate storm sewer system.

(B) A USGS 7.5 minute topographic map (or equivalent topographic map with a scale between 1:10,000 and 1:24,000 if cost effective) extending one mile beyond the service boundaries of the municipal storm sewer system covered by the permit application. The following information shall be provided:

(1) The location of known municipal storm sewer system outfalls discharging to waters of the State:

(2) A description of the land use activities (e.g. divisions indicating undeveloped, residential, commercial agricultural and industrial uses) accompanied with estimates of population densities and projected growth for a ten year period within the drainage area served by the separate storm sewer. For each land use type, an estimate of an average runoff coefficient shall be provided;

(3) The location and a description of the activities of the facility of each currently operating or closed municipal landfill or other treatment, storage or disposal facility for municipal waste;

(4) The location and the permit number of any known discharge to the municipal storm sewer that has been issued an NPDES permit;

(5) The location of major structural controls for storm water discharge (retention basins, detention basins, major infiltration devices, etc.); and

(6) The identification of publicly owned parks, recreational areas, and other open lands.

(iv) Discharge characterization.

(A) Monthly mean rain and snow fall estimates (or summary of weather bureau data) and the monthly average number of storm events.

(B) Existing quantitative data describing the volume and quality of discharges from the municipal storm sewer, including a description of the outfalls sampled, sampling procedures and analytical methods used.

(C) A list of water bodies that receive discharges from the municipal separate storm sewer system, including downstream segments, lakes and estuaries, where pollutants from the system discharges may accumulate and cause water degradation and a brief description of known water quality impacts. At a minimum, the description of impacts shall include a description of whether the water bodies receiving such discharges have been:

(1) Assessed and reported in section 305(b) reports submitted by the State, the basis for the assessment (evaluated or monitored), a summary of designated use support and attainment of Clean Water Act (CWA) goals (fishable and swimmable waters) and causes of nonsupport of designated uses;

(2) Listed under section 304(l)(1)(A)(i), section 304(l)(1)(A)(ii) or section 304(l)(1)(B) of the CWA that is not expected to meet water quality standards or water quality goals;

(3) Listed in State Nonpoint Source Assessments required by section 319(a) of the CWA that, without additional action to control nonpoint sources of pollution, cannot reasonably be expected to attain or maintain water quality standards due to storm sewers, construction, highway maintenance and runoff from municipal landfills and municipal sludge adding significant pollution (or contributing to a violation of water quality standards);

(4) Identified and classified according to eutrophic condition of publicly owned lakes listed in State reports required under section 314(a) of the CWA (include the following: a description of those publicly owned lakes for which uses are known to be impaired; a description of procedures, processes and methods to control the discharge of pollutants from municipal separate storm sewers into such lakes; and a description of methods and procedures to restore the quality of such lakes);

(5) [Reserved]

(6) Designated estuaries under the National Estuary Program under section 320 of the CWA;

(7) Recognized by the applicant as highly valued or sensitive waters;

(8) Defined by the State or U.S. Fish and Wildlife Service's National Wetlands Inventory as wetlands; and

(9) Found to have pollutants in bottom sediments, fish tissue or biosurvey data.

(D) Field screening. Results of a field screening analysis for illicit connections and illegal dumping for either selected field screening points or major outfalls covered in the permit application. At a minimum, a screening analysis shall include a narrative description, for either each field screening point or major outfall, of visual observations made during dry weather periods. If any flow is observed, two grab samples shall be collected during a 24 hour period with a minimum period of four hours between samples. For all such samples, a narrative description of the color, odor, turbidity, the presence of an oil sheen or surface scum as well as any other relevant observations regarding the potential presence of non-storm water discharges or illegal dumping shall be provided. In addition, a narrative description of the results of a field analysis using suitable methods to estimate pH, total chlorine, total copper, total phenol, and detergents (or surfactants) shall be provided along with a description of the flow rate. Where the field analysis does not involve analytical methods approved under 40 CFR Part 136, the applicant shall provide a description of the method used including the name of the manufacturer of the test method along with the range and accuracy of the test. Field screening points shall be either major outfalls or other outfall points (or any other point of access such as manholes) randomly located throughout the storm sewer system by placing a grid over a drainage system map and identifying those cells of the grid which contain a segment of the storm sewer system or major outfall. The field screening points shall be established using the following guidelines and criteria:

(1) A grid system consisting of perpendicular north-south and east-west lines spaced $\frac{1}{4}$ mile apart shall be overlaid on a map of the municipal storm sewer system, creating a series of cells;

(2) All cells that contain a segment of the storm sewer system shall be identified; one field screening point shall be selected in each cell; major outfalls may be used as field screening points;

(3) Field screening points should be located downstream of any sources of suspected illegal or illicit activity;

(4) Field screening points shall be located to the degree practicable at the farthest manhole or other accessible location downstream in the system, within each cell; however, safety of personnel and accessibility of the location should be considered in making this determination;

(5) Hydrological conditions; total drainage area of the site; population density of the site; traffic density; age of the structures or buildings in the area; history of the area; and land use types;

(6) For medium municipal separate storm sewer systems, no more than 250 cells need to have identified field screening points; in large municipal separate storm sewer systems, no more than 500 cells need to have identified field screening points; cells established by the grid that contain no storm sewer segments will be eliminated from consideration; if fewer than 250 cells in medium municipal sewers are created, and fewer than 500 in large systems are created by the overlay on the municipal sewer map, then all those cells which contain a segment of the sewer system shall be subject to field screening (unless access to the separate storm sewer system is impossible); and

(7) Large or medium municipal separate storm sewer systems which are unable to utilize the procedures described in paragraphs (d)(1)(iv)(D)(1) through (6) of this section, because a sufficiently detailed map of the separate storm sewer systems is unavailable, shall field screen no more than 500 or 250 major outfalls respectively (or all major outfalls in the system, if less); in such circumstances, the applicant shall establish a grid system consisting of north-south and east-west lines spaced ¼ mile apart as an overlay to the boundaries of the municipal storm sewer system, thereby creating a series of cells; the applicant will then select major outfalls in as many cells as possible until at least 500 major outfalls (large municipalities) or 250 major outfalls (medium municipalities) are selected; a field screening analysis shall be undertaken at these major outfalls.

(E) Characterization plan. Information and a proposed program to meet the requirements of paragraph (d)(2)(iii) of this section. Such description shall include: the location of outfalls or field screening points appropriate for representative data collection under paragraph (d)(2)(iii)(A) of this section, a description of why the outfall or field screening point is representative, the seasons during which sampling is intended, a description of the sampling equipment. The proposed location of outfalls or field screening points for such sampling should reflect water quality concerns (see paragraph (d)(1)(iv)(C) of this section) to the extent practicable.

(v) Management Programs.

(A) A description of the existing management programs to control pollutants from the municipal separate storm sewer system. The description shall provide information on existing structural and source controls, including operation and maintenance measures for structural controls, that are currently being implemented. Such controls may include, but are not limited to: procedures to control pollution resulting from construction activities; floodplain management controls; wetland protection measures; best management practices for new subdivisions; and emergency spill response programs. The description may address controls established under State law as well as local requirements.

(B) A description of the existing program to identify illicit connections to the municipal storm sewer system. The description should include inspection procedures and methods for detecting and preventing illicit discharges and describe areas where this program has been implemented.

(vi) Fiscal resources. A description of the financial resources currently available to the municipality to complete part 2 of the permit application. A description of the municipality's budget for existing storm water programs, including an overview of the municipality's financial resources and budget, including overall indebtedness and assets, and sources of funds for storm water programs.

(2) Part 2. Part 2 of the application shall consist of:

(i) Adequate legal authority. A demonstration that the applicant can operate pursuant to legal authority established by statute, ordinance or series of contracts which authorizes or enables the applicant at a minimum to:

(A) Control through ordinance, permit, contract, order or similar means, the contribution of pollutants to the municipal storm sewer by storm water discharges associated with industrial activity and the quality of storm water discharged from sites of industrial activity;

(B) Prohibit through ordinance, order or similar means, illicit discharges to the municipal separate storm sewer;

(C) Control through ordinance, order or similar means the discharge to a municipal separate storm sewer of spills, dumping, or disposal of materials other than storm water;

(D) Control through interagency agreements among co-applicants the contribution of pollutants from one portion of the municipal system to another portion of the municipal system;

(E) Require compliance with conditions in ordinances, permits, contracts or orders; and

(F) Carry out all inspection, surveillance and monitoring procedures necessary to determine compliance and noncompliance with permit conditions including the prohibition on illicit discharges to the municipal separate storm sewer.

(ii) Source identification. The location of any major outfall that discharges to waters of the State that was not reported under paragraph (d)(1)(iii)(B)(1) of this section. Provide an inventory, organized by watershed of the name and address, and a description (such as SIC codes) which best reflects the principal products or services provided by each facility which may discharge to the municipal separate storm sewer, storm water associated with industrial activity;

(iii) Characterization data. When "quantitative data" for a pollutant are required under paragraph (d)(2)(iii)(A)(3) of this paragraph, the applicant must collect a sample of effluent in accordance with section 122.21(g)(7) and analyze it for the pollutant in accordance with analytical methods approved under 40 CFR Part 136. When no analytical method is approved, the applicant may use any suitable method but must provide a description of the method. The applicant must provide information characterizing the quality and quantity of discharges covered in the permit application, including:

(A) Quantitative data from representative outfalls designated by the Department (based on information received in part 1 of the application, the Department shall designate between five and ten outfalls or field screening points as representative of the commercial, residential and industrial land use activities of the drainage area contributing to the system, or where there are less than five outfalls covered in the application, the Department shall designate all outfalls) developed as follows:

(1) For each outfall or field screening point designated under this subparagraph, samples shall be collected of storm water discharges from three storm events occurring at least one month apart in accordance with the requirements at section 122.21(g)(7) (the Department may allow exemptions to sampling three storm events when climatic conditions create good cause for such exemptions);

(2) A narrative description shall be provided of the date and duration of the storm event(s) sampled, rainfall estimates of the storm event which generated the sampled discharge and the duration between the storm event sampled and the end of the previous measurable (greater than 0.1 inch rainfall) storm event;

(3) For samples collected and described under paragraphs (d)(2)(iii)(A)(1) and (A)(2) of this section, quantitative data shall be provided for: the organic pollutants listed in Table II; the pollutants listed in Table III (toxic metals, cyanide, and total phenols) of appendix D, and for the following pollutants;

(a) Total suspended solids (TSS)

(b) Total dissolved solids (TDS)

(c) COD

(d) BOD₅

(e) Oil and grease

- (f) Fecal coliform
- (g) Fecal streptococcus
- (h) pH
- (i) Total Kjeldahl nitrogen
- (j) Nitrate plus nitrite
- (k) Dissolved phosphorus
- (l) Total ammonia plus organic nitrogen
- (m) Total phosphorus

(4) Additional limited quantitative data required by the Department for determining permit conditions (the Department may require that quantitative data shall be provided for additional parameters, and may establish sampling conditions such as the location, season of sample collection, form of precipitation (snow melt, rainfall) and other parameters necessary to insure representativeness);

(B) Estimates of the annual pollutant load of the cumulative discharges to waters of the State from all identified municipal outfalls and the event mean concentration of the cumulative discharges to waters of the State from all identified municipal outfalls during a storm event (as described under section 122.21(g)(7)) for BOD₅, COD, TSS, dissolved solids, total nitrogen, total ammonia plus organic nitrogen, total phosphorus, dissolved phosphorus, cadmium, copper, lead, and zinc. Estimates shall be accompanied by a description of the procedures for estimating constituent loads and concentrations, including any modelling, data analysis, and calculation methods;

(C) A proposed schedule to provide estimates for each major outfall identified in either paragraph (d)(2)(ii) or (d)(1)(iii)(B)(1) of this section of the seasonal pollutant load and of the event mean concentration of a representative storm for any constituent detected in any sample required under paragraph (d)(2)(iii)(A) of this section; and

(D) A proposed monitoring program for representative data collection for the term of the permit that describes the location of outfalls or field screening points to be sampled (or the location of instream stations), why the location is representative, the frequency of sampling, parameters to be sampled, and a description of sampling equipment.

(iv) Proposed management program. A proposed management program covers the duration of the permit. It shall include a comprehensive planning process which involves public participation and where necessary intergovernmental coordination, to reduce the discharge of pollutants to the maximum extent practicable using management practices, control techniques and system, design and engineering methods, and such other provisions which are appropriate. The program shall also include a description of staff and equipment available to implement the program. Separate proposed programs may be submitted by each co-applicant. Proposed programs may impose controls on a system-wide basis, a watershed basis, a jurisdiction basis, or on individual outfalls. Proposed programs will be considered by the Department when developing permit conditions to reduce pollutants in discharges to the maximum extent practicable. Proposed management programs shall describe priorities for implementing controls. Such programs shall be based on:

(A) A description of structural and source control measures to reduce pollutants from runoff from commercial and residential areas that are discharged from the municipal storm sewer system that are to be implemented during the life of the permit, accompanied with an estimate of the expected reduction of pollutant loads and a proposed schedule for implementing such controls. At a minimum, the description shall include:

(1) A description of maintenance activities and a maintenance schedule for structural controls to reduce pollutants (including floatables) in discharges from municipal separate storm sewers;

(2) A description of planning procedures including a comprehensive master plan to develop, implement and enforce controls to reduce the discharge of pollutants from municipal separate storm sewers which receive discharges from areas of new development and significant redevelopment. Such plan shall address controls to reduce pollutants in discharges from municipal separate storm sewers after construction is completed. (Controls to reduce pollu-

tants in discharges from municipal separate storm sewers containing construction site runoff are addressed in paragraph (d)(2)(iv)(D) of this section;

(3) A description of practices for operating and maintaining public streets, roads and highways and procedures for reducing the impact on receiving waters of discharges from municipal storm sewer systems, including pollutants discharged as a result of deicing activities;

(4) A description of procedures to assure that flood management projects assess the impacts on the water quality of receiving water bodies and that existing structural flood control devices have been evaluated to determine if retrofitting the device to provide additional pollutant removal from storm water is feasible;

(5) A description of a program to monitor pollutants in runoff from operating or closed municipal landfills or other treatment, storage or disposal facilities for municipal waste, which shall identify priorities and procedures for inspections and establishing and implementing control measures for such discharges (this program can be coordinated with the program developed under paragraph (d)(2)(iv)(C) of this section); and

(6) A description of a program to reduce to the maximum extent practicable, pollutants in discharges from municipal separate storm sewers associated with the application of pesticides, herbicides and fertilizer which will include, as appropriate, controls such as educational activities, permits, certifications and other measures for commercial applicators and distributors, and controls for application in public right-of-ways and at municipal facilities;

(B) A description of a program, including a schedule, to detect and remove (or require the discharger to the municipal separate storm sewer to obtain a separate NPDES permit for) illicit discharges and improper disposal into the storm sewer. The proposed program shall include:

(1) A description of a program, including inspections, to implement and enforce an ordinance, orders or similar means to prevent illicit discharges to the municipal separate storm sewer system; this program description shall address all types of illicit discharges; however, the following category of non-storm water discharges or flows shall be addressed where such discharges are identified by the municipality as sources of pollutants to waters of the State:; water line flushing, landscape irrigation, diverted stream flows, rising ground waters, uncontaminated ground water infiltration (as defined at 40 CFR 35.2005(20)) to separate storm sewers, uncontaminated pumped ground water, discharges from potable water sources, foundation drains, air conditioning condensation, irrigation water, springs, water from crawl space pumps, footing drains, lawn watering, individual residential car washing, flows from riparian habitats and wetlands, dechlorinated swimming pool discharges, and street wash water (program descriptions shall address discharges or flows from fire fighting only where such discharges or flows are identified as significant sources of pollutants to waters of the State);

(2) A description of procedures to conduct on-going field screening activities during the life of the permit, including areas or locations that will be evaluated by such field screens;

(3) A description of procedures to be followed to investigate portions of the separate storm sewer system that, based on the results of the field screen, or other appropriate information, indicate a reasonable potential of containing illicit discharges or other sources of non-storm water (such procedures may include: sampling procedures for constituents such as fecal coliform, fecal streptococcus, surfactants (MBAS), residual chlorine, fluorides, and potassium; testing with fluorometric dyes; or conducting in storm sewer inspections where safety and other considerations allow. Such description shall include the location of storm sewers that have been identified for such evaluation);

(4) A description of procedures to prevent, contain, and respond to spills that may discharge into the municipal separate storm sewer;

(5) A description of a program to promote, publicize, and facilitate public reporting of the presence of illicit discharges or water quality impacts associated with discharges from municipal separate storm sewers;

(6) A description of educational activities, public information activities, and other appropriate activities to facilitate the proper management and disposal of used oil and toxic materials; and

(7) A description of controls to limit infiltration of seepage from municipal sanitary sewers to municipal separate storm sewer systems where necessary;

(C) A description of a program to monitor and control pollutants in storm water discharges to municipal systems from municipal landfills, hazardous waste treatment, disposal and recovery facilities, industrial facilities that are subject to section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA), and industrial facilities that the municipal permit applicant determines are contributing a substantial pollutant loading to the municipal storm sewer system. The program shall:

(1) Identify priorities and procedures for inspections and establishing and implementing control measures for such discharges;

(2) Describe a monitoring program for storm water discharges associated with the industrial facilities identified in paragraph (d)(2)(iv)(C) of this section, to be implemented during the term of the permit, including the submission of quantitative data on the following constituents: any pollutants limited in effluent guidelines subcategories, where applicable; any pollutant listed in an existing NPDES permit for a facility; oil and grease, COD, pH, BOD₅, TSS, total phosphorus, total Kjeldahl nitrogen, nitrate plus nitrite nitrogen, and any information on discharges required under section 122.21(g)(7)(vi) and (vii).

(D) A description of a program to implement and maintain structural and non-structural best management practices to reduce pollutants in storm water runoff from construction sites to the municipal storm sewer system, which shall include:

(1) A description of procedures for site planning which incorporate consideration of potential water quality impacts;

(2) A description of requirements for nonstructural and structural best management practices;

(3) A description of procedures for identifying priorities for inspecting sites and enforcing control measures which consider the nature of the construction activity, topography, and the characteristics of soils and receiving water quality; and

(4) A description of appropriate educational and training measures for construction site operators.

(v) Assessment of controls. Estimated reductions in loadings of pollutants from discharges of municipal storm sewer constituents from municipal storm sewer systems expected as the result of the municipal storm water quality management program. The assessment shall also identify known impacts of storm water controls on ground water.

(vi) Fiscal analysis. For each fiscal year to be covered by the permit, a fiscal analysis of the necessary capital and operation and maintenance expenditures necessary to accomplish the activities of the programs under paragraphs (d)(2)(iii) and (iv) of this section. Such analysis shall include a description of the source of funds that are proposed to meet the necessary expenditures, including legal restrictions on the use of such funds.

(vii) Where more than one legal entity submits an application, the application shall contain a description of the roles and responsibilities of each legal entity and procedures to ensure effective coordination.

(viii) Where requirements under paragraph (d)(1)(iv)(E), (d)(2)(ii), (d)(2)(iii)(B) and (d)(2)(iv) of this section are not practicable or are not applicable, the Department may exclude any operator of a discharge from a municipal separate storm sewer which is designated under paragraph (a)(1)(v), (b)(4)(ii) or (b)(7)(ii) of this section from such requirements. The Department shall not exclude the operator of a discharge from a municipal separate storm sewer identified in Appendix F, G, H, or I from any of the permit application requirements under this paragraph, except where authorized under this section.

(e) Application deadlines. Any operator of a point source required to obtain a permit under paragraph (a)(1) of this section that does not have an effective NPDES permit covering its storm water outfalls shall submit an application in accordance with the following deadlines;

(1) Storm water discharges associated with industrial activity.

(i) Except as provided in paragraph (e)(1)(ii) of this section, for any storm water discharge associated with industrial activity identified in paragraphs (b)(14)(i) through (xi) of this section, that is not part of a group application as described in paragraph (c)(2) of this section or which is not authorized by a storm water general permit, a permit application made pursuant to paragraph (C) of this section shall be submitted to the Department by October 1, 1992;

(ii) For any storm water discharge associated with industrial activity from a facility that is owned or operated by a municipality with a population of less than 100,000 that is not authorized by a general or individual permit, other than an airport, power plant, or uncontrolled sanitary landfill, the permit application must be submitted to the Department by March 10, 2003.

(2) For any group application submitted in accordance with paragraph (c)(2) of this section:

(i) Part 1.

(A) Except as provided in paragraph (e)(2)(i)(B) of this section, part 1 of the application shall be submitted to the Department by September 30, 1991;

(B) Any municipality with a population of less than 250,000 shall not be required to submit a part 1 application before May 18, 1992.

(C) For any storm water discharge associated with industrial activity from a facility that is owned or operated by a municipality with a population of less than 100,000 other than an airport, powerplant, or uncontrolled sanitary landfill, permit applications requirements are reserved.

(ii) Based on information in the part 1 application, the Department will approve or deny the members in the group application within 60 days after receiving part 1 of the group application.

(iii) Part 2.

(A) Except as provided in paragraph (e)(2)(iii)(B) of this section, part 2 of the application shall be submitted to the Department by October 1, 1992;

(B) Any municipality with a population of less than 250,000 shall not be required to submit a part 2 application before May 17, 1993.

(C) For any storm water discharge associated with industrial activity from a facility that is owned or operated by a municipality with a population of less than 100,000 other than an airport, powerplant, or uncontrolled sanitary landfill, permit applications requirements are reserved.

(iv) Rejected facilities.

(A) Except as provided in paragraph (e)(2)(iv)(B) of this section, facilities that are rejected as members of the group shall submit an individual application (or obtain coverage under an applicable general permit) no later than 12 months after the date of receipt of the notice of rejection or October 1, 1992, whichever comes first.

(B) Facilities that are owned or operated by a municipality and that are rejected as members of part 1 group application shall submit an individual application no later than 180 days after the date of receipt of the notice of rejection or October 1, 1992, whichever is later.

(v) A facility listed under paragraph (b)(14)(i)-(xi) of this section may add on to a group application submitted in accordance with paragraph (e)(2)(i) of this section at the discretion of the Department, and only upon a showing of good cause by the facility and the group applicant; the request for the addition of the facility shall be made no later than February 19, 1992; the addition of the facility shall not cause the percentage of the facilities that are required to submit quantitative data to be less than 10%, unless there are over 100 facilities in the group that are submitting quantitative data; approval to become part of group application must be obtained from the group or the trade association representing the individual facilities.

(3) For any discharge from a large municipal separate storm sewer system;

(i) Part 1 of the application shall be submitted to the Department by November 18, 1991;

(ii) Based on information received in the part 1 application, the Department will approve or deny a sampling plan under paragraph (d)(1)(iv)(E) of this section within 90 days after receiving the part 1 application;

- (iii) Part 2 of the application shall be submitted to the Department by November 16, 1992.
- (4) For any discharge from a medium municipal separate storm sewer system;
 - (i) Part 1 of the application shall be submitted to the Department by May 18, 1992.
 - (ii) Based on information received in the part 1 application, the Department will approve or deny a sampling plan under paragraph (d)(i)(iv)(E) of this section within 90 days after receiving the part 1 application.
 - (iii) Part 2 of the application shall be submitted to the Department by May 17, 1993.
- (5) A permit application shall be submitted to the Department within 180 days of notice, unless permission for a later date is granted by the Department [see R.61-9.124.52(c)], for:
 - (i) A storm water discharge that either the Department or the EPA Regional Administrator determines that the discharge contributes to a violation of a water quality standard or is a significant contributor of pollutants to waters of the United States [see paragraphs (a)(1)(v) and (b)(15)(ii) of this section];
 - (ii) A storm water discharge subject to paragraph (c)(1)(v) of this section.
- (6) Facilities with existing NPDES permits for storm water discharges associated with industrial activity shall maintain existing permits. New applications shall be submitted in accordance with the requirements of sections 122.21 and 122.26(c) 180 days before the expiration of such permits. Facilities with expired permits or permits due to expire before May 18, 1992, shall submit applications in accordance with the deadline set forth under paragraph (e)(1) of this section.
- (7) The Department shall issue or deny permits for discharges composed entirely of storm water under this section in accordance with the following schedule:
 - (i)(A) Except as provided in paragraph (e)(7)(i)(B) of this section, the Department shall issue or deny permits for storm water discharges associated with an industrial activity no later than October 1, 1993, or, for new sources or existing sources which fail to submit a complete permit application by October 1, 1992, one year after receipt of a complete permit application;
 - (B) For any municipality with a population of less than 250,000 which submits a timely Part I group application under paragraph (e)(2)(i)(B) of this section, the Department shall issue or deny permits for storm water discharges associated with an industrial activity no later than May 17, 1994, or, for any such municipality which fails to complete a Part II group permit application by May 17, 1993, one year after receipt of a complete permit application;
 - (ii) The Department shall issue or deny permits for large municipal separate storm sewer systems no later than November 16, 1993, or, for new sources or existing sources which fail to submit a complete permit application by November 16, 1992, one year after receipt of a complete permit application;
 - (iii) The Department shall issue or deny permits for medium municipal separate storm sewer systems no later than May 17, 1994, or, for new sources or existing sources which fail to submit a complete permit application by May 17, 1993, one year after receipt of a complete permit application.
- (8) For any storm water discharge associated with small construction activity identified in paragraph (b)(15)(i) of this section, see section 122.21(c)(1). Discharges from these sources require permit authorization by March 10, 2003, unless designated for coverage before then.
- (9) For any discharge from a regulated small MS4, the permit application made under section 122.33 must be submitted to the Department by:
 - (i) March 10, 2003 if designated under section 122.32(a)(1) unless your MS4 serves a jurisdiction with a population under 10,000 and the NPDES permitting authority has established a phasing schedule under section 40 CFR 123.35(d)(3) (see section 122.33(c)(1)); or
 - (ii) Within 180 days of notice, unless the NPDES permitting authority grants a later date, if designated under section 122.32(a)(2). (See section 122.33(c)(2)).
- (f) Petitions.
 - (1) Any operator of a municipal separate storm sewer system may petition the Department to require a separate NPDES permit for any discharge into the municipal separate storm sewer system.

(2) Any person may petition the Department to require a NPDES permit for a discharge which is composed entirely of storm water which contributes to a violation of a water quality standard or is a significant contributor of pollutants to waters of the State.

(3) The owner or operator of a municipal separate storm sewer system may petition the Department to reduce the Census estimates of population served by such separate system to account for storm water discharged to combined sewers as defined by 40 CFR 35.2005(b)(11) that is treated in a publicly owned treatment works. In municipalities in which combined sewers are operated, the Census estimates of population may be reduced proportional to the fraction, based on estimated lengths, of the length of combined sewers over the sum of the length of combined sewers and municipal separate storm sewers where an applicant has submitted the NPDES permit number associated with each discharge point and a map indicating areas served by combined sewers and the location of any combined sewer overflow discharge point.

(4) Any person may petition the Department for the designation of a large, medium, or small municipal separate storm sewer system as defined by paragraph (b)(4)(iv), (b)(7)(iv), or (b)(16) of this section.

(5) The Department shall make a final determination on any petition received under this section within 90 days after receiving the petition with the exception of petitions to designate a small MS4 in which case the Department shall make a final determination on the petition within 180 days after its receipt.

(g) Conditional exclusion for “no exposure” of industrial activities and materials to storm water. Discharges composed entirely of storm water are not storm water discharges associated with industrial activity if there is “no exposure” of industrial materials and activities to rain, snow, snowmelt and/or runoff, and the discharger satisfies the conditions in paragraphs (g)(1) through (g)(4) of this section. “No exposure” means that all industrial materials and activities are protected by a storm resistant-shelter to prevent exposure to rain, snow, snowmelt, and/or runoff. Industrial materials or activities include, but are not limited to, material handling equipment or activities, industrial machinery, raw materials, intermediate products, by-products, final products, or waste products. Material handling activities include the storage, loading and unloading, transportation, or conveyance of any raw material, intermediate product, final product or waste product.

(1) Qualification. To qualify for this exclusion, the operator of the discharge must:

(i) Provide a storm resistant shelter to protect industrial materials and activities from exposure to rain, snow, snowmelt, and runoff;

(ii) Complete and sign (according to section 122.22) a certification that there are no discharges of storm water contaminated by exposure to industrial materials and activities from the entire facility, except as provided in paragraph (g)(2) of this section;

(iii) Submit the signed certification to the NPDES permitting authority once every five (5) years. As of December 21, 2020, all certifications submitted in compliance with this section must be submitted electronically by the owner or operator to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, owners or operators may be required to report electronically if specified by a particular permit or if required to do so by State law.

(iv) Allow the Department to inspect the facility to determine compliance with the “no exposure” conditions;

(v) Allow the Department to make any “no exposure” inspection reports available to the public upon request; and

(vi) For facilities that discharge through an MS4, upon request, submit a copy of the certification of “no exposure” to the MS4 operator, as well as allow inspection and public reporting by the MS4 operator.

(2) Industrial materials and activities not requiring storm resistant shelter. To qualify for this exclusion, storm resistant shelter is not required for:

(i) Drums, barrels, tanks, and similar containers that are tightly sealed, provided those containers are not deteriorated and do not leak (“Sealed” means banded or otherwise secured and without operational taps or valves);

(ii) Adequately maintained vehicles used in material handling; and

(iii) Final products, other than products that would be mobilized in storm water discharge (e.g., rock salt).

(3) Limitations.

(i) Storm water discharges from construction activities identified in paragraphs (b)(14)(x) and (b)(15) are not eligible for this conditional exclusion.

(ii) This conditional exclusion from the requirement for an NPDES permit is available on a facility-wide basis only, not for individual outfalls. If a facility has some discharges of storm water that would otherwise be “no exposure” discharges, individual permit requirements should be adjusted accordingly.

(iii) If circumstances change and industrial materials or activities become exposed to rain, snow, snowmelt, and/or runoff, the conditions for this exclusion no longer apply. In such cases, the discharge becomes subject to enforcement for un-permitted discharge. Any conditionally exempt discharger who anticipates changes in circumstances should apply for and obtain permit authorization prior to the change of circumstances.

(iv) Notwithstanding the provisions of this paragraph, the Department retains the authority to require permit authorization (and deny this exclusion) upon making a determination that the discharge causes, has a reasonable potential to cause, or contributes to an instream excursion above an applicable water quality standard, including designated uses.

(4) Certification. The no exposure certification must require the submission of the following information, at a minimum, to aid the Department in determining if the facility qualifies for the no-exposure exclusion:

(i) The legal name, address and phone number of the discharger [see section 122.21(b)];

(ii) The facility name and address, the county name, and the latitude and longitude where the facility is located;

(iii) The certification must indicate that none of the following materials or activities are, or will be in the foreseeable future, exposed to precipitation:

(A) Using, storing, or cleaning industrial machinery or equipment, and areas where residuals from using, storing, or cleaning industrial machinery or equipment remain and are exposed to storm water;

(B) Materials or residuals on the ground or in storm water inlets from spills/leaks;

(C) Materials or products from past industrial activity;

(D) Material handling equipment (except adequately maintained vehicles);

(E) Materials or products during loading/unloading or transporting activities;

(F) Materials or products stored outdoors (except final products intended for outside use, e.g., new cars, where exposure to storm water does not result in the discharge of pollutants);

(G) Materials contained in open, deteriorated or leaking storage drums, barrels, tanks, or similar containers;

(H) Materials or products handled/stored on roads or railways owned or maintained by the discharger;

(I) Waste material (except waste in covered, non-leaking containers, e.g., dumpsters);

(J) Application or disposal of process wastewater (unless otherwise permitted); and

(K) Particulate matter or visible deposits of residuals from roof stacks/vents not otherwise regulated, i.e., under an air quality control permit, and evident in the storm water outflow;

(iv) All “no exposure” certifications must include the following certification statement, and be signed in accordance with the signatory requirements of section 122.22: “I certify under penalty of law that I have read and understand the eligibility requirements for claiming a condition of “no

exposure” and obtaining an exclusion from NPDES storm water permitting; and that there are no discharges of storm water contaminated by exposure to industrial activities or materials from the industrial facility identified in this document (except as allowed under paragraph (g)(2)) of this section. I understand that I am obligated to submit a no exposure certification form once every five years to the Department and, if requested, to the operator of the local MS4 into which this facility discharges (where applicable). I understand that I must allow the Department, or MS4 operator where the discharge is into the local MS4, to perform inspections to confirm the condition of no exposure and to make such inspection reports publicly available upon request. I understand that I must obtain coverage under an NPDES permit prior to any point source discharge of storm water from the facility. I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gathered and evaluated the information submitted. Based upon my inquiry of the person or persons who manage the system, or those persons directly involved in gathering the information, the information submitted is to the best of my knowledge and belief true, accurate, and complete. I am aware there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.”

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

122.27. Silvicultural activities.

(a) Permit requirement. Silvicultural point sources, as defined in this section, are point sources subject to the NPDES permit program.

(b) Definitions.

(1) “Silvicultural point source” means any discernible, confined and discrete conveyance related to rock crushing, gravel washing, log sorting, or log storage facilities which are operated in connection with silvicultural activities and from which pollutants are discharged into waters of the State. The term does not include non-point source silvicultural activities such as nursery operations, site preparation, reforestation and subsequent cultural treatment, thinning, prescribed burning, pest and fire control, harvesting operations, surface drainage, or road construction and maintenance from which there is natural runoff. However, some of these activities (such as stream crossing for roads) may involve point source discharges of dredged or fill material which may require a CWA section 404 permit (See 33 CFR 209.120 and Part 233).

(2) “Rock crushing and gravel washing facilities” means facilities which process crushed and broken stone, gravel, and riprap (See 40 CFR Part 436, Subpart B, including the effluent limitations guidelines).

(3) “Log sorting and log storage facilities” means facilities whose discharges result from the holding of unprocessed wood, for example, logs or roundwood with bark or after removal of bark held in self-contained bodies of water (mill ponds or log ponds) or stored on land where water is applied intentionally on the logs (wet decking). (See 40 CFR Part 429, Subpart I, including the effluent limitations guidelines).

122.28. General permits.

(a) Coverage. The Department may issue a general permit in accordance with the following:

(1) Area. The general permit shall be written to cover one or more categories or subcategories of discharges or sludge use or disposal practices or facilities described in the permit under paragraph (a)(2)(ii) of this section, except those covered by individual permits, within a geographic area. The area shall correspond to existing geographic or political boundaries such as:

- (i) Designated planning areas under sections 208 and 303 of CWA;
- (ii) Sewer districts or sewer authorities;
- (iii) City, county, or State political boundaries;
- (iv) State highway systems;
- (v) Standard metropolitan statistical areas as defined by the Office of Management and Budget;
- (vi) Urbanized areas as designated by the Bureau of the Census according to criteria in 30 FR 15202 (May 1, 1974); or

(vii) Any other appropriate division or combination of boundaries.

(viii) Watershed boundaries.

(2) Sources. The general permit may be written to regulate one or more categories or subcategories of discharges or sludge use or disposal practices or facilities within the area described in paragraph (a)(1) of this section, where the sources within a covered subcategory of discharges are either:

(i) Storm water point sources; or

(ii) One or more categories or subcategories of point sources other than storm water point sources, or one or more categories or subcategories of “treatment works treating domestic sewage”, if the sources or “treatment works treating domestic sewage” within each category or subcategory all:

(A) Involve the same or substantially similar types of operations;

(B) Discharge the same types of wastes or engage in the same types of sludge use or disposal practices;

(C) Require the same effluent limitations, operating conditions, or standards for sewage sludge use or disposal;

(D) Require the same or similar monitoring; and

(E) In the opinion of the Department are more appropriately controlled under a general permit than under individual permits.

(3) Water quality-based limits. Where sources within a specific category or subcategory of dischargers are subject to water-quality-based limits imposed pursuant to 40CFR122.44, the sources in that specific category or subcategory shall be subject to the same water-quality-based effluent limitations.

(4) Other requirements.

(i) The general permit must clearly identify the applicable conditions for each category or subcategory of dischargers or treatment works treating domestic sewage covered by the permit.

(ii) The general permit may exclude specified sources or areas from coverage.

(b) Administration.

(1) In general. General permits may be issued, modified, revoked and reissued, or terminated in accordance with applicable requirements of R61-9.124. Special procedures for issuance are found at 40 CFR 123.44.

(2) Authorization to discharge or authorization to engage in sludge use and disposal practices.

(i) Except as provided in paragraphs (b)(2)(v) and (b)(2)(vi) of this section, dischargers (or treatment works treating domestic sewage) seeking coverage under a general permit shall submit to the Department a written notice of intent to be covered by the general permit. A discharger (or treatment works treating domestic sewage) who fails to submit a notice of intent in accordance with the terms of the permit is not authorized to discharge (or in the case of sludge disposal permit, to engage in a sludge use or disposal practice), under the terms of the general permit unless the general permit, in accordance with paragraph (b)(2)(v) of this section, contains a provision that a notice of intent is not required or the Department notifies a discharger (or treatment works treating domestic sewage) that it is covered by a general permit in accordance with paragraph (b)(2)(vi) of this section. A complete and timely notice of intent (NOI) to be covered in accordance with general permit requirements, fulfills the requirements for permit applications for purposes of sections 122.6, 122.21 and 122.26. As of December 21, 2020, all notices of intent submitted in compliance with this section must be submitted electronically by the discharger (or treatment works treating domestic sewage) to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, discharger (or treatment works treating domestic sewage) may be required to report electronically if specified by a particular permit or if required to do so by State law.

(ii) The contents of the notice of intent shall be specified in the general permit and shall require the submission of information necessary for adequate program implementation, including at a minimum, the legal name and address of the owner or operator, the facility name and address, type of facility or discharges, and the receiving stream(s), and other required data elements as identified in appendix A to 40 CFR Part 127. General permits for storm water discharges associated with industrial activity from inactive mining, inactive oil and gas operations, or inactive landfills occurring on Federal lands where an operator cannot be identified may contain alternative notice of intent requirements. All notices of intent shall be signed in accordance with section 122.22. Notices of intent for coverage under a general permit for concentrated animal feeding operations (CAFO) must include the information specified in section 122.21(i)(1), including a topographic map.

(iii) General permits shall specify the deadlines for submitting notices of intent to be covered and the date(s) when a discharger is authorized to discharge under the permit.

(iv) General permits shall specify whether a discharger (or treatment works treating domestic sewage) that has submitted a complete and timely notice of intent to be covered in accordance with the general permit and that is eligible for coverage under the permit, is authorized to discharge (or in the case of a sludge disposal permit, to engage in a sludge use or disposal practice) in accordance with the permit either upon receipt of the notice of intent by the Department, after a waiting period specified in the general permit, on a date specified in the general permit, or upon receipt of notification of inclusion by the Department. Coverage may be terminated or revoked in accordance with paragraph (b)(3) of this section.

(v) Discharges other than discharges from publicly owned treatment works, combined sewer overflows, municipal separate storm sewer systems, primary industrial facilities, and storm water discharges associated with industrial activity may, at the discretion of the Department, be authorized to discharge under a general permit without submitting a notice of intent where the Department finds that a notice of intent requirement would be inappropriate. In making such a finding, the Department shall consider: the type of discharge; the expected nature of the discharge; the potential for toxic and conventional pollutants in the discharges; the expected volume of the discharges; other means of identifying discharges covered by the permit; and the estimated number of discharges to be covered by the permit. The Department shall provide in the public notice of the general permit the reasons for not requiring a notice of intent.

(vi) The Department may notify a discharger (or treatment works treating domestic sewage) that it is covered by a general permit, even if the discharger (or treatment works treating domestic sewage) has not submitted a notice of intent to be covered. A discharger (or treatment works treating domestic sewage) so notified may request an individual permit under paragraph (b)(3)(iii) of this section.

(3) Requiring an individual permit.

(i) The Department may require any person authorized by a general permit to apply for and obtain an individual NPDES permit, Land Application permit, or State permit (See R.61-9.505 for Land Application permit and State permit requirements). An applicant, any affected state, or interstate agency, the Regional Administrator, or any other interested person may petition the Department to take action under this paragraph. The petition shall indicate specific reasons why an individual permit is requested and the interest in or relationship of the petitioner to the applicant. Cases where an individual NPDES permit, Land Application permit, or State permit (See R.61-9.505 for Land Application permit and State permit requirements) may be required include the following:

(A) The discharger or "treatment works treating domestic sewage" is not in compliance with the conditions of the general NPDES permit, Land Application permit, or State permit (See R.61-9.505 for Land Application permit and State permit requirements);

(B) A change has occurred in the availability of demonstrated technology or practices for the control or abatement of pollutants applicable to the point source or treatment works treating domestic sewage;

(C) Effluent limitation guidelines are promulgated for point sources covered by the general NPDES permit, Land Application permit, or State permit (See R.61-9.505 for Land Application permit and State permit requirements);

(D) A Water Quality Management plan containing requirements applicable to such point sources is approved;

(E) Circumstances have changed since the time of the request to be covered so that the discharger is no longer appropriately controlled under the general permit, or either a temporary or permanent reduction or elimination of the authorized discharge is necessary;

(F) Standards for sewage sludge use or disposal have been promulgated for the sludge use and disposal practice covered by the general NPDES permit, Land Application permit, or State permit (See R.61-9.505 for Land Application permit and State permit requirements); or

(G) The discharge(s) is a significant contributor of pollutants. In making this determination, the Department may consider the following factors:

- (1) The location of the discharge with respect to waters of the State;
- (2) The size of the discharge;
- (3) The quantity and nature of the pollutants discharged to waters of the State; and
- (4) Other relevant factors.

(ii) [Reserved]

(iii) Any owner or operator authorized by a general permit may request to be excluded from the coverage of the general permit by applying for an individual permit. The owner or operator shall submit an application under section 122.21, with reasons supporting the request, to the Department no later than 90 days after the publication of the general permit in the State Register. The request shall be processed in accordance with R.61-9.124. The request shall be granted by issuing of an individual permit if the reasons cited by the owner or operator are adequate to support the request.

(iv) When an individual NPDES permit, Land Application permit, or State permit (See R.61-9.505 for Land Application permit and State permit requirements) is issued to an owner or operator otherwise subject to a general NPDES, Land Application, or State permit, the applicability of the general permit to the individual NPDES, Land Application, or State permittee is automatically terminated on the effective date of the individual permit.

(v) A source excluded from a general permit solely because it already has an individual permit may request that the individual permit be revoked, and that it be covered by the general permit. Upon revocation of the individual permit, the general permit shall apply to the source.

(4) Definitions:

(i) "General Permit Application" means an application filed by a potential permittee with the Department for a general permit.

(ii) Notice of Intent" (NOI) means a form used by potential permittees to notify the Department, within a specified time, that they intend to comply with the general permit or that they do not wish to be covered by the general permit and wish an individual permit.

(c) Degree of Waste Treatment Required. All pollutants shall receive such treatment or corrective action so as to insure compliance with the terms and conditions of the issued permit and with the following, whenever applicable:

(1) Effluent limitations established by the EPA pursuant to Sections 301, 302, 303, 306, 307, 308, 318, and 405 of the Federal CWA;

(2) Criteria and standards for Best Management practices established by EPA pursuant to Section 304(e) of the Federal CWA;

(3) Notwithstanding the above, more stringent effluent limitations may be required as deemed necessary by the Department (i) to meet any other existing federal laws or regulations, or (ii) to insure compliance with any applicable State water quality standards, effluent limitations, or treatment standards; and

(4) Calculations and specifications of effluent limits and standards shall be made in accordance with the provisions of section 122.45.

(d) Submittals and Signatory Requirements.

(1) An NOI shall be on forms as may be prescribed and furnished from time to time by the Department. A NOI shall be accompanied by all pertinent information as the Department may require in order to establish effluent limitations in accordance with this regulation, including, but not limited to, complete engineering reports, schedule of progress, plans, specifications, maps, measurements, quantitative and qualitative determinations, records, and all related materials.

(2) Engineering reports, plans, specifications, and other material submitted to the Department's NPDES or State permitting (See R.61-9.505 for Land Application permit and State permit requirements) divisions shall be signed by a Professional Engineer registered in State of South Carolina and competent in the field of sewage and industrial waste treatment.

(3) Material submitted shall be complete and accurate.

(4) Any NOI form submitted to the Department shall be signed in accordance with this Regulation.

(5) All other reports or requests for information required by the Department shall be signed by a person designated in section 122.22 or a duly authorized representative of such person, if:

(i) The representative so authorized is responsible for the overall operation of the facility from which the discharge originates, e.g., a plant manager, superintendent or person of equivalent responsibility;

(ii) The authorization is made in writing by the person designated under section 122.22; and

(iii) The written authorization is submitted to the Department.

(6) Any changes in the written authorization submitted to the Department which occur after the issuance of a permit shall be reported to the Department by submitting a copy of a new written authorization that meets the requirements of (5) above.

(7) Any person signing any document under (d) above shall make the following certification: "I certify under penalty of law that I have personally examined and am familiar with the information submitted in the attached document; and based on my inquiry of those individuals immediately responsible for obtaining the information, I believe the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

(e) Other Requirements.

(1) Notice and Public Participation. Public notice and participation requirements shall be in accordance with this Regulation.

(2) Terms and Conditions of Permits. General permits issued shall be subject to the terms and conditions contained in this Regulation.

(3) Monitoring, Recording and Reporting Requirements. Monitoring, recording, and reporting requirements shall be in accordance with the permit and this Regulation.

(4) Duration, Continuation, and Transferability of Permits. General permits shall be issued for a fixed term in accordance with this Regulation.

HISTORY: Amended by SCSR 43-11 Doc. No. 4888, eff November 22, 2019.

122.29. New sources and new dischargers.

(a) Definitions.

(1) "New source" and "new discharger" are defined in section 122.2.

(2) "Source" means any building, structure, facility, or installation from which there is or may be a discharge of pollutants.

(3) "Existing source" means any source which is not a new source or a new discharger.

(4) "Site" is defined in section 122.2;

(5) "Facilities or equipment" means buildings, structures, process or production equipment or machinery which form a permanent part of the new source and which will be used in its operation, if

these facilities or equipment are of such value as to represent a substantial commitment to construct. It excludes facilities or equipment used in connection with feasibility, engineering, and design studies regarding the source or water pollution treatment for the source.

(b) Criteria for new source determination.

(1) Except as otherwise provided in an applicable new source performance standard, a source is a "new source" if it meets the definition of "new source" in section 122.2, and

(i) It is constructed at a site at which no other source is located; or

(ii) It totally replaces the process or production equipment that causes the discharge of pollutants at an existing source; or

(iii) Its processes are substantially independent of an existing source at the same site. In determining whether these processes are substantially independent, the Department shall consider such factors as the extent to which the new facility is integrated with the existing plant; and the extent to which the new facility is engaged in the same general type of activity as the existing source.

(2) A source meeting the requirements of paragraphs (b)(1)(i), (ii), or (iii) of this section is a new source only if a new source performance standard is independently applicable to it. If there is no such independently applicable standard, the source is a new discharger. See section 122.2.

(3) Construction on a site at which an existing source is located results in a modification subject to section 122.62 rather than a new source (or a new discharger) if the construction does not create a new building, structure, facility, or installation meeting the criteria of paragraphs (b)(1)(ii) or (iii) of this section but otherwise alters, replaces, or adds to existing process or production equipment.

(4) Construction of a new source as defined under section 122.2 has commenced if the owner or operator has:

(i) Begun, or caused to begin as part of a continuous on-site construction program:

(A) Any placement, assembly, or installation of facilities or equipment; or

(B) Significant site preparation work including clearing, excavation, or removal of existing buildings, structures, or facilities which is necessary for the placement, assembly, or installation of new source facilities or equipment; or

(ii) Entered into a binding contractual obligation for the purchase of facilities or equipment which are intended to be used in its operation within a reasonable time. Options to purchase or contracts which can be terminated or modified without substantial loss, and contracts for feasibility, engineering, and design studies do not constitute a contractual obligation under the paragraph.

(c) [Reserved]

(d) Effect of compliance with new source performance standards. (The provisions of this paragraph do not apply to existing sources which modify their pollution control facilities or construct new pollution control facilities and achieve performance standards, but which are neither new sources or new dischargers or otherwise do not meet the requirements of this paragraph.)

(1) Except as provided in paragraph (d)(2) of this section, any new discharger, the construction of which commenced after October 18, 1972, or new source which meets the applicable promulgated new source performance standards before the commencement of discharge, may not be subject to any more stringent new source performance standards or to any more stringent technology-based standards under section 301(b)(2) of CWA for the soonest ending of the following periods:

(i) Ten years from the date that construction is completed;

(ii) Ten years from the date the source begins to discharge process or other non-construction related wastewater; or

(iii) The period of depreciation or amortization of the facility for the purposes of section 167 or 169 (or both) of the Internal Revenue Code of 1954.

(2) The protection from more stringent standards of performance afforded by paragraph (d)(1) of this section does not apply to:

(i) Additional or more stringent permit conditions which are not technology based; for example, conditions based on water quality standards, or toxic effluent standards or prohibitions under section 307(a) of CWA; or

(ii) Additional permit conditions in accordance with section 125.3 controlling toxic pollutants or hazardous substances which are not controlled by new source performance standards. This includes permit conditions controlling pollutants other than those identified as toxic pollutants or hazardous substances when control of these pollutants has been specifically identified as the method to control the toxic pollutants or hazardous substances.

(3) When an NPDES permit issued to a source with a “protection period” under paragraph (d)(1) of this section will expire on or after the expiration of the protection period, that permit shall require the owner or operator of the source to comply with the requirements of section 301 and any other then applicable requirements of CWA immediately upon the expiration of the protection period. No additional period for achieving compliance with these requirements may be allowed except when necessary to achieve compliance with requirements promulgated less than 3 years before the expiration of the protection period.

(4) The owner or operator of a new source, a new discharger which commenced discharge after August 13, 1979, or a recommencing discharger shall install and have in operating condition, and shall “start-up” all pollution control equipment required to meet the conditions of its permits before beginning to discharge. Within the shortest feasible time (not to exceed 90 days), the owner or operator must meet all permit conditions. The requirements of this paragraph do not apply if the owner or operator is issued a permit containing a compliance schedule under section 122.47(a)(2).

(5) After the effective date of new source performance standards, it shall be unlawful for any owner or operator of any new source to operate the source in violation of those standards applicable to the source.

122.30. What are the objectives of the storm water regulations for small MS4s?

(a) Sections 122.30 through 122.36 are written in a “readable regulation” format.

(b) Under the statutory mandate in section 402(p)(6) of the Clean Water Act, the purpose of this portion of the storm water program is to designate additional sources that need to be regulated to protect water quality and to establish a comprehensive storm water program to regulate these sources. (Because the storm water program is part of the National Pollutant Discharge Elimination System (NPDES) Program, you should also refer to section 122.1 which addresses the broader purpose of the NPDES program.)

(c) Storm water runoff continues to harm the nation’s waters. Runoff from lands modified by human activities can harm surface water resources in several ways including changing natural hydrologic patterns and elevating pollutant concentrations and loadings. Storm water runoff may contain or mobilize high levels of contaminants, such as sediment, suspended solids, nutrients, heavy metals, pathogens, toxins, oxygen-demanding substances, and floatables.

(d) EPA and the Department strongly encourage partnerships and the watershed approach as the management framework for efficiently, effectively, and consistently protecting and restoring aquatic ecosystems and protecting public health.

122.31. Indian Tribes. As a Tribe, what is my role under the NPDES storm water program?

As a Tribe you may:

(a) Be authorized to operate the NPDES program including the storm water program, after EPA determines that you are eligible for treatment in the same manner as a State under sections 123.31 through 123.34. (If you do not have an authorized NPDES program, the Department implements the program for discharges on your reservation.);

(b) Be classified as an owner of a regulated small MS4, as defined in section 122.32. (Designation of your Tribe as an owner of a small MS4 for purposes of this part is an approach that is consistent with U.S. EPA’s 1984 Indian Policy of operating on a government-to-government basis with EPA looking to Tribes as the lead governmental authorities to address environmental issues on their reservations as appropriate. If you operate a separate storm sewer system that meets the definition

of a regulated small MS4, you are subject to the requirements under sections 122.33 through 122.35. If you are not designated as a regulated small MS4, you may ask EPA to designate you as such for the purposes of this part.); or

(c) Be a discharger of storm water associated with industrial activity or small construction activity under sections 122.26(b)(14) or (b)(15), in which case you must meet the applicable requirements. Within Indian country, the NPDES permitting authority is the Department, unless you are authorized to administer the NPDES program.

122.32. Is an operator of a small MS4 regulated under the NPDES storm water program?

(a) Unless you qualify for a waiver under paragraph (c) of this section, you are regulated if you operate a small MS4, including but not limited to systems operated by federal, State, Tribal, and local governments, including State departments of transportation, and:

(1) Your small MS4 is located in an urbanized area as determined by the latest Decennial Census by the Bureau of the Census (If your small MS4 is not located entirely within an urbanized area, only the portion that is within the urbanized area is regulated.); or

(2) You are designated by the Department, including where the designation is pursuant to 40 CFR 123.35(b)(3) or (b)(4) or is based upon a petition under section 122.26(f).

(b) You may be the subject of a petition to the NPDES permitting authority to require an NPDES permit for your discharge of storm water. If the NPDES permitting authority determines that you need a permit, you are required to comply with sections 122.33 through 122.35.

(c) The Department may waive the requirements otherwise applicable to you if you meet the criteria of paragraph (d) or (e) of this section. If you receive a waiver under this section, you may subsequently be required to seek coverage under an NPDES permit in accordance with section 122.33(a) if circumstances change. (See also section 123.35(b) of 40CFR123.)

(d) The Department may waive permit coverage if your MS4 serves a population of less than 1,000 within the urbanized area and you meet the following criteria:

(1) Your system is not contributing substantially to the pollutant loadings of a physically interconnected MS4 that is regulated by the NPDES storm water program (see section 123.35(b)(4) of 40CFR123) and

(2) If you discharge any pollutant(s) that have been identified as a cause of impairment of any water body to which you discharge, storm water controls are not needed based on wasteload allocations that are part of an EPA-approved or established total maximum daily load (TMDL) that addresses the pollutant(s) of concern.

(e) The Department may waive permit coverage if your MS4 serves a population under 10,000 and you meet the following criteria:

(1) The Department has evaluated all waters of the U.S., including small streams, tributaries, lakes, and ponds, that receive a discharge from your MS4;

(2) For all such waters, the Department has determined that storm water controls are not needed based on wasteload allocations that are part of an EPA-approved or established TMDL that addresses the pollutant(s) of concern or, if a TMDL has not been developed or approved, an equivalent analysis that determines sources and allocations for the pollutant(s) of concern;

(3) For the purpose of this paragraph (e), the pollutant(s) of concern include biochemical oxygen demand (BOD), sediment or a parameter that addresses sediment (such as total suspended solids, turbidity or siltation), pathogens, oil and grease, and any pollutant that has been identified as a cause of impairment of any water body that will receive a discharge from your MS4; and

(4) The Department has determined that future discharges from your MS4 do not have the potential to result in exceedances of water quality standards, including impairment of designated uses, or other significant water quality impacts, including habitat and biological impacts.

(f) Process for designating small MS4 to require storm water NPDES permitting. The Department will designate small MS4s according to the following criteria as a determination that a storm water discharge results in or has the potential to result in exceedances of water quality standards, including impairment of designated uses, or other significant water quality impacts, including habitat and biological impacts.

(1) The Department will make initial designations on a watershed basis but no later than December 8, 2004 [except see the phasing considerations in (h)(3) for MS4 with population less than 10,000], as follows:

(i) All MS4 which are located within an urbanized area as defined by the U.S. Bureau of the Census are to be designated and must obtain permits, unless a waiver is granted. (Many of the municipalities and counties which are small MS4 covered by this requirement are listed in Appendix 6 of 64FR68722, December 8, 1999.)

(ii) Consider all small MS4 with a population density of at least 1000 persons per square mile and a population of at least 10,000 located outside urban areas, according to the criteria. (Six municipalities which meet these descriptions are listed in Appendix 7 of 64FR68722.)

(iii) Consider small MS4 which are adjacent to and impact a designated MS4, according to criteria.

(iv) Consider other government entities which are MS4 relevant to criteria (e.g., military installations, prisons, and state, county, or municipal school, or hospital campuses).

(v)(A) Consider MS4 for which petitions are received requesting that permitting be required.

(B) See section 122.26(f)(5) as to the period for making a determination on designation.

(2) The Department will designate small MS4 to require permitting, as follows:

(i) Small MS4 within urbanized areas;

(ii) Entire municipalities which meet the criteria;

(iii) Counties, military installations, prisons, and state, county, or municipal school or hospital campuses, giving consideration to whether solely the urbanized areas should be designated;

(iv) Small MS4 physically interconnected with and substantially affecting regulated MS4, according to the criteria.

(3) In the process of designating small MS4, the Department will inform entities of the waiver requirements of 40 CFR 123.35(d) and evaluate any requested waiver in making a designation decision.

(4) The Department will evaluate any entity for which a petition is received requesting that a permit be required, based on criteria.

(5) The Department will reevaluate to designate appropriate, additional MS4 whenever the 303(d) list is revised.

(6) The Department will reevaluate at each census only to designate additional small MS4.

(g) Criteria for Designating Small MS4 for Storm Water NPDES Permitting

(1) Any small MS4 with a population of 10,000 or more and a population density of 1000 persons per square mile meeting any criterion will be designated, unless one or more of the exceptions in (1)(i) below applies. For smaller or less-densely populated MS4, the following criteria will be used in any evaluation of whether they should be designated to require a permit.

(i) Any water body receiving storm water from the MS4 is on the South Carolina {303(d)} list of impaired waters for a pollutant discharged in the storm water of the entity or a pollutant contributing to the standards violation leading to listing, unless the MS4 shows that it meets one of the following exceptions:

(A) The runoff from the MS4 caused by a 2-inch rainstorm would be less than one (1) percent of the annual average flow of each receiving stream on the 303(d) list;

(B) The MS4 has excellent BMP in place and presents data showing exemplary quality storm water runoff;

(C) The MS4 has a low ratio of runoff to rainfall (e.g., sandy soil) and moderate (that is, not high) water table; or

(D) The MS4 is shown to have a significantly lower percentage of impermeable area than would be expected for its level of development.

(ii) Any water body receiving storm water from the MS4 is classed ONRW, ORW, or Freshwater-Trout or is open for shellfish harvesting.

(iii) Population growth in the MS4 between the 1990 and 2000 (or the two most-recent) censuses has been 10 percent or more or growth has been 2 percent or more in each of the three (3) most-recent years.

(iv) The MS4 is located within 3 miles of an urbanized area, and the MS4 under consideration discharges storm water to one or more of the water bodies which receive storm water from the urbanized area.

(v) An MS4 which has been partly (at least 25%) designated (e.g., part lying within an urbanized area). Consideration will be given to designating only the portion of a county, military installation, prison, or state, county, or municipal school or hospital campus which is in the relevant urbanized area or, for the more extensively developed counties, designating areas up to three (3) miles from the boundary of the urbanized area.

(vi) The population density of the MS4 is at least 1500 persons per square mile.

(2) The following matters may also be considered in deciding whether a permit is required.

(i) The storm water discharge of an MS4 is causing or contributing to a violation of a water quality standard.

(ii) An MS4 is subject to activity contributing or expected to contribute to storm water contamination; for example, frequent military training exercises.

(iii) An MS4 includes industries with significant particulate emissions (such as battery manufacturing {e.g., lead}, steel manufacturing, etc.)

(iv) An MS4 includes a high percentage of impermeable area (pavement, roof).

(v) An MS4 owns or operates a wastewater treatment facility which has a history of being on the NPDES "Significant Non-compliance List" for effluent violations.

(vi) An MS4 approaches but does not reach two or more of the criteria in (1) above.

(3) Government-owned educational institutions, hospital and prison complexes, and military bases outside of urban areas will be considered in the same manner as municipalities outside urban areas. That is, if they have a population of 10,000 or more and a population density of 1500 persons per square mile, they will be designated. If they are less populated or less-densely populated, they will be considered based on the criteria, if a petition requests that a permit be required.

(4) As an initial decision, designate any small MS4 which has either greater than 2000 total population with a density of at least 1500 persons per square mile or greater than 4000 total population with a density of at least 1000 persons per square mile and which is within the boundaries of or whose boundaries touch, and which drains to at least one basin which receives drainage from, a permitted or designated MS4. However, consider exceptions and "other considerations" stated elsewhere in these criteria.

(h) Waivers and Phasing. The Department may waive or phase in the requirements otherwise applicable to regulated small MS4s, as defined in Sec. 122.32(a)(1) and (2) of this item, under the following circumstances:

(1) The Department may waive permit coverage for each small MS4 in jurisdictions with a population under 1,000 within the urbanized area according to section 122.32(d).

(2) The Department may waive permit coverage for each small MS4 in jurisdictions with a population under 10,000 according to section 122.32(e).

(3) The Department may phase in permit coverage for small MS4s serving jurisdictions with a population under 10,000 on a schedule consistent with a State watershed permitting approach. Under this approach, the Department will permit coverage for small MS4s that qualify for such phased-in coverage during the year assigned for permitting in the basin where it is located. Under this option, all regulated small MS4s are required to have coverage under an NPDES permit no later than March 8, 2007.

(4) The Department will periodically review any waivers granted in accordance with paragraph (h)(2) of this section to determine whether any of the information required for granting the waiver has changed. At a minimum, the reviews will be conducted once every five years during pertinent years for basin permit issuance. In addition, the Department will consider any petition to review

any waiver when the petitioner provides evidence that the information required for granting the waiver has substantially changed.

122.33. How does an operator of a regulated, small MS4 apply for an NPDES permit, and when must he apply?

(a) If you operate a regulated, small MS4 under section 122.32, you must seek coverage under a NPDES permit issued by the Department. As South Carolina is an NPDES authorized State, then the State is your NPDES permitting authority.

(b) You must seek authorization to discharge under a general or individual NPDES permit, as follows:

(1) If the Department has issued a general permit applicable to your discharge and you are seeking coverage under the general permit, you must submit a Notice of Intent (NOI) that includes the information on your best management practices and measurable goals required by section 122.34(d). You may file your own NOI, or you and other municipalities or governmental entities may jointly submit an NOI. If you want to share responsibilities for meeting the minimum measures with other municipalities or governmental entities, you must submit an NOI that describes which minimum measures you will implement and identify the entities that will implement the other minimum measures within the area served by your MS4. The general permit will explain any other steps necessary to obtain permit authorization.

(2)(i) If you are seeking authorization to discharge under an individual permit and wish to implement a program under section 122.34, you must submit an application to the Department that includes the information required under sections 122.21(f) and 122.34(d), an estimate of the area in square miles served by your small MS4, and any additional information that your NPDES permitting authority requests. A storm sewer map that satisfies the requirement of section 122.34(b)(3)(i) will satisfy the map requirement in section 122.21(f)(7).

(ii) If you are seeking authorization to discharge under an individual permit and wish to implement a program that is different from the program under section 122.34, you will need to comply with the permit application requirements of section 122.26(d). You must submit both Parts of the application requirements in sections 122.26(d)(1) and (2) by March 10, 2003. You do not need to submit the information required by sections 122.26(d)(1)(ii) and (d)(2) regarding your legal authority, unless you intend for the permit writer to take such information into account when developing your other permit conditions.

(iii) If allowed by the Department, you and another regulated entity may jointly apply under either paragraph (b)(2)(i) or (b)(2)(ii) of this section to be co-permittees under an individual permit.

(3) If your small MS4 is in the same urbanized area as a medium or large MS4 with an NPDES storm water permit and that other MS4 is willing to have you participate in its storm water program, you and the other MS4 may jointly seek a modification of the other MS4 permit to include you as a limited co-permittee. As a limited co-permittee, you will be responsible for compliance with the permit's conditions applicable to your jurisdiction. If you choose this option you will need to comply with the permit application requirements of section 122.26, rather than the requirements of section 122.34. You do not need to comply with the specific application requirements of section 122.26(d)(1)(iii) and (iv) and (d)(2)(iii) (discharge characterization). You may satisfy the requirements in section 122.26 (d)(1)(v) and (d)(2)(iv) (identification of a management program) by referring to the other MS4's storm water management program.

(c) If you operate a regulated, small MS4:

(1) Designated under section 122.32(a)(1), you must apply for coverage under an NPDES permit, or apply for a modification of an existing NPDES permit under paragraph (b)(3) of this section by March 10, 2003, unless your MS4 serves a jurisdiction with a population under 10,000 and the Department has established a phasing schedule under 40CFR123.35(d)(3).

(2) Designated under section 122.32(a)(2), you must apply for coverage under an NPDES permit, or apply for a modification of an existing NPDES permit under paragraph (b)(3) of this section, within 180 days of receiving the notice of designation, unless the Department grants a later date.

122.34. As an operator of a regulated, small MS4, what will my NPDES MS4 storm water permit require?

(a) Your NPDES MS4 permit will require at a minimum that you develop, implement, and enforce a storm water management program designed to reduce the discharge of pollutants from your MS4 to the maximum extent practicable (MEP), to protect water quality, and to satisfy the appropriate water quality requirements of the Clean Water Act. Your storm water management program must include the minimum control measures described in paragraph (b) of this section unless you apply for a permit under section 122.26(d). For purposes of this section, narrative effluent limitations requiring implementation of best management practices (BMP) are generally the most appropriate form of effluent limitations when designed to satisfy technology requirements (including reductions of pollutants to the maximum extent practicable) and to protect water quality. Implementation of best management practices consistent with the provisions of the storm water management program required pursuant to this section and the provisions of the permit required pursuant to section 122.33 constitutes compliance with the standard of reducing pollutants to the “maximum extent practicable.” The Department will specify a period of up to 5 years from the date of permit issuance for you to develop and implement your program.

(b) Minimum control measures:

(1) Public education and outreach on storm water impacts. You must implement a public education program to distribute educational materials to the community or conduct equivalent outreach activities about the impacts of storm water discharges on water bodies and the steps that the public can take to reduce pollutants in storm water runoff.

(2) Public involvement/participation. You must, at a minimum, comply with State and local public notice requirements when implementing a public involvement/participation program.

(3) Illicit discharge detection and elimination.

(i) You must develop, implement and enforce a program to detect and eliminate illicit discharges [as defined at section 122.26(b)(2)] into your small MS4.

(ii) You must:

(A) Develop, if not already completed, a storm sewer system map, showing the location of all outfalls and the names and locations of all waters of the United States that receive discharges from those outfalls;

(B) To the extent allowable under State or local law, effectively prohibit, through ordinance, or other regulatory mechanism, non-storm water discharges into your storm sewer system and implement appropriate enforcement procedures and actions;

(C) Develop and implement a plan to detect and address non-storm-water discharges, including illegal dumping, to your system; and

(D) Inform public employees, businesses, and the general public of hazards associated with illegal discharges and improper disposal of waste.

(iii) You need address the following categories of non-storm water discharges or flows (i.e., illicit discharges) only if you identify them as significant contributors of pollutants to your small MS4: water line flushing, landscape irrigation, diverted stream flows, rising ground waters, uncontaminated ground water infiltration [as defined at 40 CFR 35.2005(20)], uncontaminated, pumped ground water, discharges from potable water sources, foundation drains, air conditioning condensate, irrigation water, springs, water from crawl space pumps, footing drains, lawn watering, individual residential car washing, flows from riparian habitats and wetlands, dechlorinated swimming pool discharges, and street wash water (discharges or flows from fire fighting activities are excluded from the effective prohibition against non-storm water and need only be addressed where they are identified as significant sources of pollutants to waters of the United States).

(4) Construction site storm water runoff control.

(i) You must develop, implement, and enforce a program to reduce pollutants in any storm water runoff to your small MS4 from construction activities that result in a land disturbance of greater than or equal to one acre. Reduction of storm water discharges from construction activity disturbing less than one acre must be included in your program if that construction activity is part of a larger common plan of development or sale that would disturb one acre or more. If the

Department waives requirements for storm water discharges associated with small construction activity in accordance with section 122.26(b)(15)(i), you are not required to develop, implement, and/or enforce a program to reduce pollutant discharges from such sites.

(ii) Your program must include the development and implementation of, at a minimum:

(A) An ordinance or other regulatory mechanism to require erosion and sediment controls, as well as sanctions to ensure compliance, to the extent allowable under State or local law;

(B) Requirements for construction site operators to implement appropriate erosion and sediment control best management practices;

(C) Requirements for construction site operators to control waste such as discarded building materials, concrete-truck washout, chemicals, litter, and sanitary waste at the construction site that may cause adverse impacts to water quality;

(D) Procedures for site plan review which incorporate consideration of potential water quality impacts;

(E) Procedures for receipt and consideration of information submitted by the public; and

(F) Procedures for site inspection and enforcement of control measures.

(5) Post-construction storm water management in new development and redevelopment.

(i) You must develop, implement, and enforce a program to address storm water runoff from new development and redevelopment projects that disturb greater than or equal to one acre, including projects less than one acre that are part of a larger common plan of development or sale, that discharge into your small MS4. Your program must ensure that controls are in place that would prevent or minimize water quality impacts.

(ii) You must:

(A) Develop and implement strategies which include a combination of structural and/or non-structural best management practices (BMP) appropriate for your community;

(B) Use an ordinance or other regulatory mechanism to address post-construction runoff from new development and redevelopment projects to the extent allowable under State, Tribal, or local law; and

(C) Ensure adequate long-term operation and maintenance of BMP.

(6) Pollution prevention/good housekeeping for municipal operations. You must develop and implement an operation and maintenance program that includes a training component and has the ultimate goal of preventing or reducing pollutant runoff from municipal operations. Using training materials that are available from EPA, your State, Tribe, or other organizations, your program must include employee training to prevent and reduce storm water pollution from activities such as park and open space maintenance, fleet and building maintenance, new construction and land disturbances, and storm water system maintenance.

(c) If an existing, qualifying local program requires you to implement one or more of the minimum control measures of paragraph (b) of this section, the Department may include conditions in your NPDES permit that direct you to follow the Department's requirements rather than the requirements of paragraph (b) of this section. A qualifying local program is a local storm water management program that imposes, at a minimum, the relevant requirements of paragraph (b) of this section.

(d)(1) In your permit application (either a notice of intent for coverage under a general permit or an individual permit application), you must identify and submit to the Department the following information:

(i) The best management practices (BMP) that you or another entity will implement for each of the storm water minimum control measures at paragraphs (b)(1) through (b)(6) of this section;

(ii) The measurable goals for each of the BMP including, as appropriate, the months and years in which you will undertake required actions, including interim milestones and the frequency of the action; and

(iii) The person or persons responsible for implementing or coordinating your storm water management program.

(2) If you obtain coverage under a general permit, you are not required to meet any measurable goal(s) identified in your notice of intent in order to demonstrate compliance with the minimum control measures in paragraphs (b)(3) through (b)(6) of this section unless, prior to submitting your NOI, EPA or the Department has provided or issued a menu of BMP that addresses each such minimum measure. Even if no regulatory authority issues the menu of BMP, however, you still must comply with other requirements of the general permit, including good faith implementation of BMP designed to comply with the minimum measures.

(e) You must comply with any more stringent effluent limitations in your permit, including permit requirements that modify, or are in addition to, the minimum control measures based on an approved total maximum daily load (TMDL) or equivalent analysis. The Department may include such more stringent limitations based on a TMDL or equivalent analysis that determines such limitations are needed to protect water quality.

(f) You must comply with other applicable NPDES permit requirements, standards and conditions established in the individual or general permit, developed consistent with the provisions of sections 122.41 through 122.49, as appropriate.

(g) Evaluation and assessment:

(1) Evaluation. You must evaluate program compliance, the appropriateness of your identified best management practices, and progress towards achieving your identified measurable goals.

Note to Paragraph (g)(1): The Department may determine monitoring requirements for you in accordance with State/Tribal monitoring plans appropriate to your watershed. Participation in a group monitoring program is encouraged.

(2) Recordkeeping. You must keep records required by the NPDES permit for at least 3 years. You must submit your records to the Department only when specifically asked to do so. You must make your records, including a description of your storm water management program, available to the public at reasonable times during regular business hours (see section 122.7 for confidentiality provision). (You may assess a reasonable charge for copying. You may require a member of the public to provide advance notice.)

(3) Reporting. Unless you are relying on another entity to satisfy your NPDES permit obligations under section 122.35(a), you must submit annual reports to the Department for your first permit term. For subsequent permit terms, you must submit reports in year two and four unless the Department requires more frequent reports. As of December 21, 2020, all reports submitted in compliance with this section must be submitted electronically by the owner, operator, or the duly authorized representative of the small MS4 to the Department as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, the owner, operator, or the duly authorized representative of the small MS4 may be required to report electronically if specified by a particular permit or if required to do so by State law. Your report must include:

(i) The status of compliance with permit conditions, an assessment of the appropriateness of your identified best management practices and progress towards achieving your identified measurable goals for each of the minimum control measures;

(ii) Results of information collected and analyzed, including monitoring data, if any, during the reporting period;

(iii) A summary of the storm water activities you plan to undertake during the next reporting cycle;

(iv) A change in any identified best management practices or measurable goals for any of the minimum control measures; and

(v) Notice that you are relying on another governmental entity to satisfy some of your permit obligations (if applicable).

HISTORY: Amended by SCSR 43-11 Doc. No. 4888, eff November 22, 2019.

122.35. May an operator of a regulated small MS4 share the responsibility to implement the minimum control measures with other entities?

(a) You may rely on another entity to satisfy your NPDES permit obligations to implement a minimum control measure if:

- (1) The other entity, in fact, implements the control measure;
- (2) The particular control measure, or component thereof, is at least as stringent as the corresponding NPDES permit requirement; and
- (3) The other entity agrees to implement the control measure on your behalf. In the reports you must submit under section 122.34(g)(3), you must also specify that you rely on another entity to satisfy some of your permit obligations. If you are relying on another governmental entity regulated under section 122 to satisfy all of your permit obligations, including your obligation to file periodic reports required by section 122.34(g)(3), you must note that fact in your NOI, but you are not required to file the periodic reports. You remain responsible for compliance with your permit obligations if the other entity fails to implement the control measure (or component thereof). Therefore, EPA encourages you to enter into a legally binding agreement with that entity if you want to minimize any uncertainty about compliance with your permit.

(b) In some cases, the Department may recognize, either in your individual NPDES permit or in an NPDES general permit, that another governmental entity is responsible under an NPDES permit for implementing one or more of the minimum control measures for your small MS4 or that the Department itself is responsible. Where the Department does so, you are not required to include such minimum control measure(s) in your storm water management program. (For example, if a State or Tribe is subject to an NPDES permit that requires it to administer a program to control construction site runoff at the State or Tribal level and that program satisfies all of the requirements of section 122.34(b)(4), you could avoid responsibility for the construction measure, but would be responsible for the remaining minimum control measures.) Your permit may be reopened and modified to include the requirement to implement a minimum control measure if the entity fails to implement it.

122.36. As an operator of a regulated small MS4, what happens if I don't comply with the application or permit requirements in sections 122.33 through 122.35?

NPDES permits are federally enforceable. Violators may be subject to the enforcement actions and penalties described in Clean Water Act sections 309 (b), (c), and (g) and 505, or under applicable State, Tribal, or local law. Compliance with a permit issued pursuant to section 402 of the Clean Water Act is deemed compliance, for purposes of sections 309 and 505, with sections 301, 302, 306, 307, and 403, except any standard imposed under section 307 for toxic pollutants injurious to human health. If you are covered as a co-permittee under an individual permit or under a general permit by means of a joint Notice of Intent you remain subject to the enforcement actions and penalties for the failure to comply with the terms of the permit in your jurisdiction except as set forth in section 122.35(b).

PART C PERMIT CONDITIONS

122.41. Conditions applicable to all permits.

The following conditions apply to all NPDES permits. Additional conditions applicable to NPDES permits are in section 122.42. All conditions applicable to NPDES permit shall be incorporated into the permits either expressly or by reference. If incorporated by reference, a specific citation to the federal regulations (or the corresponding approved State regulations) must be given in the permit.

- (a) Duty to comply. The permittee must comply with all conditions of the permit. Any permit noncompliance constitutes a violation of the Clean Water Act and the Pollution Control Act and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or denial of a permit renewal application. The Department's approval of wastewater facility Plans and Specifications does not relieve the permittee of responsibility to meet permit limits.
 - (1) The permittee shall comply with effluent standards or prohibitions established under section 307(a) of the Clean Water Act for toxic pollutants and with standards for sewage sludge use or disposal established under section 405(d) of the CWA within the time provided in the regulations that establish these standards or prohibitions or standards for sewage sludge use or disposal, even if the permit has not yet been modified to incorporate the requirement.
 - (2) Failure to comply with permit conditions or the provisions of this regulation may subject the permittee to civil penalties under S.C. Code Section 48-1-330 or criminal sanctions under S.C.

Code Section 48-1-320. Sanctions for violations of the Federal Clean Water Act may be imposed in accordance with the provisions of 40 CFR Part 122.41(a)(2) and (3).

(3) A person who violates any provision of this regulation, a term, condition or schedule of compliance contained within a valid NPDES permit, or the State law is subject to the actions defined in the State law.

(b) Duty to reapply. If the permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, the permittee must apply for and obtain a new permit. (But see 122.4(g)(2)).

(c) Need to halt or reduce activity not a defense. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

(d) Duty to mitigate. The permittee shall take all reasonable steps to minimize or prevent any discharge or sludge use or disposal in violation of this permit which has a reasonable likelihood of adversely affecting human health or the environment.

(e)(1) Proper operation and maintenance. The permittee shall at all times properly operate and maintain in good working order and operate as efficiently as possible all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the terms and conditions of this permit. Proper operation and maintenance includes effective performance based on design facility removals, adequate funding, adequate operator staffing and training and also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems which are installed by a permittee only when the operation is necessary to achieve compliance with the conditions of the permit.

(2) The permittee shall develop and maintain at the facility a complete Operations and Maintenance Manual for the waste treatment facilities and/or land application system. The manual shall be made available for on-site review during normal working hours. The manual shall contain operation and maintenance instructions for all equipment and appurtenances associated with the waste treatment facilities and land application system. The manual shall contain a general description of the treatment process(es), the operational procedures to meet the requirements of (e)(1) above, and the corrective action to be taken should operating difficulties be encountered.

(3)(i) Except as stated in (ii) below, the permittee shall provide for the performance of daily treatment facility inspections by a certified operator of the appropriate grade as defined in the permit for the facility. The inspections shall include, but should not necessarily be limited to, areas which require visual observation to determine efficient operation and for which immediate corrective measures can be taken using the O & M manual as a guide. All inspections shall be recorded and shall include the date, time, and name of the person making the inspection, corrective measures taken, and routine equipment maintenance, repair, or replacement performed. The permittee shall maintain all records of inspections at the permitted facility as required by the permit, and the records shall be made available for on-site review during normal working hours.

(ii) The Department may make exceptions to operating requirements, if stated in the permit, as follows:

(A) Attendance by the certified operator of the appropriate grade ("the operator") is normally required only on days when treatment or discharge occurs.

(B) For performance of daily inspections, permits may allow a reduced grade of operator for limited time periods under specific circumstances when justified by the permittee in a staffing plan and approved by the Department.

(C) Reduced inspection frequency, but in no case less than weekly, may be suitable when specified in the permit, if there is complete telemetry of operating data and there is either a simple treatment system with a low potential for toxicity but requiring pumps or other electrical functions or the ability to stop the discharge for an appropriate period when necessary.

(D) In other circumstances where the permittee demonstrates the capability to evaluate the facility in an alternative manner equivalent to the inspection requirements in subparagraph 3(i).

(E) Any exceptions allowed under (A), (B), (C), and (D) above may be subject to compliance with the permit conditions.

(4)(i) Purpose. This regulation establishes rules for governing the operation and maintenance of wastewater sewer systems, including gravity or pressure interceptor sewers. It is the purpose of this rule to establish standards for the management of sewer systems to prevent and/or minimize system failures that would lead to public health or environmental impacts.

(ii) Authority and applicability. Under Section 48–1–30 of the Code of Laws of South Carolina (1976 as amended), the Department is authorized to adopt such rules and regulations as may be necessary to implement the Pollution Control Act. This regulation applies to all sewer systems that have been or would be subject to a DHEC construction permit under Regulation 61–67 and whose owner owns or operates the wastewater treatment system to which the sewer discharges and which discharges under NPDES. Nothing in this regulation supercedes a more stringent requirement that may be imposed by sewer system owners that manage wastewater from satellite systems. This regulation (122.41(e)(4)) is effective when published in the State Register.

(iii) General requirements. The requirements to properly operate and maintain sewer systems are the responsibility of the system owner. General Standards. The sewer system owner must:

(A) Properly manage, operate, and maintain at all times all parts of its sewer system(s), to include maintaining contractual operation agreements to provide services, if appropriate;

(B) Provide adequate capacity to convey base flows and peak flows for all parts of the sewer system or, if capital improvements are necessary to meet this standard, develop a schedule of short and long term improvements;

(C) Take all reasonable steps to stop and mitigate the impact of releases of wastewater to the environment; and

(D) Notify the Department within 30 days of a proposed change in ownership of a sewer system.

(iv) [Reserved]

(f) Permit actions. This permit may be modified, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance does not stay any permit condition.

(g) Property rights. This permit does not convey any property rights of any sort, or any exclusive privilege.

(h) Duty to provide information. The permittee shall furnish to the Department, within a reasonable time, any information which the Department may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit or to determine compliance with this permit. The permittee shall also furnish to the Department upon request, copies of records required to be kept by this permit.

(i) Inspection and entry. The permittee shall allow the Department, or an authorized representative (including an authorized contractor acting as a representative of the Department), upon presentation of credentials and other documents as may be required by law, to:

(1) Enter upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;

(2) Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

(3) Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and

(4) Sample or monitor at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by the Clean Water Act and Pollution Control Act, any substances or parameters at any location.

(j) Monitoring and records.

(1)(i)(A) Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity.

(B) Samples shall be reasonably distributed in time, while maintaining representative sampling.

(C) No analysis, which is otherwise valid, shall be terminated for the purpose of preventing the analysis from showing a permit or water quality violation.

(ii) Flow Measurements.

(A) Where primary flow meters are required, appropriate flow measurement devices and methods consistent with accepted scientific practices shall be present and used to ensure the accuracy and reliability of measurements of the volume of monitored discharges. The devices shall be installed, calibrated, and maintained to ensure that the accuracy of the measurements is consistent with the accepted capability of that type of device. Devices selected shall be capable of measuring flows with a maximum deviation of not greater than 10 percent from the true discharge rates throughout the range of expected discharge volumes. The primary flow device, where required, must be accessible to the use of a continuous flow recorder.

(B) Where permits require an estimate of flow, the permittee shall maintain at the permitted facility a record of the method(s) used in "estimating" the discharge flow (e.g., pump curves, production charts, water use records) for the outfall(s) designated on limits pages to monitor flow by an estimate.

(C) Records of any necessary calibrations must be kept.

(iii) The Department may designate a single, particular day of the month on which any group of parameters listed in the permit must be sampled. When this requirement is imposed in a permit, the Department may waive or alter compliance with the permit requirement for a specific sampling event for extenuating circumstances.

(iv) The Department may require that a permittee monitor parameters in the stream receiving his permitted discharge as necessary to evaluate the need for and to establish limits and conditions and to insure compliance with water quality standards (i.e., R.61-68).

(2) Except for records of monitoring information required by this permit related to the permittee's sewage sludge use and disposal activities, which shall be retained for a period of at least five years (or longer as required by R.61-9.503 or R.61-9.504); the permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit, and records of all data used to complete the application for this permit, for a period of at least 3 years from the date of the sample, measurement, report or application. This period may be extended by request of the Department at any time.

(3) Records of monitoring information shall include:

- (i) The date, exact place, and time of sampling or measurements;
- (ii) The individual(s) who performed the sampling or measurements;
- (iii) The date(s) analyses were performed;
- (iv) The individual(s) who performed the analyses;
- (v) The analytical techniques or methods used; and
- (vi) The results of such analyses.

(4) Analyses for required monitoring must be conducted according to test procedures approved under 40 CFR Part 136 unless other test procedures have been specified in the permit or, in the case of sludge use or disposal, unless otherwise specified in R.61-9.503 or R.61-9.504.

(5) The PCA provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under this permit shall,

upon conviction, be punished by a fine of not more than \$25,000 or by imprisonment for not more than 2 years, or both. If a conviction of a person is for a violation committed after a first conviction of such person under this paragraph, punishment provided by the Clean Water Act is also by imprisonment of not more than 4 years.

(k) Signatory requirement.

(1) All applications, reports, or information submitted to the Department shall be signed and certified (See section 122.22).

(2) The PCA provides that any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance or non-compliance shall, upon conviction, be punished by a fine of not more than \$25,000 per violation, or by imprisonment for not more than two years per violation, or by both.

(l) Reporting requirements.

(1) Planned changes. The permittee shall give notice to the Department as soon as possible of any planned physical alterations or additions to the permitted facility. Notice is required only when:

(i) The alteration or addition to a permitted facility may meet one of the criteria for determining whether a facility is a new source in section 122.29(b); or

(ii) The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants which are subject neither to effluent limitations in the permit, nor to notification requirements under section 122.42(a)(1).

(iii) The alteration or addition results in a significant change in the permittee's sewage sludge or industrial sludge use or disposal practices, and such alteration, addition, or change may justify the application of permit conditions that are different from or absent in the existing permit, including notification of additional use or disposal sites not reported during the permit application process or not reported pursuant to an approved land application plan (included in the NPDES permit directly or by reference);

(2) Anticipated noncompliance. The permittee shall give advance notice to the Department of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements.

(3) Transfers. This permit is not transferable to any person except after notice to the Department. The Department may require modification or revocation and reissuance of the permit to change the name of permittee and incorporate such other requirements as may be necessary under the Pollution Control Act and the Clean Water Act. (See section 122.61; in some cases, modification or revocation and reissuance is mandatory.)

(4) Monitoring reports. Monitoring results shall be reported at the intervals specified in the permit.

(i) Monitoring results must be reported on a Discharge Monitoring Report (DMR) or forms provided or specified by the Department for reporting results of monitoring of sludge use or disposal practices. As of December 21, 2016, all reports and forms submitted in compliance with this section must be submitted electronically by the permittee to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, permittees may be required to report electronically if specified by a particular permit or if required to do so by State law.

(ii) If the permittee monitors any pollutant more frequently than required by the permit using test procedures approved under 40 CFR Part 136 or, in the case of sludge use or disposal, approved under 40 CFR Part 136 unless otherwise specified in R.61-9.503 or R.61-9.504, or as specified in the permit, the results of this monitoring shall be included in the calculation and reporting of the data submitted in the DMR or sludge reporting form specified by the Department.

(iii) Calculations for all limitations which require averaging of measurements shall utilize an arithmetic mean unless otherwise specified by the Department in the permit.

(5) Compliance schedules. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of this permit shall be submitted no later than 14 days following each schedule date.

(6) Twenty-four hour reporting.

(i) The permittee shall report any noncompliance which may endanger health or the environment. Any information shall be provided orally within twenty-four (24) hours from the time the permittee becomes aware of the circumstances. A written submission shall also be provided within five (5) days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times, and if the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent reoccurrence of the noncompliance. For noncompliance events related to combined sewer overflows, sanitary sewer overflows, or bypass events, these reports must include the data described above (with the exception of time of discovery), as well as the type of event (combined sewer overflows, sanitary sewer overflows, or bypass events), type of sewer overflow structure (e.g., manhole, combine sewer overflow outfall), discharge volumes untreated by the treatment works treating domestic sewage, types of human health and environmental impacts of the sewer overflow event, and whether the noncompliance was related to wet weather. As of December 21, 2020, all reports related to combined sewer overflows, sanitary sewer overflows, or bypass events submitted in compliance with this section must be submitted electronically by the permittee to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, permittees may be required to electronically submit reports related to combined sewer overflows, sanitary sewer overflows, or bypass events under this section by a particular permit or if required to do so by State law. The Department may also require permittees to electronically submit reports not related to combined sewer overflows, sanitary sewer overflows, or bypass events under this section.

(ii) The following shall be included as information which must be reported within 24 hours under this paragraph.

(A) Any unanticipated bypass which exceeds any effluent limitation in the permit. (See section 122.44(g)).

(B) Any upset which exceeds any effluent limitation in the permit.

(C) Violation of a maximum daily discharge limitation for any of the pollutants listed by the Department in the permit to be reported within 24 hours (See section 122.44(g)).

(iii) The Department may waive the written report on a case-by-case basis for reports under paragraph (l)(6)(ii) of this section if the oral report has been received within 24 hours.

(7) Other noncompliance. The permittee shall report all instances of noncompliance not reported under paragraphs (l)(4), (5), and (6) of this section, at the time monitoring reports are submitted. The reports shall contain the information listed in paragraph (l)(6) of this section. For noncompliance events related to combined sewer overflows, sanitary sewer overflows, or bypass events, these reports shall contain the information described in paragraph (l)(6) and the applicable required data in appendix A to 40 CFR Part 127. As of December 21, 2020, all reports related to combined sewer overflows, sanitary sewer overflows, or bypass events submitted in compliance with this section must be submitted electronically by the permittee to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, permittees may be required to electronically submit reports related to combined sewer overflows, sanitary sewer overflows, or bypass events under this section by a particular permit or if required to do so by State law. The Department may also require permittees to electronically submit reports

not related to combined sewer overflows, sanitary sewer overflows, or bypass events under this section.

(8) Other information. Where the permittee becomes aware that it failed to submit any relevant facts in a permit application, or submitted incorrect information in a permit application or in any report to the Department, it shall promptly submit such facts or information.

(9) Identification of the initial recipient for NPDES electronic reporting data. The owner, operator, or the duly authorized representative of an NPDES-regulated entity is required to electronically submit the required NPDES information (as specified in appendix A to 40 CFR Part 127) to the appropriate initial recipient, as determined by EPA, and as defined in Section 127.2(b) of this chapter. EPA will identify and publish the list of initial recipients on its website and in the Federal Register, by State and by NPDES data group [see Section 127.2(c) of this chapter]. EPA will update and maintain this listing.

(m) Bypass.

(1) Definitions.

(i) "Bypass" means the intentional diversion of waste streams from any portion of a treatment facility.

(ii) "Severe property damage" means substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.

(2) Bypass not exceeding limitations. The permittee may allow any bypass to occur which does not cause effluent limitations to be exceeded but only if it also is for essential maintenance to assure efficient operation. These bypasses are not subject to the provisions of paragraph (m)(3) and (m)(4) of this section.

(3) Notice.

(i) Anticipated bypass. If the permittee knows in advance of the need for a bypass, it shall submit prior notice, if possible, at least ten (10) days before the date of the bypass. As of December 21, 2020, all notices submitted in compliance with this section must be submitted electronically by the permittee to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, permittees may be required to report electronically if specified by a particular permit or if required to do so by State law.

(ii) Unanticipated bypass. The permittee shall submit notice of an unanticipated bypass as required in paragraph (l)(6) of this section (24-hour notice). As of December 21, 2020, all notices submitted in compliance with this section must be submitted electronically by the permittee to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, permittees may be required to report electronically if specified by a particular permit or if required to do so by State law.

(4) Prohibition of bypass

(i) Bypass is prohibited, and the Department may take enforcement action against a permittee for bypass, unless:

(A) Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;

(B) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass which occurred during normal periods of equipment downtime or preventive maintenance; and

(C) The permittee submitted notices as required under paragraph (m)(3) of this section.

(ii) The Department may approve an anticipated bypass, after considering its adverse effects, if the Department determines that it will meet the three conditions listed above in paragraph (m)(4)(i) of this section.

(n) Upset.

(1) Definition. "Upset" means an exceptional incident in which there is unintentional and temporary noncompliance with technology based permit effluent limitations because of factors beyond the reasonable control of the permittee. A upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventive maintenance, or careless or improper operation.

(2) Effect of an upset. An upset constitutes an affirmative defense to an action brought for noncompliance with such technology based permit effluent limitations if the requirements of paragraph (n)(3) of this section are met. No determination made during administrative review of claims that noncompliance was caused by upset, and before an action for noncompliance, is final administrative action subject to judicial review.

(3) Conditions necessary for a demonstration of upset. A permittee who wishes to establish the affirmative defense of upset shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence that:

(i) An upset occurred and that the permittee can identify the cause(s) of the upset;

(ii) The permitted facility was at the time being properly operated; and

(iii) The permittee submitted notice of the upset as required in paragraph (l)(6)(ii)(B) of this section (24 hour notice).

(iv) The permittee complied with any remedial measures required under paragraph (d) of this section.

(4) Burden of proof. In any enforcement proceeding, the permittee seeking to establish the occurrence of an upset has the burden of proof.

(o) Misrepresentation of Information.

(1) Any person making application for a NPDES discharge permit or filing any record, report, or other document pursuant to a regulation of the Department, shall certify that all information contained in such document is true. All application facts certified to by the applicant shall be considered valid conditions of the permit issued pursuant to the application.

(2) Any person who knowingly makes any false statement, representation, or certification in any application, record, report, or other documents filed with the Department pursuant to the State law, and the rules and regulations pursuant to that law, shall be deemed to have violated a permit condition and shall be subject to the penalties provided for pursuant to 48-1-320 or 48-1-330.

HISTORY: Amended by SCSR 43-11 Doc. No. 4888, eff November 22, 2019.

122.42. Additional conditions applicable to specified categories of NPDES permits.

The following conditions, in addition to those set forth in section 122.41, apply to all NPDES permits within the categories specified below:

(a) Existing manufacturing, commercial, mining, and silvicultural dischargers. In addition to the reporting requirements under section 122.41(1), all existing manufacturing, commercial, mining, and silvicultural dischargers must notify the Department as soon as they know or have reason to believe:

(1) That any activity has occurred or will occur which would result in the discharge on a routine or frequent basis, of any toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":

(i) One hundred micrograms per liter (100 ug/l);

(ii) Two hundred micrograms per liter (200 ug/l) for acrolein and acrylonitrile; five hundred micrograms per liter (500 ug/l) for 2,4-dinitrophenol and for 2-methyl-4,6-dinitrophenol; and one milligram per liter (1 mg/l) for antimony;

(iii) Five (5) times the maximum concentration value reported for that pollutant in the permit application in accordance with section 122.21(g)(7); or

(iv) The level established by the Department in accordance with section 122.44(f).

(2) That any activity has occurred or will occur which would result in any discharge, on a non-routine or infrequent basis, of a toxic pollutant which is not limited in the permit, if that discharge will exceed in the highest of the following "notification levels":

(i) Five hundred micrograms per liter (500 *ug/l*);

(ii) One milligram per liter (1 *mg/l*) for antimony;

(iii) Ten (10) times the maximum concentration value reported for that pollutant in the permit application in accordance with section 122.21(g)(7).

(iv) The level established by the Department in accordance with section 122.44(f).

(b) Publicly owned treatment works. All POTWs must provide adequate notice to the Department of the following:

(1) Any new introduction of pollutants into the POTW from an indirect discharger which would be subject to sections 301 or 306 of CWA if it were directly discharging those pollutants; and

(2) Any substantial change in the volume or character of pollutants being introduced into that POTW by a source introducing pollutants into the POTW at the time of issuance of the permit.

(3) For purposes of this paragraph, adequate notice shall include information on:

(i) The quality and quantity of effluent introduced into the POTW, and

(ii) Any anticipated impact of the change on the quantity or quality of effluent to be discharged from the POTW.

(c) Municipal separate storm sewer systems. The operator of a large or medium municipal separate storm sewer system or a municipal separate storm sewer that has been designated by the Department under section 122.26(a)(1)(v) of this regulation must submit an annual report by the anniversary of the date of the issuance of the permit for such system. As of December 21, 2020, all reports submitted in compliance with this section must be submitted electronically by the owner, operator, or the duly authorized representative of the MS4 to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, the owner, operator, or the duly authorized representative of the MS4 may be required to report electronically if specified by a particular permit or if required to do so by State law. The report shall include:

(1) The status of implementing the components of the storm water management program that are established as permit conditions;

(2) Proposed changes to the storm water management programs that are established as permit conditions. Such proposed changes shall be consistent with section 122.26(d)(2)(iii); and

(3) Revisions, if necessary, to the assessment of controls and the fiscal analysis reported in the permit application under section 122.26(d)(2)(iv) and (d)(2)(v);

(4) A summary of data, including monitoring data, that is accumulated throughout the reporting year;

(5) Annual expenditures and budget for year following each annual report;

(6) A summary describing the number and nature of enforcement actions, inspections, and public education programs;

(7) Identification of water quality improvements or degradation.

(d) Storm water discharges. The initial permits for discharges composed entirely of storm water issued pursuant to section 122.26(e)(7) of this regulation shall require compliance with the conditions of the permit as expeditiously as practicable, but in no event later than three years after the date of issuance of the permit.

(e) Concentrated animal feeding operations (CAFO). Any permit issued to a CAFO must include:

(1) Requirements to develop and implement a nutrient management plan. At a minimum, a nutrient management plan must include best management practices and procedures necessary to implement applicable effluent limitations and standards. Permitted CAFO must have their

nutrient management plans developed and implemented by December 31, 2006. CAFO that seek to obtain coverage under a permit after December 31, 2006 must have a nutrient management plan developed and implemented upon the date of permit coverage. The nutrient management plan must, to the extent applicable:

- (i) Ensure adequate storage of manure, litter, and process wastewater, including procedures to ensure proper operation and maintenance of the storage facilities;
- (ii) Ensure proper management of mortalities (i.e., dead animals) to ensure that they are not disposed of in a liquid manure, storm water, or process wastewater storage or treatment system that is not specifically designed to treat animal mortalities;
- (iii) Ensure that clean water is diverted, as appropriate, from the production area;
- (iv) Prevent direct contact of confined animals with waters of the United States;
- (v) Ensure that chemicals and other contaminants handled on-site are not disposed of in any manure, litter, process wastewater, or storm water storage or treatment system unless specifically designed to treat such chemicals and other contaminants;
- (vi) Identify appropriate site-specific conservation practices to be implemented, including as appropriate buffers or equivalent practices, to control runoff of pollutants to waters of the State;
- (vii) Identify protocols for appropriate testing of manure, litter, process wastewater, and soil;
- (viii) Establish protocols to land apply manure, litter, or process wastewater in accordance with site-specific nutrient management practices that ensure appropriate agricultural utilization of the nutrients in the manure, litter, or process wastewater; and
- (ix) Identify specific records that will be maintained to document the implementation and management of the minimum elements described in paragraphs (e)(1)(i) through (e)(1)(viii) of this section.

(2) Recordkeeping requirements.

(i) The permittee must create, maintain for five years, and make available to the Department upon request, the following records:

(A) All applicable records identified pursuant to paragraph (e)(1)(ix) of this section;

(B) In addition, all CAFO subject to 40 CFR 412 must comply with record keeping requirements specified in sections 412.37(b) and (c) and sections 412.47(b) and (c).

(ii) A copy of the CAFO's site-specific nutrient management plan must be maintained on site and made available to the Department upon request.

(3) Requirements relating to transfer of manure or process wastewater to other persons. Prior to transferring manure, litter, or process wastewater to other persons, Large CAFO must provide the recipient of the manure, litter, or process wastewater with the most current nutrient analysis. The analysis provided must be consistent with the requirements of 40 CFR 412. Large CAFO must retain for five years records of the date, recipient name and address, and approximate amount of manure, litter, or process wastewater transferred to another person.

(4) Annual reporting requirements for CAFO. The permittee must submit an annual report to the Department. As of December 21, 2020, all annual reports submitted in compliance with this section must be submitted electronically by the permittee to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, the permittee may be required to report electronically if specified by a particular permit or if required to do so by State law. The annual report must include:

- (i) The number and type of animals (beef cattle, broilers, layers, swine weighing 55 pounds or more, swine weighing less than 55 pounds, mature dairy cows, dairy heifers, veal calves, sheep and lambs, horses, ducks, turkeys, other), whether in open confinement or housed under roof;
- (ii) Estimated total amount of manure, litter, and process wastewater generated by the CAFO in the previous 12 months (tons/gallons);

(iii) Estimated total amount of manure, litter, and process wastewater transferred to other person(s) by the CAFO in the previous 12 months (tons/gallons);

(iv) Total number of acres for land application covered by the nutrient management plan developed in accordance with paragraph (e)(1) of this section;

(v) Total number of acres under control of the CAFO that were used for land application of manure, litter, and process wastewater in the previous 12 months;

(vi) Summary of all manure, litter, and process wastewater discharges from the production area that have occurred in the previous twelve (12) months, including for each discharge, the date of discovery, duration of discharge, and approximate volume; and

(vii) A statement indicating whether the current version of the CAFO's nutrient management plan was developed or approved by a certified nutrient management planner.

(f) Easements. Easements for Storm Water NPDES Permits or Leaking Underground Storage Tank Groundwater Remediation NPDES Permits. Easements for ditch discharges from either a storm water point source or a leaking underground storage tank groundwater remediation project will not be required to be submitted to the Department as a prerequisite for obtaining an individual NPDES permit or for coverage under a general permit. The permittee must ensure that all easements necessary for the discharge are obtained prior to the discharge occurring.

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

122.43. Establishing permit conditions.

(a) In addition to conditions required in all permits (sections 122.41 and 122.42), the Department shall establish conditions, as required on a case-by-case basis, to provide for and ensure compliance with all applicable requirements of CWA and PCA and regulations. These shall include conditions under section 122.46 (duration of permits), section 122.47(a) (schedules of compliance), and section 122.48 (monitoring), and electronic reporting requirements of 40 CFR Part 3 (Cross-Media Electronic Reporting Regulation) and 40 CFR Part 127 (NPDES Electronic Reporting).

(b)(1) An “applicable requirement” is a State statutory or regulatory requirement which takes effect prior to final administrative disposition of a permit. An applicable requirement is also any requirement which takes effect prior to the modification or revocation and reissuance of a permit, to the extent allowed in section 122.62.

(2) New or reissued permits, and to the extent allowed under section 122.62 modified or revoked and reissued permits, shall incorporate each of the applicable requirements referenced in section 122.44 and section 122.45.

(c) Incorporation. All permit conditions shall be incorporated either expressly or by reference. If incorporated by reference, a specific citation to the applicable regulations or requirements must be given in the permit.

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

122.44. Establishing limitations, standards, and other permit conditions.

In addition to the conditions established under section 122.43(a), each NPDES permit shall include conditions meeting the following requirements when applicable.

(a)(1) Technology-based effluent limitations and standards based on effluent limitations and standards promulgated under section 301 of the CWA, new source performance standards promulgated under section 306 of CWA, or case-by-case effluent limitations determined under section 402(a)(1) of CWA, or a combination of the three, in accordance with section 125.3. For new sources or new dischargers, these technology based limitations and standards are subject to the provisions of section 122.29(d) (protection period).

(2) Monitoring waivers for certain guideline-listed pollutants.

(i) The Department may authorize a discharger subject to technology-based effluent limitations guidelines and standards in an NPDES permit to forego sampling of a pollutant found at 40 CFR Subchapter N if the discharger has demonstrated through sampling and other technical factors that the pollutant is not present in the discharge or is present only at background levels from intake water and without any increase in the pollutant due to activities of the discharger.

(ii) This waiver is good only for the term of the permit and is not available during the term of the first permit issued to a discharger.

(iii) Any request for this waiver must be submitted when applying for a reissued permit or modification of a reissued permit. The request must demonstrate through sampling or other technical information, including information generated during an earlier permit term that the pollutant is not present in the discharge or is present only at background levels from intake water and without any increase in the pollutant due to activities of the discharger.

(iv) Any grant of the monitoring waiver must be included in the permit as an expressed permit condition and the reasons supporting the grant must be documented in the permit's fact sheet or statement of basis.

(v) This provision does not supersede certification processes and requirements already established in existing effluent limitations guidelines and standards.

(b)(1) Other effluent limitations and standards under sections 301, 302, 303, 307, 318 and 405 of CWA. If any applicable toxic effluent standard or prohibition (including any schedule of compliance specified in such effluent standard or prohibition) is promulgated under section 307(a) of CWA for a toxic pollutant and that standard or prohibition is more stringent than any limitation on the pollutant in the permit, the Department shall institute proceedings under these regulations to modify or revoke and reissue the permit to conform to the toxic effluent standard or prohibition. See also section 122.41(a).

(2) Standards for sewage sludge use or disposal under section 405(d) of the CWA unless those standards have been included in a permit issued under the appropriate provisions of subtitle C of the Solid Waste Disposal Act, Part C of Safe Drinking Water Act, the Marine Protection, Research, and Sanctuaries Act of 1972, or the Clean Air Act, or under State NPDES permit programs approved by the Administrator. When there are no applicable standards for sewage sludge use or disposal, the permit may include requirements developed on a case-by-case basis to protect public health and the environment from any adverse effects which may occur from toxic pollutants in sewage sludge. If any applicable standard for sewage sludge use or disposal is promulgated under section 405(d) of the CWA and that standard is more stringent than any limitation on the pollutant or practice in the permit, the Department may initiate proceedings under these regulations to modify or revoke and reissue the permit to conform to the standard for sewage sludge use or disposal.

(c) Reopener clause:

(1) For any permit issued to a treatment works treating domestic sewage (including "sludge-only facilities"), the Department shall include a reopener clause to incorporate any applicable standard for sewage sludge use or disposal promulgated under section 405(d) of the CWA. The Department may promptly modify or revoke and reissue any permit containing the reopener clause required by this paragraph, if the standard for sewage sludge use or disposal is more stringent than any requirements for sludge use or disposal in the permit or controls a pollutant or practice not limited in the permit.

(2) A permit may include a reopener referring to a permit modification reasonably foreseen based on expected revision to law or regulation or based on the expectation of receipt of information when either of these would be the basis for a modification under R.61-9.122.62.

(d) Water quality standards and State requirements: any requirements in addition to or more stringent than promulgated effluent limitations guidelines or standards under sections 301, 304, 306, 307, and 318, and 405 of CWA necessary to:

(1) Achieve water quality standards established under section 303 of the CWA, including State narrative criteria for water quality.

(i) Limitations must control all pollutants or pollutant parameters (either conventional, nonconventional, or toxic pollutants) which the Department determines are or may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any State water quality standard, including State narrative criteria for water quality.

(ii) When determining whether a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative or numeric criteria within a State water quality standard, the permitting authority shall use procedures which account for existing controls on point and nonpoint sources of pollution, the variability of the pollutant or pollutant parameter in the effluent, the sensitivity of the species to toxicity testing (when evaluating whole effluent toxicity), and where appropriate, the dilution of the effluent in the receiving water.

(iii) When the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above the allowable ambient concentration of a State numeric criteria within a State water quality standard for an individual pollutant, the permit must contain effluent limits for that pollutant.

(iv) When the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above the numeric criterion for whole effluent toxicity, the permit must contain effluent limits for whole effluent toxicity.

(v) Except as provided in this subparagraph, when the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, toxicity testing data, or other information, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative criterion within an applicable State water quality standard, the permit must contain effluent limits for whole effluent toxicity. Limits on whole effluent toxicity are not necessary where the permitting authority demonstrates in the fact sheet or statement of basis of the NPDES permit, using the procedures in paragraph (d)(1)(ii) of this section, that chemical-specific limits for the effluent are sufficient to attain and maintain applicable numeric and narrative State water quality standards.

(vi) Where the Department has not established a water quality criterion for a specific chemical pollutant that is present in an effluent at a concentration that causes, has the reasonable potential to cause, or contributes to an excursion above a narrative criterion within an applicable State water quality standard, the permitting authority must establish effluent limits using one or more the following options:

(A) Establish effluent limits using calculated numeric water quality criterion for the pollutant which the permitting authority demonstrates will attain and maintain applicable narrative water quality criteria and will fully protect the designated use. Such a criterion may be derived using a proposed State criterion, or an explicit State policy or regulation interpreting its narrative water quality criterion, supplemented with other relevant information which may include: EPA's Water Quality Standards Handbook, October 1983, risk assessment data, exposure data, information about the pollutant from the Food and Drug Administration, and current EPA criteria documents; or

(B) Establish effluent limits on a case-by-case basis, using EPA's water quality criteria, published under section 307(a) of the CWA, supplemented where necessary by other relevant information; or

(C) Establish effluent limitations on an indicator parameter for the pollutant of concern, provided:

(1) The permit identifies which pollutants are intended to be controlled by the use of the effluent limitation;

(2) The fact sheet required by R.61-9.124.56 sets forth the basis for the limit, including a finding that compliance with the effluent limit on the indicator parameter will result in controls on the pollutant of concern which are sufficient to attain and maintain applicable water quality standards;

(3) The permit requires all effluent and ambient monitoring necessary to show that during the term of the permit the limit on the indicator parameter continues to attain and maintain applicable water quality standards; and

(4) The permit contains a reopener clause allowing the permitting authority to modify or revoke and reissue the permit if the limits on the indicator parameter no longer attain and maintain applicable water quality standards.

(vii) When developing water quality-based effluent limits under this paragraph, the permitting authority shall ensure that:

(A) The level of water quality to be achieved by limits on point sources established under this paragraph is derived from, and complies with all applicable water quality standards; and

(B) Effluent limits developed to protect a narrative water quality criterion, a numeric water quality criterion, or both, are consistent with the assumptions and requirements of any available wasteload allocation for the discharge prepared by the State and approved by EPA pursuant to 40 CFR 130.7.

(2) Attain or maintain a specified water quality through water quality related effluent limits established under section 302 of CWA;

(3) Conform to the conditions to a State certification under R.61-101 and section 401 of the CWA.

(4) Conform to applicable water quality requirements under section 401(a)(2) of CWA when the discharge affects a State other than the certifying State:

(5) Incorporate any more stringent limitations, treatment standards, or schedule of compliance requirements established under Federal or State law or regulations in accordance with section 301(b)(1)(C) of CWA;

(6) Ensure consistency with the requirements of a Water Quality Management plan approved by EPA under section 208(b) of CWA;

(7) Incorporate section 403(c) criteria under R.61-9.125 Part M, for ocean discharges;

(8) Incorporate alternative effluent limitations or standards where warranted by “fundamentally different factors,” under R.61-9.125 Part D;

(9) [Reserved]

(e) Technology-based controls for toxic pollutants. Limitations established under paragraphs (a), (b), or (d) of this section, to control pollutants meeting the criteria listed in paragraph (e)(1) of this section. Limitations will be established in accordance with paragraph (e)(2) of this section. An explanation of the development of these limitations shall be included in the fact sheet under R.61-9.124.56(b)(1)(i).

(1) Limitations must control all toxic pollutants which the Department determines (based on information reported in a permit application under section 122.21(g)(7) or in a notification under section 122.42(a)(1) or on other information) are or may be discharged at a level greater than the level which can be achieved by the technology-based treatment requirements appropriate to the permittee under R.61-9.125.3(c); or

(2) The requirement that the limitations control the pollutants meeting the criteria of paragraph (e)(1) of this section will be satisfied by:

(i) Limitations on those pollutants; or

(ii) Limitations on other pollutants which, in the judgement of the Department, will provide treatment of the pollutants under paragraph (e)(1) of this section to the levels required by 125.3(c).

(f) Notification level. A “notification level” which exceeds the notification level of section 122.42(a)(1)(i), (ii) or (iii), upon a petition from the permittee or on the Department’s initiative. This new notification level may not exceed the level which can be achieved by the technology-based treatment requirements appropriate to the permittee under R.61-9.125.3(c).

(g) Twenty-four hour reporting. Pollutants for which the permittee must report violations of maximum daily discharge limitations under section 122.41(l)(6)(ii)(C) (24-hour reporting) shall be listed in the permit. This list shall include any toxic pollutant or hazardous substance, or any pollutant specifically identified as the method to control a toxic pollutant or hazardous substance.

(h) Durations for permits, as set forth in section 122.46.

(i) Monitoring requirements. In addition to section 122.48, the following monitoring requirements:

(1) To ensure compliance with the permit and protection of the environment, requirements to monitor:

(i) The mass (or other measurement specified in the permit) for each pollutant limited in the permit and as necessary to characterize any other pollutant, which may be in the wastewater, which has a significant potential to have an effect on the environment or operation of treatment or disposal facilities,

(ii) The volume of effluent discharged from each outfall;

(iii) Other measurements as appropriate including pollutants in internal waste streams under section 122.45(h), pollutants in intake water for net limitations under section 122.45(g); frequency, rate of discharge, etc., for noncontinuous discharges under section 122.45(e); pollutants subject to notification requirements under section 122.42(a); and pollutants in sewage sludge or other monitoring as specified in R.61-9.503 or R.61-9.504; or as determined to be necessary on a case-by-case basis pursuant to section 405(d)(4) of the CWA.

(iv) According to sufficiently sensitive test procedures (i.e., methods) approved under 40 CFR Part 136 for the analyses of pollutants or pollutant parameters or required under 40 CFR chapter I, subchapter N or O.

(A) For the purposes of this paragraph, a method is “sufficiently sensitive” when:

(1) The method minimum level (ML) is at or below the level of the effluent limit established in the permit for the measured pollutant or pollutant parameter; or

(2) The method has the lowest ML of the analytical methods approved under 40 CFR Part 136 or required under 40 CFR chapter I, subchapter N or O for the measured pollutant or pollutant parameter.

Note to paragraph (i)(1)(iv)(A):

Consistent with 40 CFR Part 136, applicants or permittees have the option of providing matrix or sample specific minimum levels rather than the published levels. Further, where an applicant or permittee can demonstrate that, despite a good faith effort to use a method that would otherwise meet the definition of “sufficiently sensitive,” the analytical results are not consistent with the QA/QC specifications for that method, then the Department may determine that the method is not performing adequately and the Department should select a different method from the remaining EPA-approved methods that is sufficiently sensitive consistent with 40 CFR 122.44(i)(1)(iv)(A). Where no other EPA-approved methods exist, the Department should select a method consistent with Section 122.44(i)(1)(iv)(B).

(B) In the case of pollutants or pollutant parameters for which there are no approved methods under 40 CFR Part 136 or methods are not otherwise required under 40 CFR chapter I, subchapter N or O, monitoring shall be conducted according to a test procedure specified in the permit for such pollutants or pollutant parameters.

(2) Except as provided in paragraphs (i)(4) and (i)(5) of this section, requirements to report monitoring results shall be established on a case-by-case basis with a frequency dependent on the nature and effect of the discharge but in no case less than once a year. For sewage sludge use or disposal practices, requirements to monitor and report results shall be established on a case-by-case basis with a frequency dependent on the nature and effect of the sewage sludge use or disposal practice; minimally this shall be as specified in R.61–9.503 (where applicable) but in no case less than once a year. All results must be electronically reported in compliance with 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127.

(3) Requirements to report monitoring results for storm water discharges associated with industrial activity which are subject to an effluent limitation guideline shall be established on a case-by-case basis with a frequency dependent on the nature and effect of the discharge, but in no case less than once a year.

(4) Requirements to report monitoring results for storm water discharges associated with industrial activity (other than those addressed in paragraph (i)(3) of this section) shall be established on a case-by-case basis with a frequency dependent on the nature and effect of the discharge. At a minimum, a permit for such a discharge must require:

- (i) The discharger to conduct an annual inspection of the facility site to identify areas contributing to a storm water discharge associated with industrial activity and evaluate whether measures to reduce pollutant loadings identified in a storm water pollution prevention plan are adequate and properly implemented in accordance with the terms of the permit or whether additional control measures are needed;
 - (ii) The discharger to maintain for a period of three years a record summarizing the results of the inspection and a certification that the facility is in compliance with the plan and the permit, and identifying any incidents of non-compliance.
 - (iii) Such report and certification be signed in accordance with section 122.22 and
 - (iv) Permits for storm water discharges associated with industrial activity from inactive mining operations may, where annual inspections are impracticable, require certification once every three years by a Registered Professional Engineer that the facility is in compliance with the permit, or alternative requirements.
- (5) Permits which do not require the submittal of monitoring result reports at least annually shall require that the permittee report all instances of noncompliance not reported under section 122.41(l)(1), (4), (5) and (6) at least annually.
- (j) Pretreatment program for POTWs. Requirements for POTWs to:
- (1) Identify, in terms of character and volume of pollutants, any Significant Industrial Users discharging into the POTW subject to Pretreatment Standards under section 307(b) of CWA and R.61-9.403.
 - (2)(i) Submit a local program when required by and in accordance with R.61-9.403 to assure compliance with pretreatment standards to the extent applicable under section 307(b). The local program shall be incorporated into the permit as described in R.61-9.403. The program must require all indirect dischargers to the POTW to comply with the reporting requirements of R.61-9.403.
 - (ii) Provide a written technical evaluation of the need to revise local limits under R.61-9.403.5(c)(1), following permit issuance or reissuance.
 - (3) For POTWs which are "sludge-only facilities," a requirement to develop a pretreatment program under R.61-9.403 when the Department determines that a pretreatment program is necessary to assure compliance with section 405(d) of the CWA.
- (k) Best management practices (BMP) to control or abate the discharge of pollutants when:
- (1) Authorized under section 304(e) of CWA for the control of toxic pollutants and hazardous substances from ancillary industrial activities;
 - (2) Authorized under section 402(p) of the CWA for the control of storm water discharges;
 - (3) Numeric effluent limitations are infeasible; or
 - (4) The practices are reasonably necessary to achieve effluent limitations and standards or to carry out the purposes and intent of the CWA.

Note to paragraph (k)(4):

Additional technical information on BMPs, and the elements of BMPs, is contained in the following documents: Guidance Manual for Developing Best Management Practices (BMPs), October 1993, EPA No. 833/B-93-004, NTIS No. PB 94-178324, ERIC No. W498); Storm Water Management for Construction Activities: Developing Pollution Prevention Plans and Best Management Practices, September 1992, EPA No. 832/R-92-005, NTIS No. PB 92-235951, ERIC No. N482); Storm Water Management for Construction Activities, Developing Pollution Prevention Plans and Best Management Practices: Summary Guidance, EPA No. 833/R-92-001, NTIS No. PB 93-223550; ERIC No. W139; Storm Water Management for Industrial Activities, Developing Pollution Prevention Plans and Best Management Practices, September 1992; EPA 832/R-92-006, NTIS No. PB 92-235969, ERIC No. N477; Storm Water Management for Industrial Activities, Developing Pollution Prevention Plans and Best Management Practices: Summary Guidance, EPA 833/R-92-002, NTIS No. PB 94-133782; ERIC No. W492. These and other EPA guidance documents can be obtained through the National Service Center for Environmental Publications (NSCEP) at <http://www.epa.gov/nscep>. In addition, States may have BMP guidance documents. These EPA guidance documents are listed here only for informational

purposes; they are not binding and EPA does not intend that these guidance documents have any mandatory, regulatory effect by virtue of their listing in this note.

(l) Reissued permits.

(1) Except as provided in paragraph (l)(2) or (l)(3) of this section when a permit is renewed or reissued, interim effluent limitations, standards or conditions must be at least as stringent as the final effluent limitations, standards, or conditions in the previous permit (unless the circumstances on which the previous permit was based have materially and substantially changed since the time the permit was issued and would constitute cause for permit modification or revocation and reissuance under section 122.62).

(2) In the case of effluent limitations established on the basis of Section 402(a)(1)(B) of the CWA, a permit may not be renewed, reissued, or modified on the basis of effluent guidelines promulgated under section 304(b) subsequent to the original issuance of such permit, to contain effluent limitations which are less stringent than the comparable effluent limitations in the previous permit.

(i) Exceptions — A permit with respect to which paragraph (l)(2) of this section applies may be renewed, reissued, or modified to contain a less stringent effluent limitation applicable to a pollutant, if —

(A) Material and substantial alterations or additions to the permitted facility occurred after permit issuance which justify the application of a less stringent effluent limitation;

(B)(1) Information is available which was not available at the time of permit issuance (other than revised regulations, guidance, or test methods) and which would have justified the application of a less stringent effluent limitation at the time of permit issuance; or

(2) The Department determines that technical mistakes or mistaken interpretations of law were made in issuing the permit under section 402(a)(1)(b);

(C) A less stringent effluent limitation is necessary because of events over which the permittee has no control and for which there is no reasonably available remedy;

(D) The permittee has received a permit modification under section 301(c), 301(k), 301(n), or 316(a); or

(E) The permittee has installed the treatment facilities required to meet the effluent limitations in the previous permit and has properly operated and maintained the facilities but has nevertheless been unable to achieve the previous effluent limitations, in which case the limitations in the reviewed, reissued, or modified permit may reflect the level of pollutant control actually achieved (but shall not be less stringent than required by effluent guidelines in effect at the time of permit renewal, reissuance, or modification).

(ii) Limitations. In no event may a permit with respect to which paragraph (l)(2) of this section applies be renewed, reissued, or modified to contain an effluent limitation which is less stringent than required by effluent guidelines in effect at the time the permit is renewed, reissued, or modified. In no event may such a permit to discharge into waters be renewed, reissued, or modified to contain a less stringent effluent limitation if the implementation of such limitation would result in a violation of a water quality standard under section 303 of the CWA applicable to such waters.

(3) In the event this section (section 122.44(l)) of the regulations conflicts with the provisions of the Clean Water Act, the CWA will apply.

(m) Privately owned treatment works. For a privately owned treatment works, any conditions expressly applicable to any user, as a limited co-permittee, that may be necessary in the permit issued to the treatment works to ensure compliance with applicable requirements under this part. Alternatively, the Department may issue separate permits to the treatment works and to its users, or may require a separate permit application from any user. The Department's decision to issue a permit with no conditions applicable to any user, to impose conditions on one or more users, to issue separate permits, or to require separate applications, and the basis for that decision, shall be stated in the fact sheet for the draft permit for the treatment works.

(n) Grants. Any conditions imposed in grants made by the Department to POTWs under sections 201 and 204 of CWA which are reasonably necessary for the achievement of effluent limitations under Section 301 of CWA.

(o) Sewage sludge. Requirements under section 405 of CWA governing the disposal of sewage sludge from publicly owned treatment works or any other treatment works treating domestic sewage for any use for which regulations have been established, in accordance with any applicable regulations.

(p) Coast Guard. When a permit is issued to a facility that may operate at certain times as a means of transportation over water, a condition that the discharge shall comply with any applicable regulations promulgated by the Secretary of the Department in which the Coast Guard is operating, that establish specifications for safe transportation, handling, carriage, and storage of pollutants.

(q) Navigation. Any conditions that the Secretary of the Army considers necessary to ensure that navigation and anchorage will not be substantially impaired, in accordance with R61-9.124.59.

(r) [Reserved]

(s) Qualifying State, Tribal, or local programs.

(1) For storm water discharges associated with small construction activity identified in section 122.26(b)(15), the Director may include permit conditions that incorporate qualifying State, Tribal, or local erosion and sediment control program requirements by reference. Where a qualifying State, Tribal, or local program does not include one or more of the elements in this paragraph (s)(1), then the Director must include those elements as conditions in the permit. A qualifying State, Tribal, or local erosion and sediment control program is one that includes:

(i) Requirements for construction site operators to implement appropriate erosion and sediment control best management practices;

(ii) Requirements for construction site operators to control waste such as discarded building materials, concrete truck washout, chemicals, litter, and sanitary waste at the construction site that may cause adverse impacts to water quality;

(iii) Requirements for construction site operators to develop and implement a storm water pollution prevention plan. (A storm water pollution prevention plan includes site descriptions, descriptions of appropriate control measures, copies of approved State, Tribal or local requirements, maintenance procedures, inspection procedures, and identification of non-storm water discharges); and

(iv) Requirements to submit a site plan for review that incorporates consideration of potential water quality impacts.

(2) For storm water discharges from construction activity identified in section 122.26(b)(14)(x), the Director may include permit conditions that incorporate qualifying State, Tribal, or local erosion and sediment control program requirements by reference. A qualifying State, Tribal or local erosion and sediment control program is one that includes the elements listed in paragraph (s)(1) of this section and any additional requirements necessary to achieve the applicable technology-based standards of “best available technology” and “best conventional technology” based on the best professional judgment of the permit writer.

HISTORY: Amended by SCSR 43-11 Doc. No. 4888, eff November 22, 2019.

122.45. Calculating NPDES permit conditions.

(a) Outfalls and discharge points. All permit effluent limitations, standards and prohibitions shall be established for each outfall or discharge point of the permitted facility, except as otherwise provided under section 122.44(k) (BMPs where limitations are infeasible) and paragraph (h) of this section (limitations on internal waste streams).

(b) Production-based limitations.

(1) In the case of POTWs, permit effluent limitations, standards, or prohibitions shall be calculated based on design flow.

(2)(i) Except in the case of POTWs or as provided in paragraph (b)(2)(ii) of this section, calculation of any permit limitations, standards, or prohibitions which are based on production (or other measure of operation) shall be based not upon the designed production capacity but rather upon a reasonable measure of actual production of the facility. For new sources or new dischargers, actual production shall be estimated using projected production. The time period of the measure of

production shall correspond to the time period of the calculated permit limitations; for example, monthly production shall be used to calculate average monthly discharge limitations.

(ii)(A)(1) The Department may include a condition establishing alternate permit limitations, standards, or prohibitions based upon anticipated increased (not to exceed maximum production capability) or decreased production levels.

(2) For the automotive manufacturing industry only, the Department may establish a condition under paragraph (b)(2)(ii)(A)(1) of this section if the applicant satisfactorily demonstrates to the Department at the time the application is submitted that its actual production, as indicated in paragraph (b)(2)(i) of this section, is substantially below maximum production capability and that there is a reasonable potential for an increase above actual production during the duration of the permit.

(B) If the Department establishes permit conditions under paragraph (b)(2)(ii)(A) of this section:

(1) The permit shall require the permittee to notify the Department at least two business days prior to a month in which the permittee expects to operate at a level higher than the lowest production level identified in the permit. The notice shall specify the anticipated level and the period during which the permittee expects to operate at the alternate level. If the notice covers more than one month, the notice shall specify the reasons for the anticipated production level increase. New notice of discharge at alternate levels is required to cover a period or production level not covered by prior notice or, if during two consecutive months otherwise covered by a notice, the production level at the permitted facility does not in fact meet the higher level designated in the notice.

(2) The permittee shall comply with the limitations, standards, or prohibitions that correspond to the lowest level of production specified in the permit, unless the permittee has notified the Department under paragraph (b)(2)(ii)(B)(1) of this section, in which case the permittee shall comply with the lower of the actual level of production during each month or the level specified in the notice.

(3) The permittee shall submit with the DMR the level of production that actually occurred during each month and the limitations, standards, or prohibitions applicable to that level of production.

(c) Metals. All permit effluent limitations, standards, or prohibitions for a metal shall be expressed in terms of "total recoverable metal" as defined in 40 CFR Part 136 unless:

(1) An applicable effluent standard or limitation has been promulgated under the CWA or under R.61-68 and specifies the limitation for the metal in the dissolved or valent or total form; or

(2) In establishing permit limitations on a case-by-case basis under R.61-9.125.3, it is necessary to express the limitation on the metal in the dissolved or valent or total form to carry out the provisions of the CWA; or

(3) All approved analytical methods for the metal inherently measure only its dissolved form (e.g. hexavalent chromium).

(d) Continuous discharges. For continuous discharges all permit effluent limitations, standards, and prohibitions, including those necessary to achieve water quality standards, shall unless impracticable be stated as:

(1) Maximum daily and average monthly discharge limitations for all dischargers other than publicly owned treatment works; and

(2) Average weekly and average monthly discharge limitations for POTWs.

(e) Non-continuous discharges. Discharges which are not continuous, as defined in section 122.2, shall be particularly described and limited, considering the following factors, as appropriate:

(1) Frequency (for example a batch discharge shall not occur more than once every 3 weeks);

(2) Total mass (for example, not to exceed 100 kilograms of zinc and 200 kilograms of chromium per batch discharge);

(3) Maximum rate of discharge of pollutants during the discharge (for example, not to exceed 2 kilograms of zinc per minute); and

(4) Prohibition or limitation of specified pollutants by mass, concentration, or other appropriate measure (for example, shall not contain at any time more than 0.1 mg/l zinc or more than 250 grams (¼ kilogram) of zinc in any discharge).

(f) Mass limitations.

(1) All pollutants limited in permits shall have limitations, standards, or prohibitions expressed in terms of mass except:

(i) For pH, temperature, radiation, or other pollutants which cannot appropriately be expressed in mass:

(ii) When applicable standards and limitations are expressed in terms of other units of measurement; or

(iii) If in establishing permit limitations on a case-by-case basis under R.61-9.125.3, limitations expressed in terms of mass are infeasible because the mass of the pollutant discharged cannot be related to a measure of operation (for example, discharges of TSS from certain mining operations), and permit conditions ensure that dilution will not be used as a substitute for treatment.

(2) Pollutants limited in terms of mass additionally may be limited in terms of other units of measurement, and the permit shall require the permittee to comply with both limitations.

(g) Pollutants in intake water.

(1) Upon request of the discharger, technology-based effluent limitations or standards shall be adjusted to reflect credit for pollutants in the discharger's intake water if:

(i) The applicable effluent limitations and standards contained in 40 CFR Subchapter N specifically provide that they shall be applied on a net basis; or

(ii) The discharger demonstrates that the control system it proposes or uses to meet applicable technology-based limitations and standards would, if properly installed and operated, meet the limitations and standards in the absence of pollutants in the intake waters.

(2) Credit for generic pollutants such as biochemical oxygen demand (BOD) or total suspended solids (TSS) should not be granted unless the permittee demonstrates that the constituents of the generic measure in the effluent are substantially similar to the constituents of the generic measure in the intake water or unless appropriate additional limits are placed on process water pollutants either at the outfall or elsewhere.

(3) Credit shall be granted only to the extent necessary to meet the applicable limitation or standard, up to a maximum value equal to the influent value. Additional monitoring may be necessary to determine eligibility for credits and compliance with permit limits.

(4) Credit shall be granted only if the discharger demonstrates that the intake water is drawn from the same body of water into which the discharge is made. The Department may waive this requirement if it finds that no environmental degradation will result.

(5) This section does not apply to the discharge of raw water clarifier sludge generated from the treatment of intake water.

(h) Internal waste streams.

(1) When permit effluent limitations or standards imposed at the point of discharge are impractical or infeasible, effluent limitations or standards for discharges of pollutants may be imposed on internal waste streams before mixing with other waste streams or cooling water streams. In those instances, the monitoring required by section 122.48 shall also be applied to the internal waste streams.

(2) Limits on internal waste streams will be imposed only when the fact sheet under R.61-9.124.56 sets forth the exceptional circumstances which make such limitations necessary, such as when the final discharge point is inaccessible (for example, under 10 meters of water), the wastes at the point of discharge are so diluted as to make monitoring impracticable, or the interferences among pollutants at the point of discharge would make detection or analysis impracticable.

(i) Disposal of pollutants into wells, into POTWs. Permit limitations and standards shall be calculated as provided in section 122.50.

122.46. Duration of permits.

(a) An NPDES permit issued pursuant to State law and this regulation shall be effective for a fixed term not to exceed 5 years. A person who wishes to continue to operate under such permit shall apply for re-issuance of a permit pursuant to this regulation.

(b) Except as provided in section 122.6, the term of a permit shall not be extended by modification beyond the maximum duration specified in this section.

(c) The Department may issue any permit for a duration that is less than the full allowable term under this section.

(d) A permit may be issued to expire on or after the statutory deadline set forth in section 301(b)(2)(A), (C), and (E), if the permit includes effluent limitations to meet the requirements of section 301(b)(2) (A), (C), (D), (E) and (F), whether or not applicable effluent limitations guidelines have been promulgated or approved.

(e) A determination that a particular discharger falls within a given industrial category for purposes of setting a permit expiration date under paragraph (d) of this section is not conclusive as to the discharger's inclusion in that industrial category for any other purposes, and does not prejudice any rights to challenge or change that inclusion at the time that a permit based on that determination is formulated.

122.47. Schedule of compliance.

(a) General. The NPDES permit may, when appropriate, specify a schedule of compliance leading to compliance with CWA, PCA, and regulations.

(1) Time for compliance. Any schedules of compliance under this section shall require compliance as soon as possible, but not later than the applicable statutory deadline under the CWA or as provided for under section 122.47(c).

(2) The first NPDES permit issued to a new source or a new discharger shall contain a schedule of compliance only when necessary to allow a reasonable opportunity to attain compliance with requirements issued or revised after commencement of construction but less than three years before commencement of the relevant discharge. For recommencing dischargers, a schedule of compliance shall be available only when necessary to allow a reasonable opportunity to attain compliance with requirements issued or revised less than three years before recommencement of discharge.

(3) Interim dates. Except as provided in paragraph (b)(1)(ii) of this section, if a permit establishes a schedule of compliance which exceeds nine (9) months from the date of permit issuance, the schedule shall set forth interim requirements and the date for their achievement.

(i) The time between interim dates shall not exceed nine (9) months, except that in the case of a schedule for compliance with standards for sewage sludge use and disposal, the time between interim dates shall not exceed six months.

(ii) If the time necessary for completion of any interim requirement (such as the construction of a control facility) is more than nine (9) months and is not readily divisible into stages for completion, the permit shall specify interim dates for the submission of reports of progress toward completion of the interim requirements and indicate a projected completion date.

(4) Reporting. The permit shall be written to require that no later than 10 days following each interim date and the final date of compliance, the permittee shall notify the Department in writing of its compliance or noncompliance with the interim or final requirements, or submit progress reports if paragraph (a)(3)(ii) is applicable.

(b) Alternative schedules of compliance. An NPDES permit applicant or permittee may cease conducting regulated activities (by terminating of direct discharge for NPDES sources) rather than continuing to operate and meet permit requirements as follows:

(1) If the permittee decides to cease conducting regulated activities at a given time within the term of a permit which has already been issued:

(i) The permit may be modified to contain a new or additional schedule leading to timely cessation of activities; or

(ii) The permittee shall cease conducting permitted activities before non-compliance with any interim or final compliance schedule requirement already specified in the permit.

(2) If the decision to cease conducting regulated activities is made before issuance of a permit whose term will include the termination date, the permit shall contain a schedule leading to termination which will ensure timely compliance with applicable requirements no later than the statutory deadline.

(3) If the permittee is undecided whether to cease conducting regulated activities, the Department may issue or modify a permit to contain two schedules as follows:

(i) Both schedules shall contain an identical interim deadline requiring a final decision on whether to cease conducting regulated activities no later than a date which ensures sufficient time to comply with applicable requirements in a timely manner if the decision is to continue conducting regulated activities;

(ii) One schedule shall lead to timely compliance with applicable requirements, no later than the statutory deadline;

(iii) The second schedule shall lead to cessation of regulated activities by a date which will ensure timely compliance with applicable requirements no later than the statutory deadline.

(iv) Each permit containing two schedules shall include a requirement that after the permittee has made a final decision under paragraph (b)(3)(i) of this section it shall follow the schedule leading to compliance if the decision is to continue conducting regulated activities, and follow the schedule leading to termination if the decision is to cease conducting regulated activities.

(4) The applicant's or permittee's decision to cease conducting regulated activities shall be evidenced by a firm public commitment satisfactory to the Department, such as a resolution of the board of directors of a corporation.

(c) Terms and Conditions of Permits: Schedules of Compliance.

(1) A person issued an NPDES permit by the Department who is not in compliance with applicable effluent standards and limitations or other requirements contained therein at the time the permit is issued, shall be required to achieve compliance within a period of time as set forth by the Department, with effluent standards and limitations, with water quality standards, or with specific requirements or conditions set by the Department. The Department shall require compliance with terms and conditions of the permit in the shortest reasonable period of time as determined thereby or within a time schedule for compliance which shall be specified in the issued permit.

(2) If a time schedule for compliance specified in an NPDES permit which is established by the Department pursuant to Subpart (1) above, exceeds nine (9) months, the time schedule shall provide for interim dates of achievement for compliance with certain applicable terms and conditions of the permit.

(d) Terms and Conditions of Permits: Compliance Reports by Dischargers.

(1) Within ten (10) days after an interim date of compliance or the final date of compliance specified in an NPDES permit, a permittee shall provide the Department with written notice of his compliance or noncompliance with the requirements or conditions specified to be completed by that date.

(2) Failure to submit the written notice to the Department is just cause for the Department to pursue enforcement action against the discharger pursuant to the State law or this regulation.

(e) Noncompliance. A discharger who fails or refuses to comply with an interim or final date of compliance specified in an NPDES permit, may be deemed by the Department to be in violation of the permit and may be subject to enforcement action prescribed in the State law or this regulation.

122.48. Requirements for recording and reporting of monitoring results.

(a) All permits shall specify:

(1) Requirements concerning the proper use, maintenance, and installation, when appropriate, of monitoring equipment or methods (including biological monitoring methods when appropriate);

(2) Monitoring shall include type, intervals, and frequency sufficient to yield data which are representative of the monitored activity including, when appropriate, continuous monitoring;

(3) Applicable reporting requirements based upon the impact of the regulated activity and as specified in section 122.44. Reporting shall be no less frequent than specified in the above regulation.

(4) That a permittee required to monitor a waste discharge shall maintain records of all information resulting from such monitoring, including the date, place and time of sampling; the dates analyses were performed; the person performing the analyses; the analytical techniques, procedures or methods used; and the results of such analyses. All records and results of monitoring activities and calibration and maintenance records shall be retained by the permittee a minimum of three (3) years unless otherwise required or extended by the Department.

(b) Any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required by the Department to be maintained as a condition in a permit, or who alters or falsifies the results obtained by such devices or methods, shall be deemed to have violated a permit condition and shall be subject to the penalties provided for pursuant to 48-1-320 and 48-1-330 of the Code.

(c) Applicable reporting requirements based upon the impact of the regulated activity and as specified in 40 CFR Part 3 (Cross-Media Electronic Reporting Regulation), Section 122.44, and 40 CFR Part 127 (NPDES Electronic Reporting). Reporting shall be no less frequent than specified in Section 122.44. EPA will maintain the start dates for the electronic reporting of monitoring results for each State on its website.

HISTORY: Amended by SCSR 43-11 Doc. No. 4888, eff November 22, 2019.

122.50. Disposal of pollutants into publicly-owned treatment works.

(a) When part of a discharger's process wastewater is not being discharged into waters of the State or contiguous zone because it is disposed into a POTW, thereby reducing the flow or level of pollutants being discharged into waters of the State, applicable effluent standards and limitations for the discharge in an NPDES permit shall be adjusted to reflect the reduced raw waste resulting from such disposal. Effluent limitations and standards in the permit shall be calculated by one of the following methods:

(1) If none of the waste from a particular process is discharged into waters of the State, and effluent limitations guidelines provide separate allocation for wastes from that process, all allocations for the process shall be eliminated from calculation of permit effluent limitations or standards.

(2) In all cases other than those described in paragraph (a)(1) of this section, effluent limitations shall be adjusted by multiplying the effluent limitation derived by applying effluent limitation guidelines to the total waste stream by the amount of wastewater flow to be treated and discharged into waters of the State, and dividing the result by the total wastewater flow. Effluent limitations and standards so calculated may be further adjusted under R.61-9.125 Part D to make them more or less stringent if discharges to publicly owned treatment works change the character or treatability of the pollutants being discharged to receiving waters. This method may be algebraically expressed as:

$$P = \frac{E \times N}{T}$$

where P is the permit effluent limitation, E is the limitation derived by applying effluent guidelines to the total wastestream, N is the wastewater flow to be treated and discharged to waters of the State, and T is the total wastewater flow.

(b) Paragraph (a) of this section does not apply to the extent that promulgated effluent limitations guidelines:

(1) Control concentrations of pollutants discharged but not mass; or

(2) Specify a different specific technique for adjusting effluent limitations to account for well injection, or disposal into POTWs.

(c) Paragraph (a) of this section does not alter a discharger's obligation to meet any more stringent requirements established under sections 122.41, 122.42, 122.43, and 122.44.

PART D

TRANSFER, MODIFICATION, REVOCATION, AND REISSUANCE AND TERMINATION OF PERMITS

122.61. Transfer of permits.

(a) Transfers by modification. Except as provided in paragraph (b) of this section, a permit may be transferred by the permittee to a new owner or operator only if the permit has been modified or revoked and reissued (under section 122.62(e)(2)), or a minor modification made (under section 122.63(d)), to identify the new permittee and incorporate such other requirements as may be necessary under CWA.

(b) Other transfers. As an alternative to transfers under paragraph (a) of this section, any NPDES permit may be transferred to a new permittee if:

(1) The current permittee notifies the Department at least 30 days in advance of the proposed transfer date in paragraph (b)(2) of this section;

(2) The notice includes a written agreement between the existing and new permittees containing a specific date for transfer of permit responsibility, coverage, and liability between them; and

(3) Permits are non-transferable except with prior consent of the Department. A modification under this subparagraph may also be a minor modification under section 122.63.

122.62. Modification or revocation and reissuance of permits.

(a) When the Department receives any information (for example, inspects the facility, receives information submitted by the permittee as required in the permit (see section 122.41), receives a request for modification or revocation and reissuance under section 124.5, or conducts a review of the permit file), it may determine whether or not one or more of the causes listed in paragraph (d) and (e) of this section for modification or revocation and reissuance or both exist.

(b) If cause exists, the Department may modify or revoke and reissue the permit accordingly, subject to the limitations of R.61-9.124.5(c), and may request an updated application if necessary. When a permit is modified, only the conditions subject to modification are reopened. If a permit is revoked and reissued, the entire permit is reopened and subject to revision and the permit is reissued for a new term. See R.61-9.124.5(c)(2).

(c) If cause does not exist under this section or section 122.63, the Department shall not modify or revoke and reissue the permit. If a permit modification satisfies the criteria in section 122.63 for "minor modifications" the permit may be modified without a draft permit or public review. Otherwise, a draft permit must be prepared and other procedures in R.61-9.124 followed.

(d) Causes for modification. The following are causes for modification but not revocation and reissuance of permits except when the permittee requests or agrees.

(1) Alterations. There are material and substantial alterations or additions to the permitted facility or activity (including a change or changes in the permittee's sludge use or disposal practice) which occurred after permit issuance which justify the application of permit conditions that are different or absent in the existing permit.

(2) Information. The Department has received new information. Permits may be modified during their terms for this cause only if the information was not available at the time of permit issuance (other than revised regulations, guidance, or test methods) and would have justified the application of different permit conditions at the time of issuance. For NPDES general permits (section 122.28) this cause includes any information indicating that cumulative effects on the environment are unacceptable. For new source or new discharger NPDES permits (sections 122.21, 122.29), this cause shall include any significant information derived from effluent testing required under section 122.21(k)(5)(vi) or section 122.21(h)(4)(iii) after issuance of the permit.

(3) New regulations. The standards or regulations on which the permit was based have been changed by promulgation of amended standards or regulations or by judicial decision after the permit was issued. Permits may be modified during their terms for this cause, only as follows:

(i) For promulgation of amended standards or regulations, when:

(A) The permit condition requested to be modified was based on a promulgated effluent limitation guideline, EPA approved or promulgated water quality standards, or the Secondary Treatment Regulations under R.61-9.133; and

(B) EPA has revised, withdrawn, or modified that portion of the regulation or effluent limitation guideline on which the permit condition was based, or has approved a State action with regard to a water quality standard on which the permit condition was based; and

(C) A permittee requests modification in accordance with R.61-9.124.5 within ninety (90) days after Federal Register notice of the action on which the request is based.

(ii) For judicial decisions, a court of competent jurisdiction has remanded and stayed promulgated regulations or effluent limitation guidelines, if the remand and stay concern that portion of the regulations or guidelines on which the permit condition was based and a request is filed by the permittee in accordance with R.61-9.124.5 within ninety (90) days of judicial remand.

(iii) For changes based upon modified State certifications of NPDES permits, see R.61-9.124.55(b).

(4) Compliance schedules. The Department determines good cause exists for modification of a compliance schedule or terms and conditions of a permit, such as an act of God, strike, flood, or materials shortage or other events over which the permittee has little or no control and for which there is no reasonably available remedy. However, in no case may an NPDES compliance schedule be modified to extend beyond an applicable CWA statutory deadline. See also section 122.63(c) (minor modifications) and paragraph (d)(13) of this section (NPDES innovative technology).

(5) When the permittee has filed a request for a variance under CWA section 301(c), 301(k), or 316(a) or for "fundamentally different factors" within the time specified in section 122.21.

(6) 307(a) toxics. When required to incorporate an applicable 307(a) toxic effluent standard or prohibition (see section 122.44(b)).

(7) Reopener. When required by the "reopener" conditions in a permit, which are established in the permit under section 122.44(b) (for CWA toxic effluent limitations and standards for sewage sludge use or disposal, see also section 122.44(c)) or R.61-9. 403.18(e) (Pretreatment program).

(8)(i) Net limits. Upon request of a permittee who qualifies for effluent limitations on a net basis under section 122.45(g).

(ii) When a discharger is no longer eligible for net limitations, as provided in section 122.45(g)(1)(ii).

(9) Pretreatment. As necessary under R.61-9.403.8(e) (compliance schedule for development of pretreatment program).

(10) Failure to notify. Upon failure of an approved State to notify, as required by section 40 CFR 402(b)(3), another State whose waters may be affected by a discharge from the approved State.

(11) Non-limited pollutants. When the level of discharge of any pollutant which is not limited in the permit exceeds the level which can be achieved by the technology-based treatment requirements appropriate to the permittee under R.61-9.125.3(c).

(12) Notification levels. To establish a "notification level" as provided in section 122.44(f).

(13) Compliance schedules. To modify a schedule of compliance to reflect the time lost during construction of an innovative or alternative facility, in the case of a POTW which has received a grant under section 202(a)(3) of CWA for 100% of the costs to modify or replace facilities constructed with a grant for innovative and alternative wastewater technology under section 202(a)(2). In no case shall the compliance schedule be modified to extend beyond an applicable CWA statutory deadline for compliance.

(14) For a small MS4, to include an effluent limitation requiring implementation of a minimum control measure or measures as specified in section 122.34(b) when:

(i) The permit does not include such measure(s) based upon the determination that another entity was responsible for implementation of the requirement(s); and

(ii) The other entity fails to implement measure(s) that satisfy the requirement(s).

(15) To correct technical mistakes, such as errors in calculation, or mistaken interpretations of law made in determining permit conditions.

(16) When the discharger has installed the treatment technology considered by the permit writer in setting effluent limitations imposed under 402(a)(1) of the CWA and has properly operated and maintained the facilities but nevertheless has been unable to achieve those effluent limitations. In this case, the limitations in the modified permit may reflect the level of pollutant control actually achieved (but shall not be less stringent than required by a subsequently promulgated effluent limitations guideline).

(17) [Reserved]

(18) Land application plans. When required by an NPDES permit condition to incorporate a land application plan for beneficial reuse of sewage sludge, to revise an existing land application plan, or to add a land application plan.

(e) Causes for modification or revocation and reissuance. The following are causes to modify or, alternatively, revoke and reissue a permit:

(1) Cause exists for termination under section 122.64, and the Department determines that modification or revocation and reissuance is appropriate.

(2) The Department has received notification (as required in the permit, see section 122.41(l)(3)) of a proposed transfer of the permit. A permit also may be modified to reflect a transfer after the effective date of an automatic transfer (section 122.61(b)) but will not be revoked and reissued after the effective date of the transfer except upon the request of the new permittee.

(3) There is a violation of any terms or conditions of the permit.

(4) The permittee has obtained a permit by misrepresentation or has failed to disclose all relevant facts to the Department.

122.63. Minor modifications of permits.

Upon the consent of the permittee, the Department may modify a permit to make the corrections or allowances for changes in the permitted activity listed in this section, without following the procedures of R.61-9.124. Any permit modification not processed as a minor modification under this section must be made for cause and with R.61-9.124 draft permit and public notice as required in section 122.62. Minor modifications may only:

(a) Correct typographical errors;

(b) Require more frequent monitoring or reporting by the permittee;

(c) Change an interim compliance date in a schedule of compliance, provided the new date is not more than 120 days after the date specified in the existing permit and does not interfere with attainment of the final compliance date requirement; or

(d) Approve permit transfer for a Change in Ownership, as follows:

(1) Allow for a change in ownership or operational control of a facility where the Department determines that no other change in the permit is necessary, provided that a written agreement containing a specific date for transfer of permit responsibility, coverage, and liability between the current and new permittees has been submitted to the Department.

(2) Whenever there occurs a change in the ownership of treatment works which are the subject of a NPDES permit the new owner shall notify the Department of this change in ownership within thirty (30) days thereof and shall be bound by all the terms and conditions of said permit or permits.

(3) Change the name of the facility.

(4) Permits are non-transferable except with the prior consent of the Department.

(e)(1) Change the construction schedule for a discharger which is a new source. No such change shall affect a discharger's obligation to have all pollution control equipment installed and in operation prior to discharge under section 122.29.

(2) Delete a point source outfall when the discharge from that outfall is terminated and does not result in discharge of pollutants from other outfalls except in accordance with permit limits.

(f)(1) Add or revise requirements for certification under section 208 of CWA.

(2) [Reserved]

- (3) Change sludge disposal sites from one approved landfill to another.
- (g) Incorporate conditions of a POTW pretreatment program that has been approved in accordance with the procedures in R.61-9.403.11 (or a modification thereto that has been approved in accordance with the procedures in R.61-9.403.18) as enforceable conditions of the POTW's permits.
- (h)(1) Change the operator grade or other operator requirements, including revision to frequency of operator visits.
 - (2)(i) Change a sampling date stated in the permit or add a sampling date,
 - (ii) Add specific sample locations if unclear in the issued permit,
 - (iii) Reduce sampling frequency after some period of time, if specifically allowed in an issued permit.
- (3) Add the treatment system reliability classification.
- (4) Require submittal of closure plans.
- (5) Change page numbers of the issued permit.
- (i) Require electronic reporting requirements (to replace paper reporting requirements) including those specified in 40 CFR Part 3 (Cross-Media Electronic Reporting Regulation) and 40 CFR Part 127 (NPDES Electronic Reporting).

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

122.64. Termination of permits.

- (a) The following are causes for terminating a permit during its term, or for denying a permit renewal application:
 - (1) Noncompliance by the permittee with any condition of the permit:
 - (2) The permittee's failure in the application or during the permit issuance process to disclose fully all relevant facts, or the permittee's misrepresentation of any relevant facts at any time;
 - (3) A determination that the permitted activity endangers human health or the environment and can only be regulated to acceptable levels by permit modification or termination; or
 - (4)(i) A change in any condition that requires either a temporary or permanent reduction or elimination of any discharge or sludge use or disposal practice controlled by the permit (for example, plant closure or termination of discharge by connection to a POTW).
 - (ii) Cessation of substantially all manufacturing operations, which are a basis for effluent limits or which contribute to a discharge, for a period of 180 days or longer.
 - (5) A permittee with a permit which requires connection to a regional sewer system or other treatment facilities under the water quality management plan under section 208 of the CWA is ineligible for reissuance of a permit once notified by the Department that the regional sewer system is operational.
- (b) The Department shall follow the applicable procedures in R.61–9.124 in terminating any NPDES permit under this section, except that if the entire discharge is permanently terminated by elimination of the flow or by connection to a POTW (but not by land application or disposal into a well), the Department may terminate the permit by notice to the permittee. Termination by notice shall be effective 30 days after notice is sent, unless the permittee objects within that time. If the permittee objects during that period, the Department shall follow R.61–9.124 procedures for termination. Expedited permit termination procedures are not available to permittees that are subject to pending State and/or Federal enforcement actions including citizen suits brought under State or Federal law. If requesting expedited permit termination procedures, a permittee must certify that it is not subject to any pending State or Federal enforcement actions including citizen suits brought under State or Federal law. State-authorized NPDES programs are not required to use 40 CFR 22 procedures for NPDES permit terminations.
- (c) Permittees that wish to terminate their permit must submit a Notice of Termination (NOT) to their permitting authority. If requesting expedited permit termination procedures, a permittee must certify in the NOT that it is not subject to any pending State or Federal enforcement actions including citizen suits brought under State or Federal law. As of December 21, 2020, all NOTs submitted in compliance with this section must be submitted electronically by the permittee to the Department, as

defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), Section 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, the permittee may be required to report electronically if specified by a particular permit or if required to do so by State law.

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

APPENDIX A

NPDES Primary Industry Categories

Any permit issued after June 30, 1981 to dischargers in the following categories shall include effluent limitations and a compliance schedule to meet the requirements of section 301(b)(2)(A), (C), (D), (E) and (F) of CWA, whether or not applicable effluent limitations guidelines have been promulgated. See section 122.44 and section 122.46.

Industry Category

Adhesives and sealants
Aluminum forming
Auto and other laundries
Battery manufacturing
Coal mining
Coil coating
Copper forming
Electrical and electronic components
Electroplating
Explosives manufacturing
Foundries
Gum and wood chemicals
Inorganic chemicals manufacturing
Iron and steel manufacturing
Leather tanning and finishing
Mechanical products manufacturing
Nonferrous metal manufacturing
Ore mining
Organic chemicals manufacturing
Paint and ink formulation
Pesticides
Petroleum refining
Pharmaceutical preparations
Photographic equipment and supplies
Plastics processing
Plastic and synthetic materials manufacturing
Porcelain enameling
Printing and publishing
Pulp and paper mills
Rubber processing
Soap and detergent manufacturing
Steam electric power plants
Textile Mills
Timber Products Processing

APPENDIX C

Criteria for Determining a Concentrated Aquatic Animal Production Facility (section 122.24)

A hatchery, fish farm, or other facility is a concentrated aquatic animal production facility for purposes of section 122.24 if it contains, grows, or holds aquatic animals in either of the following categories:

(a) Cold water fish species or other cold water aquatic animals in ponds, raceways, or other similar structures which discharge at least 30 days per year but does not include:

(1) Facilities which produce less than 9,090 harvest weight kilograms (approximately 20,000 pounds) of aquatic animals per year; and

(2) Facilities which feed less than 2,272 kilograms (approximately 5,000 pounds) of food during the calendar month of maximum feeding.

(b) Warm water fish species or other warm water aquatic animals in ponds, raceways, or other similar structures which discharge at least 30 days per year, but does not include:

(1) Closed ponds which discharge only during periods of excess runoff; or

(2) Facilities which produce less than 45,454 harvest weight kilograms (approximately 100,000 pounds) of aquatic animals per year.

“Cold water aquatic animals” include, but are not limited to, the Salmonidae family of fish; e.g., trout and salmon.

“Warm water aquatic animals” include, but are not limited to, the Ictaluridae, Centrarchidae, and Cyprinidae families of fish; e.g., respectively, catfish, sunfish, and minnows.

HISTORY: Amended by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

APPENDIX D – NPDES PERMIT APPLICATION TESTING REQUIREMENTS (§ 122.21) (Refer to 40 CFR Part 122, Appendix D)

APPENDIX E – RAINFALL ZONES OF THE UNITED STATES (Refer to 40 CFR Part 122, Appendix E)

APPENDIX F – INCORPORATED PLACES WITH POPULATIONS GREATER THAN 250,000 ACCORDING TO THE 1990 DECENNIAL CENSUS BY BUREAU OF CENSUS (Refer to 40 CFR Part 122, Appendix F)

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001.

APPENDIX G. – INCORPORATED PLACES WITH POPULATIONS GREATER THAN 100,000 AND LESS THAN 250,000 ACCORDING TO 1990 DECENNIAL CENSUS BY BUREAU OF CENSUS (Refer to 40 CFR Part 122, Appendix G)

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001.

APPENDIX H. – COUNTIES WITH UNINCORPORATED URBANIZED AREAS WITH A POPULATION OF 250,000 OR MORE ACCORDING TO THE 1990 DECENNI- AL CENSUS BY THE BUREAU OF CENSUS (Refer to 40 CFR Part 122, Appendix H)

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001.

**APPENDIX I. – COUNTIES WITH UNINCORPORATED URBANIZED AREAS
GREATER THAN 100,000, BUT LESS THAN 250,000 ACCORDING TO THE 1990
DECENNIAL CENSUS BY THE BUREAU OF CENSUS (Refer to 40 CFR Part 122,
Appendix I)**

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001.

**APPENDIX J. – NPDES PERMIT TESTING REQUIREMENTS FOR PUBLICLY
OWNED TREATMENT WORKS [section 122.21(j)]**

Table 1A—Effluent Parameters for All POTWS

Biochemical oxygen demand (BOD₅ or CBOD₅), 5-day

Fecal coliforms

Design Flow Rate

pH

Temperature

Total suspended solids

Table 1—Effluent Parameters for All POTWS With a Flow Equal to or Greater Than 0.1 MGD

Ammonia (as N)

Chlorine (total residual, TRC)

Dissolved oxygen

Nitrate/nitrite

Kjeldahl nitrogen

Oil and grease

Phosphorus

Total dissolved solids

Table 2—Effluent Parameters for Selected POTWS

Cyanide

Hardness

Metals (total recoverable), cyanide and total phenols

Antimony

Arsenic

Cadmium

Copper

Mercury

Selenium

Thallium

Phenolic compounds, total

Volatile organic compounds

Acrolein

Benzene

Carbon tetrachloride

Chlorodibromomethane

2-chloroethylvinyl ether

Dichlorobromomethane

1,2-dichloroethane

1,1-dichloroethylene

1,3-dichloropropylene

Methyl bromide

Methylene chloride

Tetrachloroethylene

1,1,1-trichloroethane

Trichloroethylene

Acid-extractable compounds

Beryllium

Chromium

Lead

Nickel

Silver

Zinc

Acrylonitrile

Bromoform

Chlorobenzene

Chloroethane

Chloroform

1,1-dichloroethane

Trans-1,2-dichloroethylene

1,2-dichloropropane

Ethylbenzene

Methyl chloride

1,1,2,2-tetrachloroethane

Toluene

1,1,2-trichloroethane

Vinyl chloride

P-chloro-m-cresol	2-chlorophenol
2,4-dichlorophenol	2,4-dimethylphenol
4,6-dinitro-o-cresol	2,4-dinitrophenol
2-nitrophenol	4-nitrophenol
Pentachlorophenol	Phenol
2,4,6-trichlorophenol	
Base-neutral compounds:	
Acenaphthene	Acenaphthylene
Anthracene	Benzidine
Benzo(a)anthracene	Benzo(a)pyrene
3,4-benzofluoranthene	Benzo(ghi)perylene
Benzo(k)fluoranthene	Bis (2-chloroethoxy) methane
Bis (2-chloroethyl) ether	Bis (2-chloroisopropyl) ether
Bis (2-ethylhexyl) phthalate	4-bromophenyl phenyl ether
Butyl benzyl phthalate	2-chloronaphthalene
4-chlorophenyl phenyl ether	Chrysene
Di-n-butyl phthalate	Di-n-octyl phthalate
Dibenzo(a,h)anthracene	1,2-dichlorobenzene
1,3-dichlorobenzene	1,4-dichlorobenzene
3,3'-dichlorobenzidine	Diethyl phthalate
Dimethyl phthalate	2,4-dinitrotoluene
2,6-dinitrotoluene	1,2-diphenylhydrazine
Fluoranthene	Fluorene
Hexachlorobenzene	Hexachlorobutadiene
Hexachlorocyclo-pentadiene	Hexachloroethane
Indeno(1,2,3-cd)pyrene	Isophorone
Naphthalene	Nitrobenzene
N-nitrosodi-n-propylamine	N-nitrosodimethylamine
N-nitrosodiphenylamine	Phenanthrene
Pyrene	1,2,4 -trichlorobenzene

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001.

61-9.124. PROCEDURES FOR DECISION MAKING.

Editor's Note

The following constitutes the history for 61-9.124, 124.1 through 124.62.

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001; State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003; State Register Volume 32, Issue No. 5, eff May 23, 2008; State Register Volume 34, Issue No. 11, eff November 26, 2010.

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PART A
GENERAL PROGRAM REQUIREMENTS

124.1. Purpose and scope.

This part contains the Department's procedures for issuing, modifying, revoking and reissuing, or terminating all NPDES, Land Application, and State permits (including "sludge-only" permits issued pursuant to R.61-9.122.1(b)(2)).

124.2. Definitions.

In addition to the definitions given in R.61-9.122.2, R.61-9.503.9, R.61-9.503.11, R.61-9.503.21, R.61-9.503.31, R.61-9.503.41, R.61-9.504.9, R.61-9.504.11, R.61-9.504.21, R.61-9.504.31, R.61-9.505.2 and 40 CFR 501.2 (sludge management), the following definitions apply to this regulation. Terms not defined in this section have the meaning given by the Clean Water Act (CWA) or Pollution Control Act (PCA).

(a) "Appropriate Act and regulations" means the Clean Water Act (CWA); the Pollution Control Act (PCA); the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA); or Safe Drinking Water Act (SDWA), whichever is applicable; and applicable regulations promulgated under those statutes. Appropriate Act and regulations includes program requirements.

(b) [Reserved]

(c) "Interstate Agency" means an agency of two or more States established by or under an agreement or compact approved by the Congress, or any other agency of two or more States having substantial powers or duties pertaining to the control of pollution as determined and approved by the Administrator under the "appropriate Act and regulations."

(d) "RCRA" means the Solid Waste Disposal Act as amended by the Resource Conservation and Recovery Act of 1976 (Pub. L. 94-580, as amended by Pub. L. 95-609, 42 U.S.C. Section 6901 et seq.).

(e) "SDWA" means the Safe Drinking Water Act (Pub. L. 95-523, as amended by Pub. L. 95-1900; 42 U.S.C. 300f et seq.; and the 1986 Amendments Pub. L.99-339.

(f) "Schedule of compliance" means a schedule of remedial measures included in a permit, including an enforceable sequence of interim requirements (for example, actions, operations, or milestone events) leading to compliance with the appropriate Act and regulations.

(g) "Section 404 permit" means a permit to regulate the discharge of dredged material and the discharge of fill material under Section 404 of the Clean Water Act in the waters of the State.

(h) "UIC" means the Underground Injection Control program under Part C of the Safe Drinking Water Act, including an "approved program."

124.3. Application for a permit.

(a)(1) Any person who requires a permit under the NPDES program shall complete, sign, and submit to the Department an application for each permit required under R.61-9.122.1. Applications are not required for NPDES general permits under R.61-9.122.28.

(2) The Department shall not begin the processing of a permit until the applicant has fully complied with the application requirements for that permit.

(3) Permit applications must comply with the signature and certification requirements of R.61-9.122.22.

(4) A person discharging waste from more than one (1) location shall file a separate application for each discharge location. A single application may be filed for multiple outfalls discharging from a

single location, except that the discharge from each outfall shall be described separately in the application.

(b)(1) Any person who requires a permit under the Land Application or State program shall complete, sign, and submit to the Department an application for each permit required under R.61-9.503, R.61-9.504 or R.61-9.505. Applications are not required for General permits under R.61-9.505.23. Notices of Intent are required for General permits. See R.61-9.505.23.

(2) The Department shall not begin the processing of a permit until the applicant has fully complied with the application requirements for that permit.

(3) Permit applications must comply with the signature and certification requirements of R.61-9.505.22.

(4) A person discharging waste from more than one (1) location shall file a separate application for each discharge location. A single application may be filed for multiple sites discharging from a single location, except that the discharge from each site shall be described separately in the application.

124.5. Modification, revocation and reissuance, or termination of permits.

(a) Permits may be modified (to include any term, condition, or a schedule of compliance), revoked and reissued, suspended or terminated either at the request of any interested person (including the permittee) or upon the Department's initiative. However, permits may only be modified, revoked and reissued, or terminated after notice and for the reasons specified in R.61-9.122.62, R.61-9.122.64, R.61-9.505.62 or R.61-9.505.64. All requests shall be in writing and shall contain facts or reasons supporting the request.

(b) See section 124.19 for appeals procedure.

(c)(1) If the Department tentatively decides to modify or revoke and reissue a NPDES permit under R.61-9.122.62 or Land Application permit under R.61-9.505.62, it shall prepare a draft NPDES or Land Application permit under section 124.6 incorporating the proposed changes. The Department may request additional information and, in the case of a modified permit, may require the submission of an updated application. In the case of revoked and reissued permits, the Department shall require the submission of a new application.

(2) In a permit modification under this section, only those conditions to be modified shall be reopened when a new draft permit is prepared. All other aspects of the existing permit shall remain in effect for the duration of the unmodified permit. When a permit is revoked and reissued under this section, the entire permit is reopened just as if the permit had expired and was being reissued. During any revocation and reissuance proceeding, the permittee shall comply with all conditions of the existing permit until a new final permit is reissued and effective.

(3) "Minor Modifications" as defined in R.61-9.122.63 or R.61-9.505.63 are not subject to the requirements of this provision.

(d)(1) If the Department tentatively decides to terminate a permit under section 122.64(a) (NPDES) or a permit under section 122.64(b) (NPDES) where the permittee objects, the Department shall issue a notice of intent to terminate.

(2) If the Department tentatively decides to terminate a permit under R.61-9.505.64, it shall issue a notice of intent to terminate.

(3) A notice of intent to terminate is a type of draft permit which follows the same procedures as any draft permit prepared under section 124.6.

124.6. Draft permits.

(a) Once an application is complete, the Department shall tentatively decide whether to prepare a draft permit or to deny the application.

(b) If the Department tentatively decides to deny the permit application, it shall issue a notice of intent to deny. A notice of intent to deny the permit application is a type of draft permit which follows the same procedures as any other draft permit prepared under this section. See section 124.6(e). If the Department's final decision (section 124.15) is that the tentative decision to deny the permit application was incorrect, it shall withdraw the notice of intent to deny and proceed to prepare a draft permit under paragraph (d) of this section.

(c) If the Department tentatively decides to issue an NPDES, Land Application, State, or general permit, it shall prepare a draft NPDES, Land Application, State, general or 404 general permit under paragraph (d) of this section.

(d) If the Department decides to prepare a draft permit, it shall prepare a draft permit that contains the following information:

(1) For permits under R.61-9.122, all conditions under R.61-9.122.41 and R.61-9.122.43;

(2) For permits under R.61-9.122, all compliance schedules under R.61-9.122.47;

(3) For permits under R.61-9.122, all monitoring requirements under R.61-9.122.48;

(4)(i) For permits under R.61-9.505, all applicable conditions under R.61-9.505.41; and R.61-9.505.43;

(ii) For permits under R.61-9.505, all compliance schedules under R.61-9.505.47; and

(iii) For permits under R.61-9.505, all applicable monitoring requirements under R.61-9.505.48;

(iv) For Land Application, State or sludge disposal permits, effluent limitations, standards, prohibitions, standards for sewage sludge use or disposal, and conditions under R.61-9.503; R.61-9.504; or R.61-9.505 including R.61-9.505.41, R.61-9.505.42, R.61-9.505.44, and any applicable conditions as determined by the Department;

(v) For NPDES permits, effluent limitations, standards, prohibitions, standards for sewage sludge use or disposal, and conditions under R.61-9.122.41, R.61-9.122.42, and R.61-9.122.44, including when applicable any conditions certified by a State agency under section 124.55 and all variances that are to be included under section 124.63.

(e) Draft NPDES, Land Application, State or general permits prepared by the State shall be accompanied by a fact sheet if required under section 124.8.

124.8. Fact sheet.

(a) A fact sheet shall be prepared for every draft permit for a major NPDES facility or activity, for every Class I sludge management facility, for every NPDES general permit (R.61-9.122.28), for every NPDES draft permit that incorporates a variance or requires an explanation under section 124.56(b), for every draft permit that includes a sewage sludge land application plan under 40 CFR 501.15(a)(2)(ix), and for every draft permit which the Department finds is the subject of wide-spread public interest or raises major issues. The fact sheet shall briefly set forth the principal facts and the significant factual, legal, methodological and policy questions considered in preparing the draft permit. The Department shall send this fact sheet to the applicant and, on request, to any other person. A fact sheet may be prepared by the Department for draft permits under R.61-9.505.

(b) The fact sheet shall include, when applicable:

(1) A brief description of the type of facility or activity which is the subject of the draft permit;

(2) The type and quantity of wastes, fluids, or pollutants which are proposed to be treated, stored, disposed of, injected, emitted, or discharged;

(3) [Reserved]

(4) [Reserved]

(5) Reasons why any requested variances or alternatives to required standards do or do not appear justified;

(6) A description of the procedures for reaching a final decision on the draft permit including:

(i) The beginning and ending dates of the comment period under section 124.10 and the address where comments will be received;

(ii) Procedures for requesting a hearing and the nature of that hearing; and

(iii) Any other procedures by which the public may participate in the final decision.

(7) Name and telephone number of a person to contact for additional information.

(8) For NPDES permits, provisions satisfying the requirements of section 124.56.

(9) Justification for waiver of any application requirements under section 122.21(j) or (q) of this chapter.

124.10. Public notice of permit actions and public comment period.

(a) Scope.

(1) The Department shall give public notice of NPDES or Land Application permits that the following actions have occurred:

- (i) A permit application has been tentatively denied under section 124.6(b);
- (ii) A draft permit has been prepared under section 124.6(d);
- (iii) A hearing has been scheduled under section 124.12;
- (iv) [Reserved]
- (v) [Reserved]
- (vi) An NPDES new source determination has been made under R.61-9.122.29.

(2) No public notice is required when a request for permit modification, revocation and reissuance, or termination is denied under section 124.5(b). Written notice of that denial shall be given to the requester and to the permittee.

(3) Public notices may describe more than one permit or permit actions.

(b)(1) Public notice of the preparation of a draft NPDES or Land Application permit (including a notice of intent to deny a permit application) required under paragraph (a) of this section shall allow at least 30 days for public comment.

(2) Public notice of a public hearing shall be given at least 30 days before the hearing. (Public notice of the hearing may be given at the same time as public notice of the draft permit and the two notices may be combined).

(c) Methods. Public notice of activities described in paragraph (a)(1) of this section shall be given by the following methods:

(1) By mailing a copy of a notice to the following persons (any person otherwise entitled to receive notice under this paragraph may waive his or her rights to receive notice for any classes and categories of permits);

- (i) The applicant (except for NPDES or Land Application general permits when there is no applicant);
- (ii) Any other agency which the Department knows has issued or is required to issue a RCRA, UIC, PSD (or other permit under the Clean Air Act), NPDES, 404, sludge management permit, or ocean dumping permit under the Marine Research Protection and Sanctuaries Act for the same facility or activity (including EPA when a draft NPDES permit is prepared by the State);
- (iii) Federal and State agencies with jurisdiction over fish, shellfish, and wildlife resources and over coastal zone management plans, the Advisory Council on Historic Preservation, State Historic Preservation Officers, including any affected States.
- (iv) Any State agency responsible for plan development under CWA section 208(b)(2), 208(b)(4) or 303(e) and the U.S. Army Corps of Engineers, the U.S. Fish and Wildlife Service and the National Marine Fisheries Service;

(v) Any user identified in the permit application of a privately owned treatment works;

(vi) [Reserved]

(vii) [Reserved]

(viii) [Reserved]

(ix) Persons on a mailing list developed by:

(A) Including those who request in writing to be on the list;

(B) Soliciting persons for "area lists" from participants in past permit proceedings in that area; and

(C) Notifying the public of the opportunity to be put on the mailing list through periodic publication in the public press and in such publications as Regional and State funded newsletters, environmental bulletins, or State law journals. (The Department may update the mailing list from time to time by requesting written indication of continued interest from those listed.

The Department may delete from the list the name of any person who fails to respond to such a request).

(x)(A) To any unit of local government having jurisdiction over the area where the facility is proposed to be located; and

(B) To each State agency having any authority under State law with respect to the construction or operation of such facility.

(2)(i) For major NPDES permits, NPDES general permits, and permits that include sewage sludge land application plans under 40 CFR 501.15(a)(2)(ix), publication of a notice in a daily or weekly newspaper within the area affected by the facility or activity.

(ii) [Reserved]

(iii) [Reserved]

(iv) For NPDES major permits and NPDES general permits, in lieu of the requirement for publication of a notice in a daily or weekly newspaper, as described in paragraph (c)(2)(i) of this section, the Department may publish all notices of activities described in paragraph (a)(1) of this section to the Department's public website. If the Department selects this option for a draft permit, as defined in Section 122.2, in addition to meeting the requirements in paragraph (d) of this section, the Department must post the draft permit and fact sheet on the website for the duration of the public comment period.

Note to paragraph (c)(2)(iv):

The Department is encouraged to ensure that the method(s) of public notice effectively informs all interested communities and allows access to the permitting process for those seeking to participate.

(3) In a manner constituting legal notice to the public under State law; and

(4) Any other method reasonably calculated to give actual notice of the action in question to the persons potentially affected by it, including press releases or any other forum or medium to elicit public participation.

(d) Contents.

(1) All public notices. All public notices for NPDES and Land Application permits issued under this regulation shall contain the following minimum information:

(i) Name and address of the office processing the permit action for which notice is being given;

(ii) Name and address of the permittee or permit applicant and, if different, of the facility or activity regulated by the permit, except in the case of NPDES and 404 draft general permits under R.61-9.122.28 and 40 CFR 233.37;

(iii) A brief description of the business conducted at the facility or activity described in the permit application or the draft permit, for NPDES or 404 general permits when there is no application.

(iv) Name, address and telephone number of a person from whom interested persons may obtain further information, including copies of the draft permit or draft general permit, as the case may be, statement of basis or fact sheet, and the application; and

(v) A brief description of the comment procedures required by section 124.11 and section 124.12 and the time and place of any hearing that will be held, including a statement of procedures to request a hearing (unless a hearing has already been scheduled) and other procedures by which the public may participate in the final permit decision.

(vi) [Reserved]

(vii) For NPDES permits only (including those for "sludge-only facilities"), a general description of the location of each existing or proposed discharge point and the name of the receiving water and the sludge use and disposal practice(s) and the location of each sludge treatment works treating domestic sewage and use or disposal sites known at the time of permit application. For draft general permits, this requirement will be satisfied by a map or description of the permit area.

(viii) [Reserved]

(ix) Requirements applicable to cooling water intake structures under section 316(b) of the CWA, in accordance with 40 CFR 125, subpart I.

(x) Any additional information considered necessary or proper.

2. Public notices for hearings. In addition to the general public notice described in paragraph (d)(1) of this section, the public notice of a hearing under section 124.12 shall include the following information:

(i) Reference to the date of previous public notices relating to the permit;

(ii) Date, time, and place of the hearing;

(iii) A brief description of the nature and purpose of the hearing, including the applicable rules and procedures; and

(e) In addition to the general public notice described in paragraph (d)(1) of this section, all persons identified in paragraphs (c)(1)(i)(ii), (iii), and (iv) of this section shall be mailed a copy of the fact sheet, the permit application (if any) and the draft permit (if any).

HISTORY: Amended by SCSR 43-11 Doc. No. 4888, eff November 22, 2019.

124.11. Public comments and requests for public hearings.

During the public comment period provided under section 124.10, any interested person may submit written comments on the draft permit and may request a public hearing, if no hearing has already been scheduled. A request for a public hearing shall be in writing and shall state the nature of the issues proposed to be raised in the hearing. All comments shall be considered in making the final decision and shall be answered as provided in section 124.17.

124.12. Public hearings.

(a) Determinations and Scheduling.

(1) Within the thirty (30) day comment period or other applicable comment period provided after posting or publishing of a public notice, an applicant, any affected state or interstate agency, the Regional Administrator or any other interested person or agency may file a petition with the Department for a public hearing on an application for a permit. A petition for a public hearing shall indicate the specific reasons why a hearing is requested, the existing or proposed discharge identified therein and specifically indicate which portions of the application or other permit form or information constitutes necessity for a public hearing. If the Department determines that a petition constitutes significant cause or that there is sufficient public interest in an application for a public hearing, it may direct the scheduling of a hearing thereon.

(2) A hearing shall be scheduled not less than four (4) nor more than eight (8) weeks after the Department determines the necessity of the hearing in the geographical location of the applicant or, at the discretion of the Department, at another appropriate location, and shall be noticed at least thirty (30) days before the hearing. The notice of public hearing shall be transmitted to the applicant and shall be published in at least one (1) newspaper of general circulation in the geographical area of the existing or proposed discharge identified on the permit application and shall be mailed to any person or group upon request therefor. Notice shall be mailed to all persons and governmental agencies which received a copy of the notice or the fact sheet for the permit application.

(3) The Department may hold a single public hearing on related groups of permit applications.

(4) The Department may also hold a public hearing at its discretion, whenever, for instance, such a hearing might clarify one or more issues involved in the permit decision;

(5) Public notice of the hearing shall be given as specified in section 124.10.

(b) [Reserved]

(c) Any person may submit oral or written statements and data concerning the draft permit. Reasonable limits may be set upon the time allowed for oral statements, and the submission of statements in writing may be required. The public comment period under section 124.10 shall automatically be extended to the close of any public hearing under this section. The hearing officer may also extend the comment period by so stating at the hearing.

(d) A tape recording or written transcript of the hearing shall be made available to the public.

124.13. Obligation to raise issues and provide information during the public comment period.

All persons, including applicants, who believe any condition of a draft permit is inappropriate or that the Department's tentative decision to deny an application, terminate a permit, or prepare a draft permit is inappropriate, must raise all reasonably ascertainable issues and submit all reasonably available arguments supporting their position by the close of the public comment period (including any public hearing) under section 124.10. No issue shall be raised during an appeal by any party that was not submitted to the administrative record as part of the preparation and comment on a draft permit, unless good cause is shown for the failure to submit it. Any supporting materials which are submitted shall be included in full and may not be incorporated by reference, unless they are already part of the administrative record in the same proceeding, or consist of State or Federal statutes and regulations, Department and EPA documents of general applicability, or other generally available reference materials. Commenters shall make supporting materials not already included in the administrative record available. (A comment period longer than 30 days may be necessary to give commenters a reasonable opportunity to comply with the requirements of this section. Additional time shall be granted under section 124.10 to the extent that a commenter who requests additional time demonstrates the need for such time).

124.15. Issuance and effective date of permit.

(a) After the close of the public comment period under section 124.10 on a draft permit, the Department shall issue a final permit decision. The Department shall notify the applicant and each person who has submitted written comments or requested notice of the final permit decision. This notice shall include reference to the procedures for appealing a decision on a permit. For the purposes of this section, a final permit decision means a final decision to issue, deny, modify, revoke and reissue, or terminate a permit.

(b) A final permit decision shall become effective 30 days after the service of notice of the decision unless:

(1) A later effective date is specified in the decision; or

(2) [Reserved]

(3) No comments requested a change in the draft permit, in which case the permit shall become effective on the effective date shown in the issued permit.

124.17. Response to comments.

(a) The Department is only required to issue a response to comments when a final permit is issued. This response shall:

(1) Specify which provisions, if any, of the draft permit have been changed in the final permit decision, and the reasons for the change; and

(2) Briefly describe and respond to all significant comments on the draft permit raised during the public comment period, or during any hearing.

(b) [Reserved]

(c) The response to comments shall be available to the public.

124.19. Appeal of NPDES and State Permits.

a. A Department decision involving issuance, denial, renewal, modification, suspension, or revocation of an NPDES, Land Application, or State permit may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 1, Chapter 23 and Title 44, Chapter 1.

b. Any person to whom an order, related to an NPDES, Land Application, or State permit, is issued may appeal it pursuant to applicable law, including S.C. Code Title 1, Chapter 23 and Title 44, Chapter 1.

PART D
SPECIFIC PROCEDURES APPLICABLE TO NPDES PERMITS

124.51. Purpose and scope.

(a) This part sets forth additional requirements and procedures for decision making for the NPDES program. Part D applies only to NPDES permits prepared under R.61-9.122.

(b) Decisions on NPDES variance requests ordinarily will be made during the permit issuance process. Variances and other changes in permit conditions ordinarily will be decided through the same notice-and-comment and hearing procedures as the basic permit.

124.52. Permits required on a case-by-case basis.

(a) Various sections of R.61-9.122 Part B allow the Department to determine, on a case-by-case basis, that certain concentrated animal feeding operations (R.61-9.122.23), concentrated aquatic animal production facilities (R.61-9.122.24) storm water discharges (R.61-9.122.26) and certain other facilities covered by general permits (R.61-9.122.28) that do not generally require an individual permit may be required to obtain an individual permit because of their contributions to water pollution.

(b) Whenever the Department decides that an individual permit is required under this section, except as provided in paragraph (c) of this section, the Department shall notify the discharger in writing of that decision and the reasons for it, and shall send an application form with the notice. The discharger must apply for a permit under R.61-9.122.21 within 60 days of notice, unless permission for a later date is granted by the Department. The question whether the designation was proper will remain open for consideration during the public comment period under section 124.11 and in any subsequent hearing.

(c) Prior to a case-by-case determination that an individual permit is required for a storm water discharge under this section (see R.61-9.122.26(a)(1)(v), (a)(9)(iii), and (c)(1)(v)), the Department may require the discharger to submit a permit application or other information regarding the discharge under section 308 of the CWA. In requiring such information, the Department shall notify the discharger in writing and shall send an application form with the notice. The discharger must apply for a permit within 180 days of notice, unless permission for a later date is granted by the Department. The question whether the initial designation was proper will remain open for consideration during the public comment period under section 124.11 and in any subsequent hearing.

124.56. Fact sheets.

In addition to meeting the requirements of section 124.8, NPDES fact sheets shall contain the following:

(a) Any calculations or other necessary explanation of the derivation of specific effluent limitations and conditions or standards for sewage sludge use or disposal, including a citation to the applicable effluent limitation guideline, performance standard, or standard for sewage sludge use or disposal as required by R.61-9.122.44 and reasons why they are applicable or an explanation of how the alternate effluent limitations were developed.

(b)(1) When the draft permit contains any of the following conditions, an explanation of the reasons why such conditions are applicable:

- (i) Limitations to control toxic pollutants under R.61-9.122.44(e);
- (ii) Limitations on internal waste streams under R.61-9.122.45(h);
- (iii) Limitations on indicator pollutants under R.61-9.125.3(g);
- (iv) Limitations set on a case-by-case basis under R.61-9.125.3(c)(2) or (c)(3), or pursuant to section 405(d)(4) of the CWA;
- (v) Limitations to meet the criteria for permit issuance under R.61-9.122.4(i); or
- (vi) Waivers from monitoring requirements granted under R.61-9.122.44(a).

(2) For every permit to be issued to a treatment works owned by a person other than a State or municipality, an explanation of the Department's decision on regulation of users under R.61-9.122.44(m).

(c) When appropriate, a sketch or detailed description of the location of the discharge or regulated activity described in the application; and

(d) [Reserved]

(e) [Reserved].

124.57. Public notice.

(a) Section 316(a) requests. In addition to the information required under section 124.10(d)(1), public notice of an NPDES draft permit for a discharge where a CWA section 316(a) request has been filed under section R.61-9.122.21(l) shall include:

(1) A statement that the thermal component of the discharge is subject to effluent limitations under CWA sections 301 or 306 and a brief description, including a quantitative statement, of the thermal effluent limitations proposed under section 301 or 306;

(2) A statement that a section 316(a) request has been filed and that alternative less stringent effluent limitations may be imposed on the thermal component of the discharge under section 316(a) and a brief description, including a quantitative statement, of the alternative effluent limitations, if any, included in the request; and

(b) [Reserved]

124.59. Conditions requested by the Corps of Engineers and other government agencies.

(a) If during the comment period for an NPDES draft permit, the District Engineer advises the Department in writing that anchorage and navigation of any waters of the State would be substantially impaired by the granting of a permit, the permit shall be denied and the applicant so notified. If the District Engineer advised the Department that imposing specified conditions upon the permit is necessary to avoid any substantial impairment of anchorage or navigation, then the Department shall include the specified conditions in the permit. Review or appeal of denial of a permit or of conditions specified by the District Engineer shall be made through the applicable procedures of the Corps of Engineers, and may not be made through the procedures provided in this regulation. If the conditions are stayed by a court of competent jurisdiction or by applicable procedures of the Corps of Engineers, those conditions shall be considered stayed in the NPDES permit for the duration of that stay.

(b) If during the comment period the U.S. Fish and Wildlife Service, the National Marine Fisheries Service, or any other State or Federal agency with jurisdiction over fish, wildlife, or public health advises the Department in writing that the imposition of specified conditions upon the permit is necessary to avoid substantial impairment of fish, shellfish, or wildlife resources, the Department may include the specified conditions in the permit to the extent they are determined necessary to carry out the provisions of R.61-9.122.49 and of the CWA.

(c) In appropriate cases, the Department may consult with one or more of the agencies referred to in this section before issuing a draft permit and may reflect their views in the fact sheet, or the draft permit.

124.62. Decision on variances.

(a) The Department may grant or deny requests for the following variances (subject to EPA objection under 40 CFR Part 123.44 for State NPDES permits);

(1) [Reserved]

(2) After consultation with the Regional Administrator, extensions under CWA section 301(k) based on the use of innovative technology; or

(3) Variances under CWA section 316(a) for thermal pollution.

(b) The Department may deny, or forward to the Regional Administrator with a written concurrence, or submit to EPA without recommendation a completed request for:

(1) [Reserved]

(2) A variance based on water quality related effluent limitations under CWA section 302(b)(2) or PCA.

(c) The Regional Administrator may deny, forward, or submit to the Office Director for Water Enforcement and Permits with a recommendation for approval, a request for a variance listed in paragraph (b) of this section that is forwarded by the Department.

(d) The EPA Office Director for Water Enforcement and Permits may approve or deny any variance request submitted under paragraph (c) of this section. If the Office Director approves the variance, the Department may prepare a draft permit incorporating the variance.

(e) The Department may deny or forward to the Administrator (or his delegate) with a written concurrence a completed request for:

(1) A variance based on the presence of “fundamentally different factors” from those on which an effluent limitations guideline was based;

(2) A variance based upon certain water quality factors under CWA section 301(g).

(f) The Administrator (or his delegate) may grant or deny a request for a variance listed in paragraph (e) of this section that is forwarded by the Department. If the Administrator (or his delegate) approves the variance, the Department may prepare a draft permit incorporating the variance.

61-9.125. CRITERIA AND STANDARDS FOR THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM.

Editor’s Note

The following constitutes the history for 61-9.125, 125.1 through 125.73.

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001; State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003; State Register Volume 29, Issue No. 2, eff February 25, 2005.

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PART A
CRITERIA AND STANDARDS FOR IMPOSING TECHNOLOGY-BASED TREATMENT REQUIREMENTS
UNDER SECTIONS 301(B) AND 402 OF THE CLEAN WATER ACT

125.1. Purpose and scope.

This part establishes criteria and standards for the imposition of technology-based treatment requirements in permits under section 48-1-90 of the South Carolina Pollution Control Act and section 301(b) of the Federal Clean Water Act, including the application of EPA promulgated effluent limitations and case-by-case determinations of effluent limitations under this regulation and section 402(a)(1) of the Clean Water Act.

125.2. Definitions.

Unless otherwise noted, the definitions in R.61-9.122, 40 CFR Part 123, and R.61-9.124 apply to this part.

125.3. Technology-based treatment requirements in permits.

(a) General. Technology-based treatment requirements under section 301(b) of the CWA represent the minimum level of control that must be imposed in an NPDES permit issued under section 402 of the CWA. (See R.61-9.122.41, 122.42, and 122.44 for a discussion of additional or more stringent effluent limitations and conditions.) NPDES permits shall contain the following technology-based treatment requirements in accordance with the following statutory deadlines:

(1) For POTW's, NPDES permit effluent limitations based upon:

- (i) Secondary treatment - from date of permit issuance; and
- (ii) [Reserved]

(2) For dischargers other than POTWs except as provided in R. 61-9.122.29(d), NPDES permit effluent limitations requiring:

- (i) The best practicable control technology currently available (BPT).
 - (A) [Reserved]
 - (B) [Reserved]

(C) For all other BPT effluent limitations compliance is required from the date of permit issuance.

(ii) For conventional pollutants, the best conventional pollutant control technology (BCT).

(iii) For all toxic pollutants referred to in Committee Print No. 95-30, House Committee on Public Works and Transportation, the best available technology economically achievable (BAT).

(iv) For all toxic pollutants other than those listed in Committee Print No. 95-30, effluent limitations based on BAT.

(v) For all pollutants which are neither toxic nor conventional pollutants, effluent limitations based on BAT.

(b) Statutory variances and extensions.

(1) The following variances from technology-based treatment requirements are authorized by the CWA and may be applied for under R.61-9.122.21;

- (i) [Reserved]
- (ii) For dischargers other than POTW's;
 - (A) [Reserved]
 - (B) [Reserved]; and
 - (C) A section 316(a) thermal variance from BPT, BCT and BAT (Part H).

(2) The following extensions of deadlines for compliance with technology-based treatment requirements are authorized by the CWA and may be applied for under R.61-9.124.53:

- (i) [Reserved]

(ii) For dischargers other than POTW's:

(A) [Reserved]

(B) A section 301(k) extension of the BAT deadline.

(c) Methods of imposing technology-based treatment requirements in permits. Technology-based treatment requirements may be imposed through one of the following three methods:

(1) Application of EPA-promulgated effluent limitations developed under section 304 of the CWA to dischargers by category or subcategory. These effluent limitations are not applicable to the extent that they have been remanded or withdrawn. However, in the case of a court remand, determinations underlying effluent limitations shall be binding in permit issuance proceedings where those determinations are not required to be reexamined by a court remanding the regulations. In addition, dischargers may seek fundamentally different factors variances from these effluent limitations under R.61-9.122.21 and Part D of this regulation.

(2) On a case-by-case basis under section 402(a)(1) of the CWA, to the extent that EPA-promulgated effluent limitations are inapplicable. The permit writer shall apply the appropriate factors listed in section 125.3(d) and shall consider:

(i) The appropriate technology for the category or class of point sources of which the applicant is a member, based upon all available information; and

(ii) Any unique factors relating to the applicant.

(3) Through a combination of the methods in paragraphs (d)(1) and (d)(2) of this section. Where promulgated effluent limitations guidelines only apply to certain aspects of the discharger's operation, or to certain pollutants, other aspects or activities are subject to regulation on a case-by-case basis in order to carry out the provisions of the CWA and Pollution Control Act.

(4) Limitations developed under paragraph (d)(2) of this section may be expressed, where appropriate, in terms of toxicity (e.g., "the LC50 for fat head minnow of the effluent from outfall 001 shall be greater than 25%"), provided that it is shown that the limits reflect the appropriate requirements (for example, technology-based or water-quality-based standards) of the CWA.

(d) In setting case-by-case limitations pursuant to section 125.3(c), the permit writer must consider the following factors:

(1) For BPT requirements:

(i) The total cost of application of technology in relation to the effluent reduction benefits to be achieved from such application;

(ii) The age of equipment and facilities involved;

(iii) The process employed;

(iv) The engineering aspects of the application of various types of control techniques;

(v) Process changes; and

(vi) Non-water quality environmental impact (including energy requirements).

(2) For BCT requirements:

(i) The reasonableness of the relationship between the costs of attaining a reduction in effluent and the effluent reduction benefits derived;

(ii) The comparison of the cost and level of reduction of such pollutants from the discharge from publicly owned treatment works to the cost and level of reduction of such pollutants from a class or category of industrial sources;

(iii) The age of equipment and facilities involved;

(iv) The process employed;

(v) The engineering aspects of the application of various types of control techniques;

(vi) Process changes; and

(vii) Non-water quality environmental impact (including energy requirements).

(3) For BAT requirements:

(i) The age of equipment and facilities involved;

- (ii) The process employed;
 - (iii) The engineering aspects of the application of various types of control techniques;
 - (iv) Process changes;
 - (v) The cost of achieving such effluent reduction; and
 - (vi) Non-water quality environmental impact (including energy requirements).
- (e) Technology-based treatment requirements are applied prior to or at the point of discharge.
- (f) Technology-based treatment requirements cannot be satisfied through the use of “non-treatment” techniques such as flow augmentation and in-stream mechanical aerators. However, these techniques may be considered as a method of achieving water quality standards on a case-by-case basis when:
- (1) The technology-based treatment requirements applicable to the discharge are not sufficient to achieve the standards;
 - (2) The discharger agrees to waive any opportunity to request a variance under section 301(c), (g) or (h) of the CWA; and
 - (3) The discharger demonstrates that such a technique is the preferred environmental and economic method to achieve the standards after consideration of alternatives such as advanced waste treatment, recycle and reuse, land disposal, changes in operating methods, and other available methods.
- (g) Technology-based effluent limitations shall be established under this part for solids, sludges, filter backwash, and other pollutants removed in the course of treatment or control of wastewaters in the same manner as for other pollutants.
- (h)(1) The Department may set a permit limit for a conventional pollutant at a level more stringent than the best conventional pollution control technology (BCT), or a limit for a nonconventional pollutant which shall not be subject to modification under section 301(c) or (g) of the CWA where:
- (i) Effluent limitations guidelines specify the pollutant as an indicator for a toxic pollutant, or
 - (ii)(A) The limitation reflects BAT-level control of discharges of one or more toxic pollutants which are present in the waste stream, and a specific BAT limitation upon the toxic pollutant(s) is not feasible for economic or technical reasons;
 - (B) The permit identifies which toxic pollutants are intended to be controlled by use of the limitation; and
 - (C) The fact sheet required by R.61-9.124.56 sets forth the basis for the limitation, including a finding that compliance with the limitation will result in BAT-level control of the toxic pollutant discharges identified in paragraph (h)(1)(ii)(B) of this part, and a finding that it would be economically or technically infeasible to directly limit the toxic pollutant(s).
- (2) The Department may set a permit limit for a conventional pollutant at a level more stringent than BCT when:
- (i) Effluent limitations guidelines specify the pollutant as an indicator for a hazardous substance, or
 - (ii)(A) The limitation reflects BAT-level control of discharges (or an appropriate level determined under section 301(c) or (g) of the CWA) of one or more hazardous substance(s) which are present in the waste stream, and a specific BAT (or other appropriate) limitation upon the hazardous substance(s) is not feasible for economic or technical reasons;
 - (B) The permit identifies which hazardous substances are intended to be controlled by use of the limitation; and
 - (C) The fact sheet required by R.61-9.124.56 sets forth the basis for the limitation, including a finding that compliance with the limitations will result in BAT-level (or other appropriate level) control of the hazardous substances discharges identified in paragraph (h)(2)(ii)(B) of this section, and a finding that it would be economically or technically infeasible to directly limit the hazardous substance(s).
 - (iii) Hazardous substances which are also toxic pollutants are subject to paragraph (h)(1) of this section.

(3) The Department may not set a more stringent limit under the preceding paragraphs if the method of treatment required to comply with the limit differs from that which would be required if the toxic pollutant(s) or hazardous substance(s) controlled by the limit were limited directly.

(4) Toxic pollutants identified under paragraph (h)(1) of this section remain subject to the requirements of R.61-9.122.42(a)(1) (notification of increased discharges of toxic pollutants above levels reported in the application form).

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

PART B

CRITERIA FOR ISSUANCE OF PERMITS TO AQUACULTURE PROJECTS

125.10. Purpose and scope.

(a) These regulations establish guidelines under sections 318 and 402 of the CWA for approval of any discharge of pollutants associated with an aquaculture project.

(b) The regulations authorize, on a selective basis, controlled discharges which would otherwise be unlawful under the PCA, section 48-1-90, and the CWA in order to determine the feasibility of using pollutants to grow aquatic organisms which can be harvested and used beneficially.

(c) Permits issued for discharges into aquaculture projects under this part are NPDES permits and are subject to the applicable requirements of R.61-9.122 and 124 and 40 CFR Part 123. Any permit shall include such conditions (including monitoring and reporting requirements) as are necessary to comply with those regulations. Technology-based effluent limitations need not be applied to discharges into the approved project except with respect to toxic pollutants.

125.11. Criteria.

(a) No NPDES permit shall be issued to an aquaculture project unless:

(1) The Department determines that the aquaculture project:

(i) Is intended by the project operator to produce a crop which has significant direct or indirect commercial value (or is intended to be operated for research into possible production of such a crop); and

(ii) Does not occupy a designated project area which is larger than can be economically operated for the crop under cultivation or than is necessary for research purposes.

(2) The applicant has demonstrated, to the satisfaction of the Director, that the use of the pollutant to be discharged to the aquaculture project will result in an increased harvest of organisms under culture over what would naturally occur in the area;

(3) The applicant has demonstrated, to the satisfaction of the Department that if the species to be cultivated in the aquaculture project is not indigenous to the immediate geographical area, there will be minimal adverse effects on the flora and fauna indigenous to the area, and the total commercial value of the introduced species is at least equal to that of the displaced or affected indigenous flora and fauna;

(4) The Department determines that the crop will not have a significant potential for human health hazards resulting from its consumption;

(5) The Department determines that migration of pollutants from the designated project area to water outside of the aquaculture project will not cause or contribute to a violation of water quality standards or a violation of the applicable standards and limitations applicable to the supplier of the pollutant that would govern if the aquaculture project were itself a point source. The approval of an aquaculture project shall not result in the enlargement of a pre-existing mixing zone area beyond what had been designated by the State for the original discharge.

(b) No permit shall be issued for any aquaculture project in conflict with a plan or an amendment to a plan approved under section 208(b) of the CWA.

(c) No permit shall be issued for any aquaculture project located in the territorial sea, the waters of the contiguous zone, or the oceans, except in conformity with guidelines issued under section 403(c) of the CWA.

(d) Designated project areas shall not include a portion of a body of water large enough to expose a substantial portion of the indigenous biota to the conditions within the designated project area. For example, the designated project area shall not include the entire width of a watercourse, since all organisms indigenous to that watercourse might be subjected to discharges of pollutants that would, except for the provisions of section 318 of the CWA, violate section 301 of the CWA.

(e) Any modifications caused by the construction or creation of a reef, barrier or containment structure shall not unduly alter the tidal regimen of an estuary or interfere with migrations of unconfined aquatic species.

(f) Any pollutants not required by or beneficial to the aquaculture crop shall not exceed applicable standards and limitations when entering the designated project area.

PART D

CRITERIA AND STANDARDS FOR DETERMINING FUNDAMENTALLY DIFFERENT FACTORS UNDER SECTIONS 301(B)(1)(A), 301(B)(2)(A) AND (E) OF THE CWA

125.30. Purpose and scope.

(a) This part establishes the criteria and standards to be used in determining whether effluent limitations alternative to those required by promulgated EPA effluent limitations guidelines under sections 301 and 304 of the CWA (hereinafter referred to as “national limits”) should be imposed on a discharger because factors relating to the discharger’s facilities, equipment, processes or other factors related to the discharger are fundamentally different from the factors considered by EPA in development of the national limits. This part applies to all national limitations promulgated under sections 301 and 304 of the CWA, except for the BPT limits contained in 40 CFR 423.12 (steam electric generating point source category).

(b) In establishing national limits, EPA takes into account all the information it can collect, develop and solicit regarding the factors listed in sections 304(b) and 304(g) of the CWA. In some cases, however, data which could affect these national limits as they apply to a particular discharge may not be available or may not be considered during their development. As a result, it may be necessary on a case-by-case basis to adjust the national limits, and make them either more or less stringent as they apply to certain dischargers within an industrial category or subcategory. This will only be done if data specific to that discharger indicates it presents factors fundamentally different from those considered by EPA in developing the limit at issue. Any interested person believing that factors relating to the discharger’s facilities, equipment, processes or other facilities related to the discharger are fundamentally different from the factors considered during development of the national limits may request a fundamentally different factors variance under R.61-9.122.21(l)(1). In addition, such a variance may be proposed by the Department in the draft permit.

125.31. Criteria.

(a) A request for the establishment of effluent limitations under this part (fundamentally different factors variance) shall be approved only if:

(1) There is an applicable national limit which is applied in the permit and specifically controls the pollutant for which alternative effluent limitations or standards have been requested; and

(2) Factors relating to the discharge controlled by the permit are fundamentally different from those considered by EPA in establishing the national limits; and

(3) The request for alternative effluent limitations or standards is made in accordance with the procedural requirements of R.61-9.124.

(b) A request for the establishment of effluent limitations less stringent than those required by national limits guidelines shall be approved only if:

(1) The alternative effluent limitation or standard requested is no less stringent than justified by the fundamental difference; and

(2) The alternative effluent limitation or standard will ensure compliance with section 208(e) and 301(b)(1)(C) of the CWA; and

(3) Compliance with the national limits (either by using the technologies upon which the national limits are based or by other control alternatives) would result in:

- (i) A removal cost wholly out of proportion to the removal cost considered during development of the national limits; or
 - (ii) A non-water quality environmental impact (including energy requirements) fundamentally more adverse than the impact considered during development of the national limits.
- (c) A request for alternative limits more stringent than required by national limits shall be approved only if:
- (1) The alternative effluent limitation or standard requested is no more stringent than justified by the fundamental difference; and
 - (2) Compliance with the alternative effluent limitation or standard would not result in:
 - (i) A removal cost wholly out of proportion to the removal cost considered during development of the national limits; or
 - (ii) A non-water quality environmental impact (including energy requirements) fundamentally more adverse than the impact considered during development of the national limits.
- (d) Factors which may be considered fundamentally different are:
- (1) The nature or quality of pollutants contained in the raw waste load of the applicant's process wastewater;
 - (2) The volume of the discharger's process wastewater and effluent discharged;
 - (3) Non-water quality environmental impact of control and treatment of the discharger's raw waste load;
 - (4) Energy requirements of the application of control and treatment technology;
 - (5) Age, size, land availability, and configuration as they relate to the discharger's equipment or facilities; processes employed; process changes; and engineering aspects of the application of control technology;
 - (6) Cost of compliance with required control technology.
- (e) A variance request or portion of such a request under this section shall not be granted on any of the following grounds:
- (1) The infeasibility of installing the required waste treatment equipment within the time the CWA allows.
 - (2) The assertion that the national limits cannot be achieved with the appropriate waste treatment facilities installed, if such assertion is not based on factor(s) listed in paragraph (d) of this section;
 - (3) The discharger's ability to pay for the required waste treatment; or
 - (4) The impact of a discharge on local receiving water quality.
- (f) Nothing in this section shall be construed to impair the right of the State or locality under section 510 of the CWA to impose more stringent limitations than those required by Federal law.

125.32. Method of application.

- (a) A written request for a variance under this part D shall be submitted in duplicate to the Department in accordance with R61-9.122.21(m)(1) and R61-9.124.3.
- (b) The burden is on the person requesting the variance to explain that:
 - (1) Factor(s) listed in section 125.31(b) regarding the discharger's facility are fundamentally different from the factors EPA considered in establishing the national limits. The requester should refer to all relevant material and information, such as the published guideline regulations development document, all associated technical and economic data collected for use in developing each national limit, all records of legal proceedings, and all written and printed documentation including records of communication, etc., relevant to the regulations which are kept on public file by the EPA;
 - (2) The alternative limitations requested are justified by the fundamental difference alleged in paragraph (b)(1) of this section; and
 - (3) The appropriate requirements of section 125.31 have been met.

PART H
CRITERIA FOR DETERMINING ALTERNATIVE EFFLUENT LIMITATIONS
UNDER SECTION 316(A) OF THE CWA

125.70. Purpose and scope.

(a) Section 316(a) of the CWA provides that: "With respect to any point source otherwise subject to the provisions of section 301 or section 306 of this ACT, whenever the owner or operator of any such source, after opportunity for public hearing, can demonstrate to the satisfaction of ... the State that any effluent limitation proposed for the control of the thermal component of any discharge from such source will require effluent limitations more stringent than necessary to assure the protection and propagation of a balanced, indigenous population of shellfish, fish and wildlife in and on the body of water into which the discharge is to be made, the ...State may impose an effluent limitation under such sections on such plant, with respect to the thermal component of such discharge (taking into account the interaction of such thermal component with other pollutants), that will assure the protection and propagation of a balanced indigenous population of shellfish, fish and wildlife in and on that body of water."

(b) This part describes the factors, criteria and standards for establishment of alternative thermal effluent limitations under section 316(a) of the CWA in permits issued under section 402(a) of the CWA.

125.71. Definitions.

For the purpose of this part:

(a) "Alternative effluent limitations" means all effluent limitations or standards of performance for the control of the thermal component of any discharge which are established under section 316(a) of the CWA, this section, and the State Water Quality Standard R.61-68.

(b) "Representative important species" means species which are representative, in terms of their biological needs, of a balanced, indigenous community of shellfish, fish and wildlife in the body of water into which a discharge of heat is made.

(c) The term "balanced, indigenous community" is synonymous with the term "balanced, indigenous population" in the CWA and means a biotic community typically characterized by diversity, the capacity to sustain itself through cyclic seasonal changes, presence of necessary food chain species and by a lack of domination by pollution tolerant species. Such a community may include historically non-native species introduced in connection with a program of wildlife management and species whose presence or abundance results from substantial, irreversible environmental modifications. Normally, however, such a community will not include species whose presence or abundance is attributable to the introduction of pollutants that will be eliminated by compliance by all sources with section 301(b)(2) of the CWA; and may not include species whose presence or abundance is attributable to alternative effluent limitations imposed pursuant to section 316(a) of the CWA.

125.72. Early screening of applications for variances under section 316(a) of the CWA.

(a) Any initial application for a section 316(a) variance shall include the following early screening information:

- (1) A description of the alternative effluent limitation requested;
- (2) A general description of the method by which the discharger proposes to demonstrate that the otherwise applicable thermal discharge effluent limitations are more stringent than necessary;
- (3) A general description of the type of data, studies, experiments and other information which the discharger intends to submit for the demonstration; and
- (4) Such data and information as may be available to assist the Department in selecting the appropriate representative important species.

(b) After submitting the early screening information under paragraph (a) of this section, the discharger shall consult with the Department at the earliest practicable time (but not later than 30 days after the application is filed) to discuss the discharger's early screening information. Within 60 days after the application is filed, the discharger shall submit for the Department's approval a detailed plan

of study which the discharger will undertake to support its section 316(a) demonstration. The discharger shall specify the nature and extent of the following type of information to be included in the plan of study; Biological, hydrographical and meteorological data; physical monitoring data; engineering or diffusion models; laboratory studies; representative important species; and other relevant information. In selecting representative important species, special consideration shall be given to species mentioned in applicable water quality standards. After the discharger submits its detailed plan of study, the Department shall either approve the plan or specify any necessary revisions to the plan. The discharger shall provide any additional information or studies which the Department subsequently determines necessary to support the demonstration, including such studies or inspections as may be necessary to select representative important species. The discharger may provide any additional information or studies which the discharger feels are appropriate to support the demonstration.

(c) Any application for the renewal of a section 316(a) variance shall include only such information described in paragraph (a) and (b) of this section and section 125.73(c)(1) as the Department requests within 60 days after receipt of the permit application.

(d) [Reserved]

(e) In making the demonstration the discharge shall consider any information or guidance published by EPA to assist in making such demonstrations.

(f) If an applicant desires a ruling on a section 316(a) application before the ruling on any other necessary permit terms and conditions, it shall so request upon filing its application under paragraph (a) of this section. This request shall be granted or denied at the discretion of the Department.

125.73. Criteria and standards for the determination of alternative effluent limitations under section 316(a) of the CWA.

(a) Thermal discharge effluent limitations or standards established in permits may be less stringent than those required by applicable standards and limitations if the discharger demonstrates to the satisfaction of the Department that such effluent limitations are more stringent than necessary to assure the protection and propagation of a balanced, indigenous community of shellfish, fish and wildlife in and on the body of water into which the discharge is made. This demonstration must show that the alternative effluent limitation desired by the discharger, considering the cumulative impact of its thermal discharge together with all other significant impacts on the species affected, will assure the protection and propagation of a balanced indigenous community of shellfish, fish and wildlife in and on the body of water into which the discharge is to be made.

(b) In determining whether or not the protection and propagation of the affected species will be assured, the Department may consider any information contained or referenced in any applicable thermal water quality criteria and thermal water quality information published by the Administrator under section 304(a) of the CWA, or any other information it deems relevant.

(c)(1) Existing dischargers may base their demonstration upon the absence of prior appreciable harm in lieu of predictive studies. Any such demonstrations shall show:

(i) That no appreciable harm has resulted from the normal component of the discharge (taking into account the interaction of such thermal component with other pollutants and the additive effect of other thermal sources to a balanced, indigenous community of shellfish, fish and wildlife in and on the body of water into which the discharge has been made; or

(ii) That despite the occurrence of such previous harm, the desired alternative effluent limitations (or appropriate modifications thereof) will nevertheless assure the protection and propagation of a balanced, indigenous community of shellfish, fish and wildlife in and on the body of water into which the discharge is made.

(2) In determining whether or not prior appreciable harm has occurred, the Department shall consider the length of time in which the applicant has been discharging and the nature of the discharge.

61-9.127. NPDES Electronic Reporting.

Refer to 40 CFR Part 127, which is hereby adopted by reference.

HISTORY: Added by SCSR 43-11 Doc. No. 4888, eff November 22, 2019.

61-9.129. TOXIC POLLUTANT EFFLUENT STANDARDS.

Editor's Note

The following constitutes the history for 61-9.129, 129.1 through 129.105.

HISTORY: Amended by State Register Volume 29, Issue No. 2, eff February 25, 2005.

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PART A

TOXIC POLLUTANT EFFLUENT STANDARDS AND PROHIBITIONS

129.1. Scope and Purpose.

(a) The provisions of this Part apply to owners or operators of specified facilities discharging into waters of the State.

(b) The effluent standards or prohibitions for toxic pollutants established in this Part shall be applicable to the sources and pollutants hereinafter set forth, and may be incorporated in any NPDES permit, modification or renewal thereof, in accordance with the provisions of this Part.

(c) The provisions of R.61-9.124 and R.61-9.125 shall apply to any NPDES permit proceedings for any point source discharge containing any toxic pollutant for which a standard or prohibition is established under this Part.

129.2. Definitions.

All terms not defined herein shall have the meaning given them R.61-9.122 or R.61-9.124. As used in this regulation, the term:

(a) "Air emissions" means the release or discharge of a toxic pollutant by an owner or operator into the ambient air either (1) by means of a stack or (2) as a fugitive dust, mist, or vapor as a result inherent to the manufacturing or formulating process.

(b) "Ambient water criterion" means that concentration of a toxic pollutant in the waters of the State that, based upon available data, will not result in adverse impact in important aquatic life, or on consumers of such aquatic life, after exposure of that aquatic life for periods of time exceeding 96 hours and continuing at least through one reproductive cycle; and will not result in a significant risk of adverse health effects in a large human population based on available information such as mammalian laboratory toxicity data, epidemiological studies of human occupational exposures, or human exposure data, or any other relevant data.

(c) "Construction" means any placement, assembly, or installation of facilities or equipment (including contractual obligations to purchase such facilities or equipment) at the premises where such equipment will be used, including preparation work at such premises.

(d) "Effluent standard" means, for purposes of 307, the equivalent of effluent limitation as that term is defined in section 502(11) of the CWA with the exception that it does not include a schedule of compliance.

- (e) "Existing Source" means any source which is not a new source as defined in this section.
- (f) "Fugitive dust, mist, or vapor" means dust, mist or vapor containing a toxic pollutant regulated under this Part which is emitted from any source other than through a stack.
- (g) "Manufacturer" means any establishment engaged in the mechanical or chemical transformation of materials or substances into new products including but not limited to the blending of materials such as pesticidal products, resins, or liquors.
- (h) "New Source" means any source discharging a toxic pollutant, the construction of which is commenced after proposal of an effluent standard or prohibition applicable to such source if such effluent standard or prohibition is thereafter promulgated in accordance with section 307 of CWA.
- (i) "Owner or operator" means any person who owns, leases, operates, controls, or supervises a source as defined above.
- (j) "Permit" means a permit for the discharge of pollutants into waters of the State under the National Pollutant Discharge Elimination System established by Section 402 of the CWA, the PCA, and implemented in regulations in R.61-9.124 and R.61-9.125.
- (k) "Process Wastes" means any designated toxic pollutant, whether in wastewater or otherwise present, which is inherent to or unavoidably resulting from any manufacturing process, including that which comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product or waste product and is discharged into the waters of the state.
- (l) "Prohibited" means that the constituent shall be absent in any discharge subject to these standards, as determined by any analytical method.
- (m) "Source" means any building, structure, facility, or installation from which there is or may be the discharge of toxic pollutants designated as such by the Administration under section 307(a)(1) of the CWA.
- (n) "Stack" means any chimney, flue, conduit, or duct arranged to conduct emissions to the ambient air.
- (o) "Ten year 24-hour rainfall event" means the maximum precipitation event with a probable recurrence interval of once in 10 years as defined by the National Weather Service in technical paper No. 40, "Rainfall Frequency Atlas of the United States," May 1961, and subsequent amendments or equivalent regional or State rainfall probability information developed therefrom.
- (p) "Working day" means the hours during a calendar day in which a facility discharges effluents subject to this regulation.

129.3. Abbreviations.

The abbreviations used in this Part represent the following terms:

- lb = pound (or pounds)
- g = gram
- ug/l = micrograms per liter (1 one-millionth gram/liter)
- kg = kilogram(s)
- kkg = 1000 kilogram(s)

129.4. Toxic pollutants.

The following are the pollutants subject to regulation under the provisions of this part:

- (a) Aldrin/Dieldrin-"Aldrin" means the compound aldrin as identified by the chemical name, 1,2,3,4,10,10 -hexachloro -1,4,4a,5,8,8a -hexahydro -1,4 -endo -5,8 -exo -dimethanonaphthalene; "Dieldrin" means the compound dieldrin as identified by the chemical name 1,2,3,4,10,10 -hexachloro-6,7 -epoxy -1,4,4a,5,6,7,8,8a -octahydro -1,4 -endo -5,8 -exo -dimethanonaphthalene.
- (b) DDT-"DDT" means the compounds DDT, DDD, and DDE as identified by the chemical names; (DDT) -1,1,1 -trichloro -2,2 -bis(p-chlorophenyl) ethane and some o,p' -isomers; (DDD) or (TDE) -1,1 -dichloro -2,2 -bis(p-chlorophenyl) ethane and some o,p' -isomers; (DDE) -1,1 -dichloro -2,2, -bis(p -chlorophenyl) ethylene.

(c) Endrin—"Endrin" means the compound endrin as identified by the chemical name 1,2,3,4,10,10 -hexachloro -6,7 -epoxy -1,4,4a,5,6,7,8, 8a -octahydro -1,4, -endo -5,8, -endo -dimethanonaphthalene.

(d) Toxaphene—"Toxaphene" means the material consisting of technical grade chlorinated camphene having the approximate formula of $C_{10}H_{10}Cl_8$ and normally containing 67-69 percent chlorine by weight.

(e) Benzidine—"Benzidine" means the compound benzidine and its salts as identified by the chemical name 4,4'-diaminobiphenyl.

(f) Polychlorinated Biphenyls (PCBs) -"Polychlorinated biphenyls (PCBs)" means a mixture of compounds composed of the biphenyl molecule which has been chlorinated to varying degrees.

129.5. Compliance.

(a)(1) Within 60 days from the date of promulgation of any toxic pollutant effluent standard or prohibition, each owner or operator with a discharge subject to that standard or prohibition must notify the Department, of such discharge. Such notification shall include such information and follow such procedures as the Department may require.

(2) Any owner or operator who does not have a discharge subject to any toxic pollutant effluent standard at the time of such promulgation but who thereafter commences or intends to commence any activity which would result in such a discharge shall first notify the Department, in the manner herein provided, at least 60 days prior to any such discharge.

(b) Upon receipt of any application for issuance or reissuance of a permit or for a modification of an existing permit for a discharge subject to a toxic pollutant effluent standard or prohibition, the permitting authority shall proceed thereon in accordance with R.61-9.124 or R.61-9.125, whichever is applicable.

(c)(1) Every permit which contains limitations based upon a toxic pollutant effluent standard or prohibition under this Part is subject to revision following the completion of any proceeding revising such toxic pollutant effluent standard or prohibition regardless of the duration specified on the permit.

(2) For purposes of this section, all toxic pollutants for which standards are set under this Part are deemed to be injurious to human health within the meaning of section 402(k) of the CWA, unless otherwise specified in the standard established for any particular pollutant.

(d)(1) Upon the compliance date for any section 307(a) toxic pollutant effluent standard or prohibition, each owner or operator of a discharge subject to such standard or prohibition shall comply with such monitoring, sampling, recording, and reporting conditions as the Department may require for that discharge. Notice of such conditions shall be provided in writing to the owner or operator.

(2) In addition to any conditions required pursuant to paragraph (d)(1) and to the extent not required in conditions contained in NPDES permits, within 60 days following the close of each calendar year, each owner or operator of a discharge subject to any toxic standard or prohibition shall report to the Department concerning the compliance of such discharges. Such report shall include, as a minimum, information concerning

(i) Relevant identification of the discharger such as name, location of facility, discharge points, receiving waters, and the industrial process or operation emitting the toxic pollutant;

(ii) Relevant conditions (pursuant to paragraph (d)(1) or to an NPDES permit) as to flow, section 307(a) toxic pollutant concentrations, and section 307(a) toxic pollutant mass emission rate;

(iii) Compliance by the discharger with such conditions.

(3) When samples collected for analysis are composited, such samples shall be composited in proportion to the flow at time of collection and preserved in compliance with requirements of the Department, but shall include at least five samples collected at approximately equal intervals throughout the working day.

(e)(1) [Reserved]

(2) Nothing in these regulations shall preclude the Department from requiring in any permit a more stringent effluent limitation or standard pursuant to section 301(b)(1)(C) of the CWA and implemented in R.61-9.124.42 and other related provisions of R.61-9.124.

(f) Any owner or operator of a facility which discharges a toxic pollutant to the waters of the State and to a publicly owned treatment system shall limit the summation of the mass emissions from both discharges to the less restrictive standard, either the direct discharge standard or the pretreatment standard; but in no case will this Subsection allow a discharge to the waters greater than the toxic pollutant effluent standard established for a direct discharge to the waters of the State.

(g) [Reserved]

129.6. Adjustment of effluent standard for presence of toxic pollutant in the intake water.

(a) Upon the request of the owner or operator of a facility discharging a pollutant subject to a toxic pollutant effluent standard or prohibition, the Department shall give credit and shall adjust the effluent standard(s) in such permit to reflect credit for the toxic pollutant(s) in the owner's or operator's water supply if

(1) the source of the owner's or operator's water supply is the same body of water into which the discharge is made and if

(2) it is demonstrated to the satisfaction of the Department that the toxic pollutant(s) present in the owner's or operator's intake water will not be removed by any wastewater treatment systems whose design capacity and operation were such as to reduce toxic pollutants to the levels required by the applicable toxic pollutant effluent standards in the absence of the toxic pollutant in the intake water.

(b) Effluent limitations established pursuant to this section shall be calculated on the basis of the amount of section 307(a) toxic pollutant(s) present in the water after any water supply treatment steps have been performed by or for the owner or operator.

(c) Any permit which includes toxic pollutant effluent limitations established pursuant to this section shall also contain conditions requiring the permittee to conduct additional monitoring in the manner and locations determined by the Department for those toxic pollutants for which the toxic pollutant effluent standards have been adjusted.

129.7. Requirement and procedure for establishing a more stringent effluent limitation.

(a) In exceptional cases

(1) where the Department determines that the ambient water criterion established in these standards is not being met or will not be met in the receiving water as a result of one or more discharges at levels allowed by these standards, and

(2) where the Department further determines that this is resulting in or may cause or contribute to significant adverse effects on aquatic or other organisms usually or potentially present, or on human health, he may issue to an owner or operator a permit or a permit modification containing a toxic pollutant effluent limitation at a more stringent level than that required by the standard set forth in these regulations. Any such action shall be taken pursuant to the procedural provisions of R.61-9.124 and R.61-9.125, as appropriate.

(3) [Reserved]

(b) Any effluent limitation in an NPDES permit which the Department proposes to issue which is more stringent than the toxic pollutant effluent standards promulgated by the Administrator is subject to review by the Administrator under section 402(d) of the CWA. The Administrator may approve or disapprove such limitation(s) or specify another limitation(s) upon review of any record of any proceedings held in connection with the permit issuance or modification and any other evidence available to him. If he takes no action within ninety days of his receipt of the notification of the action of the permit issuing authority and any record thereof, the action of the Department's permit issuing authority shall be deemed to be approved.

129.8. Compliance date.

(a) The effluent standards or prohibitions set forth herein shall be complied with not later than one year after promulgation unless an earlier date is established by the Administrator for an industrial subcategory in the promulgation of the standards or prohibitions.

(b) Toxic pollutant effluent standards or prohibitions set forth herein shall become enforceable under sections 307(d) and 309 of the CWA on the date established in subsection (a) regardless of

proceedings in connection with the issuance of any NPDES permit or application therefor, or modification or renewal thereof.

129.100. Aldrin/Dieldrin.

(a) Specialized definitions.

(1) "Aldrin/Dieldrin Manufacturer" means a manufacturer, excluding any source which is exclusively an aldrin/dieldrin formulator, who produces, prepares or processes technical aldrin or dieldrin or who uses aldrin or dieldrin as a material in the production, preparation or processing of another synthetic organic substance.

(2) "Aldrin/Dieldrin Formulator" means a person who produces, prepares or processes a formulated product comprising a mixture of either aldrin or dieldrin and inert materials or other diluents, into a product intended for application in any use registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135, et seq.).

(3) The ambient water criterion for aldrin/dieldrin in navigable waters is 0.003 ug/l or the State Standard as identified in SC Regulation R.61-68, whichever is more stringent.

(b) Aldrin/Dieldrin manufacturer.

(1) Applicability.

(i) These standards or prohibitions apply to:

(A) All discharges of process wastes; and

(B) All discharges from the manufacturing areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by aldrin/dieldrin as a result of the manufacturing process, including but not limited to:

(1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and

(2) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of aldrin/dieldrin; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.

(2) Analytical method acceptable. Environmental Protection Agency method specified in 40 CFR Part 136, except that a 1-liter sample size is required to increase the analytical sensitivity.

(3) Effluent Standard.

(i) Existing Sources. Aldrin or dieldrin is prohibited in any discharge from any aldrin/dieldrin manufacturer.

(ii) New Sources. Aldrin or dieldrin is prohibited in any discharge from any aldrin/dieldrin manufacturer.

(c) Aldrin/Dieldrin Formulator.

(1) Applicability.

(i) These standards or prohibitions apply to:

(A) All discharges of process wastes; and

(B) All discharges from the formulating areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by aldrin/dieldrin as a result of the formulating process, including but not limited to:

(1) Stormwater and other runoff except as hereinafter provided in subparagraph (ii); and

(2) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of aldrin/dieldrin; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.

(2) Analytical method acceptable. Environmental Protection Agency method specified in 40 CFR Part 136, except that a 1-liter sample size is required to increase the analytical sensitivity.

(3) Effluent Standard.

(i) Existing Sources. Aldrin or dieldrin is prohibited in any discharge from any aldrin/dieldrin formulator.

(ii) New Sources. Aldrin or dieldrin is prohibited in any discharge from any aldrin/dieldrin formulator.

129.101. DDT, DDD and DDE.

(a) Specialized Definitions.

(1) "DDT Manufacturer" means a manufacturer, excluding any source which is exclusively a DDT formulator, who produces, prepares or processes technical DDT, or who uses DDT as a material in the production, preparation or processing of another synthetic organic substance.

(2) "DDT Formulator" means a person who produces, prepares or processes a formulated product comprising a mixture of DDT and inert materials or other diluents into a product intended for application in any use registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135, et seq.).

(3) The ambient water criterion for DDT in navigable waters is 0.001 ug/l, or the State Standard as identified in S.C. Regulation R.61-68, whichever is more stringent.

(b) DDT Manufacturer.

(1) Applicability.

(i) These standards or prohibitions apply to:

(A) All discharges of process wastes; and

(B) All discharges from the manufacturing areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by DDT as a result of the manufacturing process, including but not limited to:

(1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and

(2) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of DDT; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.

(2) Analytical method acceptable. Environmental Protection Agency method specified in 40 CFR Part 136, except that a 1-liter sample size is required to increase the analytical sensitivity.

(3) Effluent Standard.

(i) Existing Sources. DDT is prohibited in any discharge from any DDT manufacturer.

(ii) New Sources. DDT is prohibited in any discharge from any DDT manufacturer.

(c) DDT Formulator.

(1) Applicability.

(i) These standards or prohibitions apply to:

(A) All discharges of process wastes; and

(B) All discharges from the formulating areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by DDT as a result of the formulating process, including but not limited to:

(1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and

(2) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of DDT; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.

(2) Analytical method acceptable. Environmental Protection Agency method specified in 40 CFR Part 136, except that a 1-liter sample size is required to increase the analytical sensitivity.

(3) Effluent Standard.

(i) Existing Sources. DDT is prohibited in any discharge from any DDT formulator.

- (ii) New Sources. DDT is prohibited in any discharge from any DDT formulator.

129.102. Endrin.

(a) Specialized definitions.

(1) "Endrin Manufacturer" means a manufacturer, excluding any source which is exclusively an endrin formulator, who produces, prepares or processes technical endrin or who uses endrin as a material in the production, preparation or processing of another synthetic organic substance.

(2) "Endrin Formulator" means a person who produces, prepares or processes a formulated product comprising a mixture of endrin and inert materials or other diluents into a product intended for application in any use registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C 135, et seq.).

(3) The ambient water criterion for endrin in waters of the State is 0.004 ug/l, or the State Standard as identified in S.C. Regulation R.61-68, whichever is more stringent.

(b) Endrin manufacturer.

(1) Applicability.

(i) These standards or prohibitions apply to:

(A) All discharges of process wastes; and

(B) All discharges from the manufacturing areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by endrin as a result of the manufacturing process, including but not limited to:

(1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and

(2) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of endrin; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.

(2) Analytical method acceptable -Environmental Protection Agency method specified in 40 CFR Part 136.

(3) Effluent Standard.

(i) Existing Sources - Discharges from an endrin manufacturer shall not contain endrin concentrations exceeding an average per working day of 1.5 ug/l calculated over any calendar month; and shall not exceed a monthly average daily loading of 0.0006 kg/kkg of endrin produced; and shall not exceed 7.5 ug/l in a sample(s) representing any working day.

(ii) New Sources - Discharges from an endrin manufacturer shall not contain endrin concentrations exceeding an average per working day of 0.1 ug/l calculated over any calendar month; and shall not exceed a monthly average daily loading of 0.00004 kg/kkg of endrin produced; and shall not exceed 0.5 ug/l in a sample(s) representing any working day.

(iii) Mass Emission Standard During Shutdown of Production - In computing the allowable monthly average daily loading figure required under the preceding subparagraphs (i) and (ii), for any calendar month for which there is no endrin being manufactured at any plant or facility which normally contributes to the discharge which is subject to these standards, the applicable production value shall be deemed to be the average monthly production level for the most recent preceding 360 days of actual operation of the plant or facility.

(c) Endrin Formulator.

(1) Applicability.

(i) These standards or prohibitions apply to:

(A) All discharges of process wastes; and

(B) All discharges from the formulating areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by endrin as a result of the formulating process, including but not limited to:

(1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and

(2) Water used for routine cleanup or cleanup of spills.

- (ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of endrin; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.
- (2) Analytical method acceptable -Environmental Protection Agency method specified in 40 CFR Part 136, except that a 1-liter sample size is required to increase the analytical sensitivity.
- (3) Effluent Standard.
 - (i) Existing Sources - Endrin is prohibited in any discharge from any endrin formulator.
 - (ii) New Sources - Endrin is prohibited in any discharge from any endrin formulator.
- (d) The standards set forth in this Section shall apply to the total combined weight or concentration of endrin, excluding any associated element or compound.

129.103. Toxaphene.

(a) Specialized definitions.

(1) "Toxaphene Manufacturer" means a manufacturer, excluding any source which is exclusively a toxaphene formulator, who produces, prepares or processes toxaphene or who uses toxaphene as a material in the production, preparation or processing of another synthetic organic substance.

(2) "Toxaphene Formulator" means a person who produces, prepares or processes a formulated product comprising a mixture of toxaphene and inert materials or other diluents into a product intended for application in any use registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135, et seq.).

(3) The ambient water criterion for toxaphene in navigable waters is 0.005 ug/l or the State Standard as identified in S.C. Regulation 61-68, whichever is more stringent.

(b) Toxaphene manufacturer.

(1) Applicability.

(i) These standards or prohibitions apply to:

(A) All discharges of process wastes; and

(B) All discharges from the manufacturing areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by toxaphene as a result of the manufacturing process, including but not limited to:

(1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and

(2) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of toxaphene; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.

(2) Analytical method acceptable -Environmental Protection Agency method specified in 40 CFR Part 136.

(3) Effluent Standard.

(i) Existing Sources - Discharges from a toxaphene manufacturer shall not contain toxaphene concentrations exceeding an average per working day of 1.5 ug/l calculated over any calendar month; and shall not exceed a monthly average daily loading of 0.00003 kg/kg of toxaphene produced, and shall not exceed 7.5 ug/l in a sample(s) representing any working day.

(ii) New Sources - Discharges from a toxaphene manufacturer shall not contain toxaphene concentrations exceeding an average per working day of 0.1 ug/l calculated over any calendar month; and shall not exceed a monthly average daily loading of 0.000002 kg/kg of toxaphene produced, and shall not exceed 0.5 ug/l in a sample(s) representing any working day.

(iii) Mass Emission During Shutdown of Production - In computing the allowable monthly average daily loading figure required under the preceding subparagraphs (i) and (ii), for any calendar month for which there is no toxaphene being manufactured at any plant or facility which normally contributes to the discharge which is subject to these standards, the applicable production value shall be deemed to be the average monthly production level for the most recent preceding 360 days of actual operation of the plant or facility.

- (c) Toxaphene Formulator.
- (1) Applicability.
- (i) The standards or prohibitions apply to:
- (A) All discharges of process wastes; and
- (B) All discharges from the formulating areas; loading and unloading areas, storage areas and other areas which are subject to direct contamination by toxaphene as a result of the formulating process, including but not limited to:
- (1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and
- (2) Water used for routine cleanup or cleanup of spills.
- (ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of toxaphene; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.
- (2) Analytical method acceptable -Environmental Protection Agency method specified in 40 CFR Part 136, except that a 1-liter sample size is required to increase the analytical sensitivity.
- (3) Effluent Standards.
- (i) Existing Sources - Toxaphene is prohibited in any discharge from any toxaphene formulator.
- (ii) New Sources - Toxaphene is prohibited in any discharge from any toxaphene formulator.
- (d) The standards set forth in this Section shall apply to the total combined weight or concentration of toxaphene, excluding any associated element or compound.

129.104. Benzidine.

- (a) Specialized definitions.
- (1) "Benzidine Manufacturer" means a manufacturer who produces benzidine or who produces benzidine as an intermediate product in the manufacture of dyes commonly used for textile, leather and paper dyeing.
- (2) "Benzidine-Based Dye Applicator" means an owner or operator who uses benzidine-based dyes in the dyeing of textiles, leather or paper.
- (3) The ambient water criterion for benzidine in navigable waters is 0.1 ug/l or the State Standard as identified in S.C. Regulation 61-68 whichever is more stringent.
- (b) Benzidine manufacturer.
- (1) Applicability.
- (i) These standards apply to:
- (A) All discharges into the waters of the State of process wastes, and
- (B) All discharges into the waters of the State of wastes containing benzidine from the manufacturing areas, loading and unloading areas, storage areas, and other areas subject to direct contamination by benzidine or benzidine-contaminated product as a result of the manufacturing process, including but not limited to:
- (1) Storm water and other runoff except as hereinafter provided in paragraph (b)(1)(ii) of this section and
- (2) Water used for routine cleanup or cleanup of spills.
- (ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of benzidine; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.
- (2) Analytical method acceptable -Environmental Protection Agency method specified in 40 CFR Part 136.
- (3) Effluent standards.
- (i) Existing sources - Discharges from a benzidine manufacturer shall not contain benzidine concentrations exceeding an average per working day of 10 ug/l calculated over any calendar

month, and shall not exceed a monthly average daily loading of 0.130 kg/kkg of benzidine produced, and shall not exceed 50 ug/l in a sample(s) representing any working day.

(ii) New Sources - Discharges from a benzidine manufacturer shall not contain benzidine concentrations exceeding an average per working day of 10 ug/l calculated over any calendar month, and shall not exceed a monthly average daily loading of 0.130 kg/kkg of benzidine produced, and shall not exceed 50 ug/l in a sample(s) representing any working day.

(4) The standards set forth in this paragraph (b) shall apply to the total combined weight or concentration of benzidine, excluding any associated element or compound.

(c) Benzidine-Based Dye Applicators.

(1) Applicability.

(i) These standards apply to:

(A) All discharges into the waters of the State of process wastes, and

(B) All discharges into the waters of the State of wastes containing benzidine from the manufacturing areas, loading and unloading areas, storage areas, and other areas subject to direct contamination by benzidine or benzidine-contaminated product as a result of the manufacturing process, including but not limited to:

(1) Storm water and other runoff except as hereinafter provided in paragraph (c)(1)(ii) of this section and

(2) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of benzidine; or to storm water that exceeds that from the ten year 24-hour rainfall event.

(2) Analytical method acceptable.

(i) Environmental Protection Agency method specified in 40 CFR Part 136; or

(ii) Mass balance monitoring approach which requires the calculation of the benzidine concentration by dividing the total benzidine contained in dyes used during a working day (as certified in writing by the manufacturer) by the total quantity of water discharged during the working day.

(iii) For enforcement purposes, the Department shall rely entirely upon the method specified in 40 CFR 136 in analyses it performs.

(3) Effluent standards.

(i) Existing sources - Discharges from benzidine-based dye applicators shall not contain benzidine concentrations exceeding an average per working day of 10 ug/l calculated over any calendar month; and shall not exceed 25 ug/l in a sample(s) or calculation(s) representing any working day.

(ii) New sources - Discharges from benzidine-based dye applicators shall not contain benzidine concentrations exceeding an average per working day of 10 ug/l calculated over any calendar month; and shall not exceed 25 ug/l in a sample(s) or calculation(s) representing any working day.

(4) The standards set forth in this paragraph (c) shall apply to the total combined concentrations of benzidine, excluding any associated element or compound.

129.105. Polychlorinated biphenyls (PCBs).

(a) Specialized definitions.

(1) "PCB Manufacturer" means a manufacturer who produces polychlorinated biphenyls.

(2) "Electrical capacitor manufacturer" means a manufacturer who produces or assembles electrical capacitors in which PCB or PCB-containing compounds are part of the dielectric.

(3) "Electrical transformer manufacturer" means a manufacturer who produces or assembles electrical transformers in which PCB or PCB-containing compounds are part of the dielectric.

(4) The ambient water criterion for PCBs in navigable waters is 0.001 ug/l or the State Standard as identified in S.C. Regulation 61-68 whichever is more stringent.

(b) PCB Manufacturer.

(1) Applicability.

- (i) These standards or prohibitions apply to:
 - (A) All discharges of process wastes;
 - (B) All discharges from the manufacturing or incinerator areas, loading and unloading areas, storage areas, and other areas which are subject to direct contamination by PCBs as a result of the manufacturing process, including but not limited to:
 - (1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and
 - (2) Water used for routine cleanup or cleanup of spills.
 - (ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of PCBs; or to storm water runoff that exceeds that from the ten year 24-hour rainfall event.
 - (2) Analytical method acceptable -Environmental Protection Agency method specified in 40 CFR Part 136 except that a 1-liter sample size is required to increase analytical sensitivity.
 - (3) Effluent Standards:
 - (i) Existing Sources. PCBs are prohibited in any discharge from any PCB manufacturer;
 - (ii) New Sources. PCBs are prohibited in any discharge from any PCB manufacturer.
- (c) Electrical Capacitor Manufacturer.
- (1) Applicability.
 - (i) These standards or prohibitions apply to:
 - (A) All discharges of process wastes; and
 - (B) All discharges from the manufacturing or incineration areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by PCBs as a result of the manufacturing process, including but not limited to:
 - (1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and
 - (2) Water used for routine cleanup or cleanup of spills.
 - (ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of PCBs; or to storm water runoff that exceeds that from the ten-year 24-hour rainfall event.
 - (2) Analytical method acceptable. Environmental Protection Agency method specified in 40 CFR Part 136, except that a 1-liter sample size is required to increase analytical sensitivity.
 - (3) Effluent Standards:
 - (i) Existing Sources. PCBs are prohibited in any discharge from any electrical capacitor manufacturer;
 - (ii) New Sources. PCBs are prohibited in any discharge from any electrical capacitor manufacturer.
- (d) Electrical Transformer Manufacturer.
- (1) Applicability.
 - (i) These standards or prohibitions apply to:
 - (A) All discharges of process wastes; and
 - (B) All discharges from the manufacturing or incineration areas, loading and unloading areas, storage areas, and other areas which are subject to direct contamination by PCBs as a result of the manufacturing process, including but not limited to:
 - (1) Storm water and other runoff except as hereinafter provided in subparagraph (ii); and
 - (2) Water used for routine cleanup or cleanup of spills.
 - (ii) These standards do not apply to storm water runoff or other discharges from areas subject to contamination solely by fallout from air emissions of PCBs; or to storm water runoff that exceeds that from the ten-year 24-hour rainfall event.
 - (2) Analytical method acceptable. Environmental Protection Agency method specified in 40 CFR Part 136, except that a 1-liter sample size is required to increase analytical sensitivity.

(3) Effluent Standards:

(i) Existing Sources. PCBs are prohibited in any discharge from any electrical transformer manufacturer;

(ii) New Sources. PCBs are prohibited in any discharge from any electrical transformer manufacturer.

(e) Adjustment of effluent standard for presence of PCBs in intake water. Whenever a facility which is subject to these standards has PCBs in its effluent which result from the presence of PCBs in its intake waters, the owner may apply to the Department for a credit pursuant to the provisions of section 129.6, where the source of the water supply is the same body of water into which the discharge is made. The requirement of subparagraph (1) of section 129.6(a), relating to the source of the water supply, shall be waived, and such facility shall be eligible to apply for a credit under section 129.6, upon a showing by the owner or operator of such facility to the Department, that the concentration of PCBs in the intake water supply of such facility does not exceed the concentration of PCBs in the receiving water body to which the plant discharges its effluent.

61-9.133. SECONDARY TREATMENT REGULATION.

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133.100. Purpose.

This part provides information on the level of effluent quality attainable through the application of secondary or equivalent treatment. R.61-9.133 will apply to permits drafted or issued under R.61-9.122 (NPDES permits or NPDES general permits).

133.101. Definitions.

All terms not defined herein shall have the meaning given them R.61-9.122 or R.61-9.124. Terms used in this regulation are defined as follows:

(a) "7-day average." The arithmetic mean of pollutant parameter values for samples collected in a period of 7 consecutive days.

(b) "30-day average." The arithmetic mean of pollutant parameter values of samples collected in a period of 30 consecutive days.

(c) "BOD₅" The five day measure of the pollutant parameter biochemical oxygen demand (BOD).

(d) "CBOD₅". The five day measure of the pollutant parameter carbonaceous biochemical oxygen demand (CBOD₅).

(e) "Effluent concentrations consistently achievable through proper operation and maintenance."

(1) For a given pollutant parameter, the 95th percentile value for the 30-day average effluent quality achieved by a treatment works in a period of at least two years, excluding values attributable to upsets, bypasses, operational errors, or other unusual conditions, and

(2) A 7-day average value equal to 1.5 times the value derived under paragraph (f)(1) of this section.

(f) "Facilities eligible for treatment equivalent to secondary treatment." Treatment works shall be eligible for consideration for effluent limitations described for treatment equivalent to secondary treatment (section 133.105), if:

(1) The BOD₅ and TSS effluent concentrations consistently achievable through proper operation and maintenance (section 133.101(f) of the treatment works exceed the minimum level of the effluent quality set forth in section 133.102(a) and section 133.102(b).

(2) A trickling filter or waste stabilization pond is used as the principal process, and

(3) The treatment works provide significant biological treatment of municipal and/or domestic wastewater.

(g) "mg/l." Milligrams per liter.

(h) "Percent removal." A percentage expression of the removal efficiency across a treatment plant for a given pollutant parameter, as determined from the 30-day average values of the raw wastewater influent pollutant concentrations to the facility and the 30-day average values of the effluent pollutant concentrations for a given time period.

(i) "Significant biological treatment." The use of an aerobic or anaerobic biological treatment process in a treatment works to consistently achieve a 30-day average of at least 65 percent removal of BOD₅.

(j) "Significantly more stringent limitation" means BOD₅ and TSS limitations necessary to meet the percent removal requirements of at least 5 mg/l more stringent than the otherwise applicable concentration-based limitations (e.g., less than 25 mg/l in the case of the secondary treatment limits for BOD₅ and TSS), or the percent removal limitations in section 133.102 and section 133.105, if such limits would, by themselves, force significant construction or other significant capital expenditure.

(k) "TSS." The pollutant parameter total suspended solids.

133.102. Secondary treatment.

The following paragraphs describe the minimum level of effluent quality (in NPDES permits) attainable by secondary treatment in terms of the parameters - BOD₅, TSS and pH. All requirements for each parameter shall be achieved except as provided for in section 133.103 and section 133.105.

(a) BOD₅.

(1) The 30-day average shall not exceed 30 mg/l.

(2) The 7-day average shall not exceed 45 mg/l.

(3) The 30-day average percent removal shall not be less than 85 percent.

(4) At the option of the NPDES permitting authority, in lieu of the parameter BOD₅ and the levels of the effluent quality specified in paragraphs (a)(1), (a)(2) and (a)(3), the parameter CBOD₅ may be substituted with the following levels of the CBOD₅ effluent quality provided:

(i) The 30-day average shall not exceed 25 mg/l.

(ii) The 7-day average shall not exceed 40 mg/l.

(iii) The 30-day average percent removal shall not be less than 85 percent.

(b) TSS.

(1) The 30-day average shall not exceed 30 mg/l.

(2) The 7-day average shall not exceed 45 mg/l.

(3) The 30-day average percent removal shall not be less than 85 percent.

(c) pH. The effluent values for pH shall be maintained within the limits of 6.0 to 9.0 unless the publicly owned treatment works demonstrates that:

(1) Inorganic chemicals are not added to the waste stream as part of the treatment process; and

(2) Contributions from industrial sources do not cause the pH of the effluent to be less than 6.0 or greater than 9.0.

133.103. Special considerations.

(a) Combined sewers. Treatment works subject to this part may not be capable of meeting the percentage removal requirements established under section 133.102(a)(3) and section 133.102(b)(3), or section 133.105(a)(3) and section 133.105(b)(3) during wet weather where the treatment works receive flows from combined sewers (i.e., sewers which are designed to transport both storm water and sanitary

sewage). For such treatment works, the decisions must be made on a case-by-case basis as to whether any attainable percentage removal level can be defined, and if so, what the level should be.

(b) Industrial wastes. For certain industrial categories, the discharge to waters of the State of BOD₅ and TSS permitted under sections 301(b)(1)(A)(i), (b)(2)(E) or 306 of the CWA may be less stringent than the values given in section 133.102(a)(1), section 133.102(a)(4)(i), section 133.102(b)(1), section 133.105(a)(1), section 133.105(b)(1) and section 133.105(e)(1)(i). In cases when wastes would be introduced from such an industrial category into a publicly owned treatment works, the values for BOD₅ and TSS in section 133.102(a)(1), section 133.102(a)(4)(i), section 133.102(b)(1), section 133.105(a)(1), section 133.105(b)(1), and section 133.105(e)(1)(i) may be adjusted upwards provided that:

(1) The permitted discharge of such pollutants, attributable to the industrial category, would not be greater than that which would be permitted under sections 301(b)(1)(A)(i), 301(b)(2)(E) or 306 of the CWA if such industrial category were to discharge directly into the waters of the State, and

(2) The flow or loading of such pollutants introduced by the industrial category exceeds 10 percent of the design flow or loading of the publicly owned treatment works. When such an adjustment is made, the values for BOD₅ or TSS in section 133.102(a)(2), section 133.102(a)(4)(ii), section 133.102(b)(2), section 133.105(a)(2), section 133.105(b)(2), and section 133.105(e)(1)(ii) shall be adjusted proportionately.

(c) Waste stabilization ponds.

(1) The Department, is authorized to adjust the minimum level of effluent quality set forth in section 133.105(b)(1), (b)(2), and (b)(3) for treatment works subject to this part, to conform to the suspended solids concentrations achievable with waste stabilization ponds, provided that:

(A) Waste stabilization ponds including aerated lagoon systems are the principal process used for secondary treatment; and

(B) Operation and maintenance data indicate that the TSS values specified in section 133.105(b)(1), (b)(2), and (b)(3) cannot be achieved.

(2)(A) The term "TSS concentrations achievable with waste stabilization ponds" means a TSS value, determined by the Regional Administrator or the Department, subject to EPA approval, which is equal to the effluent concentration achieved 90 percent of the time within a State or appropriate contiguous geographical area by waste stabilization ponds that are achieving the levels of effluent quality for BOD₅ specified in section 133.105(a)(1).

(B) Allowable limits:

(i) The 30-day average shall not exceed 90 mg/l.

(ii) The 7-day average shall not exceed 135 mg/l.

(d) Less concentrated influent wastewater for separate sewers. The Department may substitute either a lower percent removal requirement or a mass loading limit for the percent removal requirements set forth in section 133.102(a)(3), section 133.102(a)(4)(iii), section 133.102(b)(3), section 133.105(a)(3), section 133.105(b)(3) and section 133.105(e)(1)(iii) provided that the permittee satisfactorily demonstrates that:

(1) The treatment works is consistently meeting, or will consistently meet, its permit effluent concentration limits but its percent removal requirements cannot be met due to less concentrated influent wastewater,

(2) To meet the percent removal requirements, the treatment works would have to achieve significantly more stringent limitations than would otherwise be required by the concentration-based standard, and

(3) The less concentrated influent wastewater is not the result of excessive I/I. The determination of whether the less concentrated wastewater is the result of excessive I/I will use the definition of excessive I/I in 40 CFR 35.2005(b)(16) plus the additional criterion that inflow is non-excessive if the total flow to the POTW (i.e., wastewater plus inflow plus infiltration) is less than 275 gallons per capita per day.

(e) Less concentrated influent wastewater for combined sewers during dry weather. The Department, subject to EPA approval, is authorized to substitute either a lower percent removal requirement or a mass loading limit for the percent removal requirements set forth in section 133.102(a)(3), section

133.102(a)(4)(iii), section 133.102(b)(3), section 133.105(a)(3), section 133.105(b)(3) and section 133.105(e)(1)(iii) provided that the permittee satisfactorily demonstrates that:

(1) The treatment works is consistently meeting, or will consistently meet, its permit effluent concentration limits, but the percent removal requirements cannot be met due to less concentrated influent wastewater;

(2) To meet the percent removal requirements, the treatment works would have to achieve significantly more stringent effluent concentrations than would otherwise be required by the concentration-based standards; and

(3) The less concentrated influent wastewater does not result from either excessive infiltration or clear water industrial discharges during dry weather periods. If the less concentrated influent wastewater is the result of clear water industrial discharges, then the treatment works must control such discharges pursuant to R.61-9.403.

133.104. Sampling and test procedures.

(a) Sampling and test procedures for pollutants listed in this part shall be in accordance with test methods set forth in 40 CFR Part 136.

(b) Chemical oxygen demand (COD) or total organic carbon (TOC) may be substituted for BOD₅ when a long-term BOD:COD or BOD:TOC correlation has been demonstrated.

133.105. Treatment equivalent to secondary treatment.

This section describes the minimum level of effluent quality (in NPDES permits) attainable by facilities eligible for treatment equivalent to secondary treatment (section 133.101(g)) in terms of the parameters - BOD₅, TSS and pH. All requirements for the specified parameters in paragraphs (a), (b) and (c) of this section shall be achieved except as provided for in section 133.103, or paragraphs (d), (e) or (f) of this section.

(a) BOD₅.

(1) The 30-day average shall not exceed 45 mg/l.

(2) The 7-day average shall not exceed 65 mg/l.

(3) The 30-day average percent removal shall not be less than 65 percent.

(b) TSS. Except where TSS values have been adjusted in accordance with section 133.103(c).

(1) The 30-day average shall not exceed 45 mg/l.

(2) The 7-day average shall not exceed 65 mg/l.

(3) The 30-day average percent removal shall not be less than 65 percent.

(c) pH. The requirements of section 133.102(c) shall be met.

(d) Alternative State requirements. Except as limited by paragraph (f) of this section, the Department may adjust the minimum levels of effluent quality set forth in paragraphs (a)(1), (a)(2), (b)(1) and (b)(2) of this section for trickling filter facilities and in paragraphs (a)(1) and (a)(2) of this section for waste stabilization pond facilities, to conform to the BOD₅ and TSS effluent concentrations consistently achievable through proper operation and maintenance (section 133.101(f)) by the median (50th percentile) facility in a representative sample of facilities within the State or appropriate contiguous geographical area that meet the definition of facilities eligible for treatment equivalent to secondary treatment (section 133.101(g)).

(e) CBOD₅ limitations:

(1) Where data are available to establish CBOD₅ limitations for a treatment works subject to this section, the Department may substitute the parameter CBOD₅ for the parameter BOD₅ in section 133.105(a)(1), section 133.105(a)(2) and section 133.105(a)(3), on a case-by-case basis provided that the levels of CBOD₅ effluent quality are not less stringent than the following:

(i) The 30-day average shall not exceed 40 mg/l.

(ii) The 7-day average shall not exceed 60 mg/l.

(iii) The 30-day average percent removal shall not be less than 65 percent.

(2) Where data are available, the parameter CBOD₅ may be used for effluent quality limitations established under paragraph (d) of this section. Where concurrent BOD effluent data are available, they must be submitted with the CBOD data as a part of the approval process outlined in paragraph (d) of this section.

(f) Permit adjustments. Any NPDES permit adjustment made pursuant to this part may not be any less stringent than the limitations required pursuant to section 133.105(a)-(e). Furthermore, the Department shall require more stringent limitations when adjusting permits if:

(1) For existing facilities the Department determines that the 30-day average and 7-day average BOD₅ and TSS effluent values that could be achievable through proper operation and maintenance of the treatment works, based on an analysis of the past performance of the treatment works, would enable the treatment works to achieve more stringent limitations, or

(2) For new facilities, the Department determines that the 30-day average and 7-day average BOD₅ and TSS effluent values that could be achievable through proper operation and maintenance of the treatment works, considering the design capability of the treatment process and geographical and climatic conditions, would enable the treatment works to achieve more stringent limitations.

61-9.403. GENERAL PRETREATMENT REGULATIONS FOR EXISTING AND NEW SOURCES OF POLLUTION.

Editor's Note

The following constitutes the history for 61-9.403, 403.1 through Appendix G.

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001; State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003; State Register Volume 32, Issue No. 5, eff May 23, 2008.

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403.1. Purpose and applicability.

(a) This regulation implements sections 204(b)(1)(C), 208(b)(2)(C)(iii), 301(b)(1)(A)(ii), 301(b)(2)(A)(ii), 301(h)(5) and 301(i)(2), 304(e) and (g), 307, 308, 309, 402(b), 405, and 501(a) of the Federal Water Pollution Control Act as amended by the Clean Water Act of 1977 (Pub. L-95-217) or

“CWA.” It establishes responsibilities of State and local government, industry and the public to implement National Pretreatment Standards to control pollutants which pass through or interfere with treatment processes in Publicly Owned Treatment Works (POTWs) or which may contaminate sewage sludge.

(b) This regulation applies:

(1) to pollutants from non-domestic sources covered by Pretreatment Standards which are indirectly discharged into or transported by truck or rail or otherwise introduced into POTWs as defined below in section 403.3;

(2) to POTWs which receive wastewater from sources subject to National Pretreatment Standards;

(3) to any new or existing source subject to Pretreatment Standards. National Pretreatment Standards do not apply to sources which discharge to a sewer which is not connected to a POTW Treatment Plant.

403.2. Objectives of general pretreatment regulations.

By establishing the responsibilities of government and industry to implement National Pretreatment Standards this regulation fulfills three objectives:

(a) to prevent the introduction of pollutants into POTWs which will interfere with the operation of a POTW, including interference with its use or disposal of municipal sludge;

(b) to prevent the introduction of pollutants into POTWs which will pass through the treatment works or otherwise be incompatible with such works; and

(c) to improve opportunities to recycle and reclaim municipal and industrial wastewaters and sludges.

403.3. Definitions.

(a) Except as discussed below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR Part 401, R.61-9.122, or R.61-9.124 apply.

(b) The term Best Management Practices or BMP means schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to implement the prohibitions listed in Sections 403.5(a)(1) and (b). BMP also include treatment requirements, operating procedures, and practices to control plant site runoff, spillage or leaks, sludge or waste disposal, or drainage from raw materials storage.

(c) The term Control Authority refers to:

(1) The POTW, if the POTW's Pretreatment Program submission has been approved in accordance with the requirements of Section 403.11; or

(2) The Department, if the submission has not been approved.

(d) The term “Approved POTW Pretreatment Program” or “Program” or “POTW Pretreatment Program” means a program administered by a POTW that meets the criteria established in this regulation (sections 403.8 and 403.9) and which has been approved by the Regional Administrator or the Department in accordance with section 403.11 of this regulation.

(e) The term “Indirect Discharge” or “Discharge” means the introduction of pollutants into a POTW from any non-domestic source regulated under section 307(b), (c) or (d) of the CWA or Section 48–1–90 of the Pollution Control Act (PCA).

(f) The term “Industrial User” or “User” means a source of Indirect Discharge.

(g) The term “interference” means a Discharge which, alone or in conjunction with a discharge or discharges from other sources, both:

(1) Inhibits or disrupts the POTW, its treatment processes or operations, or its sludge processes, use or disposal; and

(2) Therefore is a cause of a violation of any requirement of the POTW's NPDES permit (including an increase in the magnitude or duration of a violation) or of the prevention of sewage sludge use or disposal in compliance with the following statutory provisions and regulations or permits issued thereunder (or more stringent State or local regulations): Section 405 of the Clean Water Act, the Solid Waste Disposal Act (SWDA) (including Title II, more commonly referred to as the Resource Conservation and Recovery Act (RCRA), and including State regulations contained in

any State sludge management plan prepared pursuant to Subtitle D of the SWDA), the Clean Air Act, the Toxic Substances Control Act, and the Marine Protection, Research and Sanctuaries Act, and the South Carolina Pollution Control Act.

(h) The term “National Pretreatment Standard,” “Pretreatment Standard,” or “Standard” means any regulation containing pollutant discharge limits promulgated by the EPA in accordance with section 307(b) and (c) of CWA, which applies to Industrial Users. This term includes prohibitive discharge limits established pursuant to section 403.5.

(i)(1) The term “New Source” means any building, structure, facility or installation from which there is or may be a discharge of pollutants, the construction of which commenced after the publication of proposed Pretreatment Standards under section 307(c) of CWA which will be applicable to such source if such Standards are thereafter promulgated in accordance with that section, provided that:

(i) The building, structure, facility or installation is constructed at a site at which no other source is located; or

(ii) The building, structure, facility or installation totally replaces the process or production equipment that causes the discharge of pollutants at an existing source; or

(iii) The production or wastewater generating processes of the building, structure, facility or installation are substantially independent of an existing source at the same site. In determining whether these are substantially independent, factors such as the extent to which the new facility is integrated with the existing plant, and the extent to which the new facility is engaged in the same general type of activity as the existing source should be considered.

(2) Construction on a site at which an existing source is located results in a modification rather than a new source if the construction does not create a new building, structure, facility or installation meeting the criteria of subsections (1)(ii), or (1)(iii) of this section but otherwise alters, replaces, or adds to existing process or production equipment.

(3) Construction of a new source as defined under this paragraph has commenced if the owner or operator has:

(i) Begun, or caused to begin as part of a continuous on-site construction program:

(A) Any placement, assembly, or installation of facilities or equipment; or

(B) Significant site preparation work including clearing, excavation, or removal of existing buildings, structures, or facilities which is necessary for the placement, assembly, or installation of new source facilities or equipment; or

(ii) Entered into a binding contractual obligation for the purchase of facilities or equipment which are intended to be used in its operation within a reasonable time. Options to purchase or contracts which can be terminated or modified without substantial loss, and contracts for feasibility, engineering, and design studies do not constitute a contractual obligation under this paragraph.

(j) The terms “NPDES Permit” or “Permit” means a permit including a Land Application permit issued to a POTW pursuant to section 402 of CWA or Section 48–1–100 of the Pollution Control Act (See R.61–9.122 or R.61–9.505).

(k) The term “Pass Through” means a Discharge which exits the POTW into waters of the State or of the United States in quantities or concentrations which, alone or in conjunction with a discharge or discharges from other sources, is a cause of a violation of any requirement of the POTW’s NPDES permit (including an increase in the magnitude or duration of a violation).

(l) (1) The term “POTW Treatment Plant” means that portion of the POTW which is designed to provide treatment (including recycling and reclamation) of municipal sewage and industrial waste.

(2) For purposes of Part 403, the term “POTW” shall mean publicly owned treatment works or a private facility that has been determined to be a regional provider of service identified under the 208 Water Quality Management Plan.

(m) The term “Pretreatment” means the reduction of the amount of pollutants, the elimination of pollutants, or the alteration of the nature of pollutant properties in wastewater prior to or in lieu of discharging or otherwise introducing such pollutants into a POTW. The reduction or alteration may be obtained by physical, chemical or biological processes, process changes or by other means, except as prohibited by section 403.6(e). Appropriate pretreatment technology includes control equipment,

such as equalization tanks or facilities, for protection against surges or slug loadings that might interfere with or otherwise be incompatible with the POTW. However, where wastewater from a regulated process is mixed in an equalization facility with unregulated wastewater or with wastewater from another regulated process, the effluent from the equalization facility must meet an adjusted pretreatment limit calculated in accordance with section 403.6(f).

(n) The term “Pretreatment Requirements” means any substantive or procedural requirement related to Pretreatment, other than a National Pretreatment Standard, imposed on an Industrial User.

(o) Significant Industrial User.

(1) Except as provided in subsections (2) and (3) of this section, the term Significant Industrial User means:

(i) All Industrial Users subject to Categorical Pretreatment Standards under section 403.6 and 40 CFR chapter I, subchapter N and

(ii) Any other Industrial User that: discharges an average of 25,000 gallons per day or more of process wastewater to the POTW (excluding sanitary, noncontact cooling, and boiler blowdown wastewater); contributes a process wastestream which makes up 5 percent or more of the average dry weather hydraulic or organic capacity of the POTW Treatment plant; or is designated as such by the Control Authority on the basis that the Industrial User has a reasonable potential for adversely affecting the POTW’s operation or for violating any Pretreatment Standard or requirement (in accordance with section 403.8(f)(6)).

(2) The Control Authority may determine that an Industrial User subject to categorical Pretreatment Standards under Section 403.6 and 40 CFR chapter I, subchapter N is a Non-Significant Categorical Industrial User rather than a Significant Industrial User on a finding that the Industrial User never discharges more than 100 gallons per day (gpd) of total categorical wastewater (excluding sanitary, non-contact cooling and boiler blowdown wastewater, unless specifically included in the Pretreatment Standard) and the following conditions are met:

(i) The Industrial User, prior to the Control Authority’s finding, has consistently complied with all applicable categorical Pretreatment Standards and Requirements;

(ii) The Industrial User annually submits the certification statement required in Section 403.12(q) together with any additional information necessary to support the certification statement; and

(iii) The Industrial User never discharges any untreated, concentrated wastewater.

(3) Upon a finding that an Industrial User meeting the criteria in paragraph (o)(1)(ii) of this section has no reasonable potential for adversely affecting the POTW’s operation or for violating any Pretreatment Standards or requirement, the Control Authority may at any time, on its own initiative or in response to a petition received from an Industrial User or POTW, and in accordance with section 403.8(f)(6), determine that such Industrial User is not a Significant Industrial User.

(p) The term “Submission” means a request by a POTW for approval of a Pretreatment Program to the Department.

(q) The term “Water Management Division Director” means one of the Directors of the Water Management Divisions within the Regional offices of the Environmental Protection Agency or this person’s delegated representative.

403.4. State or local law.

Nothing in this regulation is intended to affect any Pretreatment Requirements, including any standards or prohibitions, established by local law as long as the local requirements are not less stringent than any set forth in National Pretreatment Standards, or any other requirements or prohibitions established under CWA or this regulation.

403.5. National pretreatment standards: Prohibited discharges.

(a)(1) General prohibitions. A User may not introduce into a POTW any pollutant(s) which cause Pass Through or Interference. These general prohibitions and the specific prohibitions in paragraph (b) of this section apply to each User introducing pollutants into a POTW whether or not the User is

subject to other National Pretreatment Standards or any national, State, or local Pretreatment Requirements.

(2) Affirmative Defenses. A User shall have an affirmative defense in any action brought against it alleging a violation of the general prohibitions established in paragraph (a)(1) of this section and the specific prohibitions in paragraphs (b)(3), (b)(4), (b)(5), (b)(6), and (b)(7) of this section where the User can demonstrate that:

(i) It did not know or have reason to know that its Discharge, alone or in conjunction with a discharge or discharges from other sources, would cause Pass Through or Interference; and

(ii)(A) A local limit designed to prevent Pass Through and/or Interference, as the case may be, was developed in accordance with paragraph (c) of this section for each pollutant in the User's Discharge that caused Pass Through or Interference, and the User was in compliance with each such local limit directly prior to and during the Pass Through or Interference; or

(B) If a local limit designed to prevent Pass Through and/or Interference, as the case may be, has not been developed in accordance with paragraph (c) of this section for the pollutant(s) that caused the Pass Through or Interference, the User's Discharge directly prior to and during the Pass Through or Interference did not change substantially in nature or constituents from the User's prior discharge activity when the POTW was regularly in compliance with the POTW's NPDES permit requirements and, in the case of Interference, applicable requirements for sewage sludge use or disposal.

(b) Specific prohibitions. In addition, the following pollutants shall not be introduced into a POTW:

(1) Pollutants which create a fire or explosion hazard in the POTW, including, but not limited to, waste streams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40 CFR 261.21.

(2) Pollutants which will cause corrosive structural damage to the POTW, but in no case Discharges with pH lower than 5.0, unless the works is specifically designed to accommodate such Discharges;

(3) Solid or viscous pollutants in amounts which will cause obstruction to the flow in the POTW resulting in Interference;

(4) Any pollutant, including oxygen demanding pollutants (BOD, etc.) released in a Discharge at a flow rate and/or pollutant concentration which will cause Interference with the POTW.

(5) Heat in amounts which will inhibit biological activity in the POTW resulting in Interference, but in no case heat in such quantities that the temperature at the POTW Treatment Plant exceeds 40°C (104°F) unless the Department, upon request of the POTW, approves alternate temperature limits.

(6) Petroleum oil, nonbiodegradable cutting oil, or products of mineral oil origin in amounts that will cause interference or pass through;

(7) Pollutants which result in the presence of toxic gases, vapors, or fumes within the POTW in a quantity that may cause acute worker health and safety problems;

(8) Any trucked or hauled pollutants, except at discharge points designated by the POTW.

(c) When specific limits must be developed by the POTW.

(1) Each POTW developing a POTW Pretreatment Program pursuant to section 403.8 shall develop and enforce specific limits to implement the prohibitions listed in paragraphs (a)(1) and (b) of this section. Each POTW with an approved pretreatment program shall continue to develop these limits as necessary and effectively enforce such limits.

(2) All other POTW shall, in cases where pollutants contributed by User(s) result in Interference or Pass Through, and such violation is likely to recur, develop and enforce specific effluent limits for Industrial User(s), and all other users, as appropriate, which, together with appropriate changes in the POTW Treatment Plant's facilities or operation, are necessary to ensure renewed and continued compliance with the POTW's NPDES permit or sludge use or disposal practices.

(i) This evaluation must reflect the POTW's reasonable potential analysis utilized for all pollutants completed by the Department as part of the NPDES process (R61-9.122). The POTW

will utilize the Department's analysis in the determination of appropriate pretreatment requirements.

(ii) This analysis must utilize the current Water Quality Standards (R.61-68).

(3) Specific effluent limits shall not be developed and enforced without individual notice to persons or groups who have requested such notice and an opportunity to respond.

(4) POTW may develop Best Management Practices (BMP) to implement paragraphs (c)(1) and (c)(2) of this section. Such BMP shall be considered local limits and Pretreatment Standards for the purposes of this part and section 307(d) of the Act.

(d) Local limits. Where specific prohibitions or limits on pollutants or pollutant parameters are developed by a POTW in accordance with paragraph (c) above, such limits shall be deemed Pretreatment Standards for the purposes of section 307(d) of CWA.

(1) The POTW shall utilize the EPA Guidance Manual (EPA 833-R-04-002) for the development of Local Limits.

(2) Appropriate removal rates shall be based on wastewater plant site-specific influent and effluent data unless otherwise approved by the Department.

(e) EPA and State enforcement actions. If, within 30 days after notice of an Interference or Pass Through violation has been sent by the Department to the POTW, and to persons or groups who have requested such notice, the POTW fails to commence appropriate enforcement action to correct the violation, the Department may take appropriate enforcement action.

(f) [Reserved]

403.6. National pretreatment standards: Categorical standards.

(a) National Pretreatment Standards specifying quantities or concentrations of pollutants or pollutant properties which may be discharged to a POTW by existing or new Industrial Users in specific industrial subcategories will be established as separate Federal regulations under the appropriate subpart of 40 CFR Chapter I, Subchapter N. These Standards, unless specifically noted otherwise, shall be in addition to all applicable pretreatment standards and requirements set forth in this part.

(b) Category Determination Request

(1) Application Deadline. Within 60 days after the effective date of a Pretreatment Standard for a subcategory under which an Industrial User may be included, the Industrial User or POTW may request that the Department provide written certification on whether the Industrial User falls within that particular subcategory. If an existing Industrial User adds or changes a process or operation which may be included in a subcategory, the existing Industrial User must request this certification prior to commencing discharge from the added or changed processes or operation. A New Source must request this certification prior to commencing discharge. Where a request for certification is submitted by a POTW, the POTW shall notify any affected Industrial User of such submission. The Industrial User may provide written comments on the POTW submission to the Department within 30 days of notification.

(2) Contents of Application. Each request shall contain a statement:

(i) Describing which subcategories might be applicable; and

(ii) Citing evidence and reasons why a particular subcategory is applicable and why others are not applicable. Any person signing the application statement submitted pursuant to this section shall make the following certification: "I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

(3) Deficient requests. The Department will only act on written requests for determinations that contain all of the information required. Persons who have made incomplete submissions will be notified by the Department that their requests are deficient and, unless the time period is extended,

will be given 30 days to correct the deficiency. If the deficiency is not corrected within 30 days or within an extended period allowed by the Department, the request for a determination shall be denied.

(4) Final decision.

(i) When the Department receives a submittal, he or she will, after determining that it contains all of the information required by paragraph (2) of this section, consider the submission, any additional evidence that may have been requested, and any other available information relevant to the request. The Department will then make a written determination of the applicable subcategory and state the reasons for the determination.

(ii) The Department shall forward the determination described in this paragraph to the Water Management Division Director who may make a final determination. The Water Management Division Director may waive receipt of these determinations. If the Water Management Division Director does not modify the Department's decision within 60 days after receipt thereof, or if the Water Management Division Director waives receipt of the determination, the Department's decision is final.

(iii) Where the Water Management Division Director elects to modify the Department's decision, the Water Management Division Director's decision will be final.

(iv) The Water Management Division Director or Department, as appropriate, shall send a copy of the determination to the affected Industrial User and the POTW. Where the final determination is made by the Water Management Division Director, he or she shall send a copy of the determination to the Department.

(5) Requests for hearing and/or legal decision. Within 30 days following the date of receipt of notice of the final determination as provided for by subsection (b)(4)(iv) of this section, the Requester may submit a petition to reconsider or contest the decision to the Regional Administrator who shall act on such petition expeditiously and state the reasons for his or her determination in writing.

(c) Deadline for compliance with categorical standards. Compliance by existing sources with categorical Pretreatment Standards shall be within 3 years of the date the Standard is effective unless a shorter compliance time is specified in the appropriate subpart of 40 CFR chapter I, subchapter N. Direct dischargers with NPDES Permits modified or reissued to provide a variance pursuant to section 301(i)(2) of the Act shall be required to meet compliance dates set in any applicable categorical Pretreatment Standard. Existing sources which become Industrial Users subsequent to promulgation of an applicable categorical Pretreatment Standard shall be considered existing Industrial Users except where such sources meet the definition of a New Source as defined in Section 403.3(i). New Sources shall install and have in operating condition, and shall "start-up" all pollution control equipment required to meet applicable Pretreatment Standards before beginning to Discharge. Within the shortest feasible time (not to exceed 90 days), New Sources must meet all applicable Pretreatment Standards.

(d)(1) Concentration and mass limits. Pollutant discharge limits in categorical Pretreatment Standards will be expressed either as concentration or mass limits. Wherever possible, where concentration limits are specified in standards, equivalent mass limits will be provided so that local, State or Federal authorities responsible for enforcement may use concentration or mass limits. Limits in categorical Pretreatment Standards shall apply to the effluent of the process regulated by the Standard, or as otherwise specified by the standard.

(2) When the limits in a categorical Pretreatment Standard are expressed only in terms of mass of pollutant per unit of production, the Control Authority may convert the limits to equivalent limitations expressed either as mass of pollutant discharged per day or effluent concentration for purposes of calculating effluent limitations applicable to individual Industrial Users.

(3) A Control Authority calculating equivalent mass-per-day limitations under subsection (d)(2) of this section shall calculate such limitations by multiplying the limits in the Standard by the Industrial User's average rate of production. This average rate of production shall be based not upon the designed production capacity but rather upon a reasonable measure of the Industrial User's actual long-term daily production, such as the average daily production during a representative year. For new sources, actual production shall be estimated using projected production.

(4) A Control Authority calculating equivalent concentration limitations under subsection (d)(2) of this section shall calculate such limitations by dividing the mass limitations derived under subsection (d)(3) of this section by the average daily flow rate of the Industrial User's regulated process wastewater. This average daily flow rate shall be based upon a reasonable measure of the Industrial User's actual long-term average flow rate, such as the average daily flow rate during the representative year.

(5) When the limits in a categorical Pretreatment Standard are expressed only in terms of pollutant concentrations, an Industrial User may request that the Control Authority convert the limits to equivalent mass limits. The determination to convert concentration limits to mass limits is within the discretion of the Control Authority and with prior approval of the Department. The Control Authority may establish equivalent mass limits after Department review and approval only if the Industrial User meets all the following conditions in paragraph (d)(5)(i)(A) through (d)(5)(i)(E) of this section.

(i) To be eligible for equivalent mass limits, the Industrial User must:

(A) Employ, or demonstrate that it will employ, water conservation methods and technologies that substantially reduce water use during the term of its control mechanism;

(B) Currently use control and treatment technologies adequate to achieve compliance with the applicable categorical Pretreatment Standard, and not have used dilution as a substitute for treatment;

(C) Provide sufficient information to establish the facility's actual average daily flow rate for all wastestreams, based on data from a continuous effluent flow monitoring device, as well as the facility's long-term average production rate. Both the actual average daily flow rate and long-term average production rate must be representative of current operating conditions;

(D) Not have daily flow rates, production levels, or pollutant levels that vary so significantly that equivalent mass limits are not appropriate to control the Discharge; and

(E) Have consistently complied with all applicable categorical Pretreatment Standards during the period, at least three years, prior to the Industrial User's request for equivalent mass limits.

(ii) An Industrial User subject to equivalent mass limits must:

(A) Maintain and effectively operate control and treatment technologies adequate to achieve compliance with the equivalent mass limits;

(B) Continue to record the facility's flow rates through the use of a continuous effluent flow monitoring device. The devices shall be installed, calibrated, and maintained to ensure that the accuracy of the measurements is consistent with the accepted capability of that type of device. Devices selected shall be capable of measuring flows with a maximum deviation of not greater than 10 percent from the true discharge rates throughout the range of expected discharge volumes;

(C) Continue to record the facility's production rates and notify the Control Authority whenever production rates are expected to vary by more than 20 percent from its baseline production rates determined in paragraph (d)(5)(i)(C) of this section. Upon notification of a revised production rate, the Control Authority must reassess the equivalent mass limit and revise the limit as necessary to reflect changed conditions at the facility; and

(D) Continue to employ the same or comparable water conservation methods and technologies as those implemented pursuant to paragraph (d)(5)(i)(A) of this section so long as it discharges under an equivalent mass limit.

(iii) A Control Authority which chooses to establish equivalent mass limits:

(A) Must calculate the equivalent mass limit by multiplying the actual average daily flow rate of the regulated process(es) of the Industrial User by the concentration-based daily maximum and monthly average Standard for the applicable categorical Pretreatment Standard and the appropriate unit conversion factor;

(B) Upon notification of a revised production rate, must reassess, with prior Department approval, the equivalent mass limit and recalculate the limit as necessary to reflect changed conditions at the facility; and

(C) May retain the same equivalent mass limit in subsequent control mechanism terms, with prior Department approval, if the Industrial User's actual average daily flow rate was reduced solely as a result of the implementation of water conservation methods and technologies, and the actual average daily flow rates used in the original calculation of the equivalent mass limit were not based on the use of dilution as a substitute for treatment pursuant to paragraph (e) of this section. The Industrial User must also be in compliance with section 403.17 (regarding the prohibition of bypass).

(iv) The Control Authority may not express limits in terms of mass for pollutants such as pH, temperature, radiation, or other pollutants which cannot appropriately be expressed as mass.

(6) The Control Authority may, with prior Department approval, convert the mass limits of the categorical Pretreatment Standards at 40 CFR parts 414, 419, and 455 to concentration limits for purposes of calculating limitations applicable to individual Industrial Users under the following conditions. When converting such limits to concentration limits, the Control Authority must use the concentrations listed in the applicable subparts of 40 CFR parts 414, 419, and 455 and document that dilution is not being substituted for treatment as prohibited by paragraph (e) of this section.

(7) Equivalent limitations calculated in accordance with paragraphs (d)(3), (d)(4), (d)(5), and (d)(6) of this section are deemed Pretreatment Standards for the purposes of section 307(d) of the CWA and this regulation. The Control Authority must document how the equivalent limits were derived and make this information publicly available. Once incorporated into its control mechanism, the Industrial User must comply with the equivalent limitations in lieu of the promulgated categorical standards from which the equivalent limitations were derived.

(8) Many categorical pretreatment standards specify one limit for calculating maximum daily discharge limitations and a second limit for calculating maximum monthly average, or 4-day average, limitations. Where such standards are being applied, the same production or flow figure shall be used in calculating both the average and the maximum equivalent limitation.

(9) Any Industrial User operating under a control mechanism incorporating equivalent mass or concentration limits calculated from a production based standard shall notify the Control Authority within two (2) business days after the User has a reasonable basis to know that the production level will significantly change within the next calendar month. Any User not notifying the Control Authority of such anticipated change will be required to meet the mass or concentration limits in its control mechanism that were based on the original estimate of the long term average production rate.

(e) Dilution prohibited as substitute for treatment. Except where expressly authorized to do so by an applicable Pretreatment Standard or Requirement, no Industrial User shall ever increase the use of process water, or in any other way attempt to dilute a Discharge as a partial or complete substitute for adequate treatment to achieve compliance with a Pretreatment Standard or Requirement. The Control Authority may impose mass limitations on Industrial Users which are using dilution to meet applicable Pretreatment Standards or Requirements, or in other cases where the imposition of mass limitations is appropriate.

(f) Combined wastestream formula. Where process effluent is mixed prior to treatment with wastewaters other than those generated by the regulated process, fixed alternative discharge limits may be derived by the Control Authority or by the Industrial User with the written concurrence of the Control Authority. These alternative limits shall be applied to the mixed effluent. When deriving alternative categorical limits, the Control Authority or Industrial User shall calculate both an alternative daily maximum value using the daily maximum value(s) specified in the appropriate categorical Pretreatment Standard(s) and an alternative consecutive sampling day average value using the monthly average value(s) specified in the appropriate categorical Pretreatment Standard(s). The Industrial User shall comply with the alternative daily maximum and monthly average limits fixed by the Control Authority until the Control Authority modifies the limits or approves an Industrial User modification request. Modification is authorized whenever there is a material or significant change in the values used in the calculation to fix alternative limits for the regulated pollutant. An Industrial User must immediately report any such material or significant change to the Control Authority. Where appropriate new alternative categorical limits shall be calculated within 30 days.

(1) Alternative limit calculation. For purposes of these formulas, the "average daily flow" means a reasonable measure of the average daily flow for a 30-day period. For new sources, flows shall be

estimated using projected values. The alternative limit for a specified pollutant will be derived by the use of either of the following formulas:

(i) Alternative concentration limit.

$$C_T = \left(\frac{\sum_{i=1}^N C_i F_i}{\sum_{i=1}^N F_i} \right) \left(\frac{F_T - F_D}{F_T} \right)$$

where

C_T = the alternative concentration limit for the combined waste stream.

C_i = the categorical Pretreatment Standard concentration limit for a pollutant in the regulated stream i .

F_i = the average daily flow (at least a 30-day average) of stream i to the extent that it is regulated for such pollutant.

F_D = the average daily flow (at least a 30-day average) from:

(a) Boiler blowdown streams, non-contact cooling streams, storm water streams, and mineralizer backwash streams: provided, however, that where such streams contain a significant amount of a pollutant, and the combination of such streams, prior to treatment, with an Industrial User's regulated process waste stream(s) will result in a substantial reduction of that pollutant, the Control Authority, upon application of the Industrial User, may exercise its discretion to determine whether such stream(s) should be classified as diluted or unregulated. In its application to the Control Authority, the Industrial User must provide engineering, production, sampling and analysis and such other information so that the Control Authority can make its determination; or (b) sanitary waste streams where such streams are not regulated by a Categorical Pretreatment Standard; or (c) from any process waste streams which were or could have been entirely exempted from Categorical Pretreatment Standards pursuant to paragraph 8 of the *NRDC v. Costle* Consent Decree (12 ERC 1833) for one or more of the following reasons (see Appendix D of this regulation):

(1) The pollutants of concern are not detectable in the effluent from the Industrial User (paragraph (8)(a)(iii));

(2) The pollutants of concern are present only in trace amounts and are neither causing nor likely to cause toxic effects (paragraph (8)(a)(iii));

(3) The pollutants of concern are present in amounts too small to be effectively reduced by technologies known to the Administrator (paragraph (8)(a)(iii)); or

(4) The waste stream contains only pollutants which are compatible with the POTW (paragraph (8)(b)(i)).

F_T = The average daily flow (at least a 30-day average) through the combined treatment facility (includes F_T , F_D and unregulated streams).

N = The total number of regulated streams.

(ii) Alternate mass limit.

$$M_T = \left(\sum_{i=1}^N M_i \right) \left(\frac{F_T - F_D}{\sum_{i=1}^N F_i} \right)$$

where

M_T = the alternative mass limit for a pollutant in the combined waste stream.

M_i = the categorical Pretreatment Standard mass limit for a pollutant in the regulated stream i (the categorical pretreatment mass limit multiplied by the appropriate measure of production).

F_i = the average daily flow (at least a 30-day average) of stream i to the extent that it is regulated for such pollutant.

F_D = the average daily flow (at least a 30-day average) from;

(a) boiler blowdown streams, non-contact cooling streams, storm water streams, and demineralizer backwash streams; provided, however, that where such streams contain a significant amount of a pollutant, and the combination of such streams, prior to treatment, with an Industrial User's regulated process waste-stream(s) will result in a substantial reduction of that pollutant, the Control Authority, upon application of the Industrial User, may exercise its discretion to determine whether such stream(s) should be classified as diluted or unregulated. In its application to the Control Authority, the Industrial User must provide engineering, production, sampling and analysis and such other information so that the Control Authority can make its determination; or

(b) sanitary waste streams where such streams are not regulated by a categorical Pretreatment Standard; or

(c) from any process waste streams which were or could have been entirely exempted from categorical Pretreatment Standards pursuant to paragraph 8 of the *NRDC v. Costle* Consent Decree (12 ERC 1833) for one or more of the following reasons (see Appendix D of this regulation);

(1) The pollutants of concern are not detectable in the effluent from the Industrial User (paragraph (8)(a)(iii));

(2) The pollutants of concern are present only in trace amounts and are neither causing nor likely to cause toxic effects (paragraph (8)(a)(iii));

(3) The pollutants of concern are present in amounts too small to be effectively reduced by technologies known to the Administrator (paragraph (8)(a)(iii)); or

(4) The waste stream contains only pollutants which are compatible with the POTW (paragraph (8)(b)-(i)).

F_T = The average flow (at least a 30-day average) through the combined treatment facility (includes F_{19} , F_D and unregulated streams).

N = The total number of regulated streams.

(2) Alternate limits below detection limit. An alternative pretreatment limit may not be used if the alternative limit is below the analytical detection limit for any of the regulated pollutants.

(3) Self-monitoring. Self-monitoring required to insure compliance with the alternative categorical limit shall be conducted in accordance with the requirements of section 403.12(g).

(4) Choice of monitoring location. Where a treated regulated process waste stream is combined prior to treatment with wastewaters other than those generated by the regulated process, the

Industrial User may monitor either the segregated process waste stream or the combined waste stream for the purpose of determining compliance with applicable Pretreatment Standards. If the Industrial User chooses to monitor the segregated process waste stream, it shall apply the applicable categorical Pretreatment Standard. If the User chooses to monitor the combined waste stream, it shall apply an alternative discharge limit calculated using the combined waste stream formula as provided in this section. The Industrial User may change monitoring points only after receiving approval from the Control Authority. The Control Authority shall ensure that any change in an Industrial User's monitoring point(s) will not allow the User to substitute dilution for adequate treatment to achieve compliance with applicable Standards.

403.7. Removal Credits.

(a) Introduction.

(1) Definitions. For the purpose of this section:

(i) "Removal" means a reduction in the amount of a pollutant in the POTW's effluent or alteration of the nature of a pollutant during treatment at the POTW. The reduction or alteration can be obtained by physical, chemical or biological means and may be the result of specifically designed POTW capabilities or may be incidental to the operation of the treatment system. Removal as used in this subpart shall not mean dilution of a pollutant in the POTW.

(ii) "Sludge Requirements" shall mean the following statutory provisions and regulations or permits issued thereunder (or more stringent local regulations): section 405 of the Clean Water Act; the Solid Waste Disposal Act (SWDA) (including Title II more commonly referred to as the Resource Conservation and Recovery Act (RCRA) and State regulations contained in any State sludge management plan prepared pursuant to Subtitle D of SWDA); the Clean Air Act; the Toxic Substances Control Act; and the Marine Protection, Research, and Sanctuaries Act, and the South Carolina Pollution Control Act.

(2) General. Any POTW receiving wastes from an Industrial User to which a categorical Pretreatment Standard(s) applies may, at its discretion and subject to the conditions of this section, grant removal credits to reflect removal by the POTW of pollutants specified in the categorical Pretreatment Standard(s). The POTW may grant a removal credit equal to or, at its discretion, less than its consistent removal rate. Upon being granted a removal credit, each affected Industrial User shall calculate its revised discharge limits in accordance with subparagraph (4) of this paragraph. Removal credits may only be given for indicator or surrogate pollutants regulated in a categorical Pretreatment Standard if the categorical Pretreatment Standard so specifies.

(3) Conditions for authorization to give removal credits. A POTW is authorized to give removal credits only if the following conditions are met:

(i) Application. The POTW applies for, and receives authorization from the Department to give a removal credit in accordance with the requirements and procedures specified in paragraph (e) of this section.

(ii) Consistent removal determination. The POTW demonstrates and continues to achieve consistent removal of the pollutant in accordance with paragraph (b) of this section.

(iii) POTW local pretreatment program. The POTW has an approved pretreatment program in accordance with and to the extent required by this regulation; provided, however, a POTW which does not have an approved pretreatment program may, pending approval of such a program, conditionally give credits as provided in paragraph (d) of this section.

(iv) Sludge requirements. The granting of removal credits will not cause the POTW to violate the local, State, and Federal Sludge Requirements which apply to the sludge management method chosen by the POTW. Alternatively, the POTW can demonstrate to the Department that even though it is not presently in compliance with applicable Sludge Requirements, it will be in compliance when the Industrial User(s) to whom the removal credit would apply is required to meet its categorical Pretreatment Standard(s) as modified by the removal credit. If granting removal credits forces a POTW to incur greater sludge management costs than would be incurred in the absence of granting removal credits, the additional sludge management costs will not be eligible for EPA grant assistance. Removal credits may be made available for the following pollutants.

(A) For any pollutant listed in Appendix G-I for the use or disposal practice employed by the POTW, when the requirements in R.61-9.503 for that practice are met.

(B) For any pollutant listed in Appendix G-II for the use or disposal practice employed by the POTW when the concentration for a pollutant listed in Appendix G-II in the sewage sludge that is used or disposed does not exceed the concentration for the pollutant in Appendix G-II.

(C) For any pollutant in sewage sludge when the POTW disposes all of its sewage sludge in a municipal solid waste landfill unit that meets the criteria in 40 CFR Part 258 and R.61-107.

(v) NPDES permit limitations. The granting of removal credits will not cause a violation of the POTW's permit limitations or conditions. Alternatively, the POTW can demonstrate to the Department that even though it is not presently in compliance with applicable limitations and conditions in its NPDES permit, it will be in compliance when the Industrial User(s) to whom the removal credit would apply is required to meet its categorical Pretreatment Standard(s), as modified by the removal credit provision.

(4) Calculation of revised discharge limits. Revised discharge limits for a specific pollutant shall be derived by use of the following formula:

$$y = \frac{x}{1 - r}$$

Where:

x = pollutant discharge limit specified in the applicable categorical Pretreatment Standard

r = removal credit for that pollutant as established under paragraph (b) of this section (percentage removal expressed as a proportion, i.e., a number between 0 and 1)

y = revised discharge limit for the specified pollutant (expressed in same units as x)

(b) Establishment of Removal Credits; Demonstration of Consistent Removal.

(1) Definition of Consistent Removal. "Consistent Removal" shall mean the average of the lowest 50 percent of the removal measured according to paragraph (b)(2) of this section. All sample data obtained for the measured pollutant during the time period prescribed in paragraph (b)(2) of this section must be reported and used in computing Consistent Removal. If a substance is measurable in the influent but not in the effluent, the effluent level may be assumed to be the limit of measurement, and those data may be used by the POTW at its discretion and subject to approval by the Department. If the substance is not measurable in the influent, the data may not be used. Where the number of samples with concentrations equal to or above the limit of measurement is between 8 and 12, the average of the lowest 6 removals shall be used. If there are less than 8 samples with concentrations equal to or above the limit of measurement, the Department may approve alternate means for demonstrating Consistent Removal. The term "measurement" refers to the ability of the analytical method or protocol to quantify as well as identify the presence of the substance in question.

(2) Consistent Removal Data. Influent and effluent operational data demonstrating Consistent Removal or other information, as provided for in paragraph (b)(1) of this section, which demonstrates Consistent Removal of the pollutants for which discharge limit revisions are proposed. This data shall meet the following requirements:

(i) Representative Data: Seasonal. The data shall be representative of yearly and seasonal conditions to which the POTW is subjected for each pollutant for which a discharge limit revision is proposed.

(ii) Representative Data: Quality and Quantity. The data shall be representative of the quality and quantity of normal effluent and influent flow if such data can be obtained. If such data are unobtainable, alternate data or information may be presented for approval to demonstrate Consistent Removal as provided for in paragraph (b)(1) of this section.

(iii) Sampling Procedures: Composite.

(A) The influent and effluent operational data shall be obtained through 24-hour flow-proportional composite samples. Sampling may be done manually or automatically, and discretely or continuously. For discrete sampling, at least 12 aliquots shall be composited. Discrete

sampling may be flow-proportioned either by varying the time interval between each aliquot or the volume of each aliquot. All composites must be flow-proportional to each stream flow at time of collection of influent aliquot or to the total influent flow since the previous influent aliquot. Volatile pollutant aliquots must be combined in the laboratory immediately before analysis.

(B)(1) Twelve samples shall be taken at approximately equal intervals throughout one full year. Sampling must be evenly distributed over the days of the week so as to include non-workdays as well as workdays. If the Department determines that this schedule will not be most representative of the actual operation of the POTW Treatment Plant, an alternative sampling schedule will be approved.

(2) In addition, upon the Department's concurrence, a POTW may utilize an historical data base amassed prior to the effective date of this section provided that such data otherwise meet the requirements of this paragraph. In order for the historical data base to be approved, it must present a statistically valid description of daily, weekly, and seasonal sewage treatment plant loadings and performance for at least one year.

(C) Effluent sample collection need not be delayed to compensate for hydraulic detention unless the POTW elects to include detention time compensation or unless the Department requires detention time compensation. The Department may require that each effluent sample be taken approximately one detention time later than the corresponding influent sample when failure to do so would result in an unrepresentative portrayal of actual POTW operation. The detention period is to be based on a 24-hour average daily flow value. The average daily flow used will be based upon the average of the daily flows during the same month of the previous year.

(iv) Sampling Procedures: Grab. Where composite sampling is not an appropriate sampling technique, a grab sample(s) shall be taken to obtain influent and effluent operational data. Collection of influent grab samples should precede collection of effluent samples by approximately one detention period. The detention period is to be based on a 24-hour average daily flow value. The average daily flow used will be based upon the average of the daily flows during the same month of the previous year. Grab samples will be required, for example, where the parameters being evaluated are those, such as cyanide and phenol, which may not be held for any extended period because of biological, chemical, or physical interactions which take place after sample collection and affect the results. A grab sample is an individual sample collected over a period of time not exceeding 15 minutes.

(v) Analytical methods. The sampling referred to in paragraphs (b)(2)(i) through (iv) of this section and an analysis of these samples shall be performed in accordance with the techniques prescribed in 40 CFR Part 136 and amendments thereto. Where 40 CFR Part 136 does not contain sampling or analytical techniques for the pollutant in question, or where the Department determines that the Part 136 sampling and analytical techniques are inappropriate for the pollutant in question, sampling and analysis shall be performed using validated analytical methods or any other applicable sampling and analytical procedures, including procedures suggested by the POTW or other parties, approved by the Department.

(vi) Calculation of removal. All data acquired under the provisions of this section must be submitted to the Department. Removal for a specific pollutant shall be determined either, for each sample, by measuring the difference between the concentrations of the pollutant in the influent and effluent of the POTW and expressing the difference as a percent of the influent concentration, or, where such data cannot be obtained, Removal may be demonstrated using other data or procedures subject to concurrence by the Department as provided for in paragraph (b)(1) of this section.

(c) Provisional credits. For pollutants which are not being discharged currently (i.e., new or modified facilities, or production changes) the POTW may apply for authorization to give removal credits prior to the initial discharge of the pollutant. Consistent removal shall be based provisionally on data from treatability studies or demonstrated removal at other treatment facilities where the quality and quantity of influent are similar. Within 18 months after the commencement of discharge of pollutants in question, consistent removal must be demonstrated pursuant to the requirements of paragraph (b) of this section. If, within 18 months after the commencement of the discharge of the pollutant in question, the POTW cannot demonstrate consistent removal pursuant to the requirements of para-

graph (b) of this section, the authority to grant provisional removal credits shall be terminated by the Department and all Industrial Users to whom the revised discharge limits had been applied shall achieve compliance with the applicable categorical Pretreatment Standard(s) within a reasonable time, not to exceed the period of time prescribed in the applicable Pretreatment Standard(s), as may be specified by the Department.

(d) Exception to POTW Pretreatment Program Requirement. A POTW required to develop a local pretreatment program by section 403.8 may conditionally give removal credits pending approval of such a program in accordance with the following terms and conditions:

(1) All Industrial Users who are currently subject to a categorical Pretreatment Standard and who wish conditionally to receive a removal credit must submit to the POTW the information required in section 403.12(b)(1) through (7) (except new or modified industrial users must only submit the information required by section 403.12(b)(1) through (6), pertaining to the categorical Pretreatment Standard as modified by the removal credit. The Industrial Users shall indicate what additional technology, if any, will be needed to comply with the categorical Pretreatment Standard(s) as modified by the removal credit:

(2) The POTW must have submitted to the Department an application for pretreatment program approval meeting the requirements of section 403.8 and section 403.9 in a timely manner, not to exceed the time limitation set forth in a compliance schedule for development of a pretreatment program included in the POTW's NPDES permit, but in no case later than July 1, 1983, where no permit deadline exists:

(3) The POTW must:

(i) Compile and submit data demonstrating its consistent removal in accordance with paragraph (b) of this section;

(ii) Comply with the conditions specified in paragraph (a)(3) of this section; and

(iii) Submit a complete application for removal credit authority in accordance with paragraph (e) of this section.

(4) If a POTW receives authority to grant conditional removal credits and the Department subsequently makes a final determination, after appropriate notice, that the POTW failed to comply with the conditions in paragraphs (d)(2) and (3) of this section, the authority to grant conditional removal credits shall be terminated by the Department and all Industrial Users to whom the revised discharge limits had been applied shall achieve compliance with the applicable categorical Pretreatment Standard(s) within a reasonable time, not to exceed the period of time prescribed in the applicable categorical Pretreatment Standard(s), as may be specified by the Department.

(5) If a POTW grants conditional removal credits and the POTW or the Department subsequently makes a final determination, after appropriate notice, that the Industrial User(s) failed to comply with the conditions in paragraph (d)(1) of this section, the conditional credit shall be terminated by the POTW or the Department for the non-complying Industrial User(s) and the Industrial User(s) to whom the revised discharge limits had been applied shall achieve compliance with the applicable categorical Pretreatment Standard(s) within a reasonable time, not to exceed the period of time prescribed in the applicable categorical Pretreatment Standard(s), as may be specified by the Department. The conditional credit shall not be terminated where a violation of the provisions of this paragraph results from causes entirely outside of the control of the Industrial User(s) or the Industrial User(s) had demonstrated substantial compliance.

(6) The Department may elect not to review an application for conditional removal credit authority upon receipt of such application, in which case the conditionally revised discharge limits will remain in effect until reviewed by the Department. This review may occur at any time in accordance with the procedures of section 403.11, but in no event later than the time of any pretreatment program approval or any NPDES permit reissuance thereunder.

(e) POTW application for authorization to give removal credits and Department review.

(1) Who must apply. Any POTW that wants to give a removal credit must apply for authorization from the Department.

(2) To whom application made. An application for authorization to give removal credits (or modify existing ones) shall be submitted by the POTW to the Department.

(3) When to apply. A POTW may apply for authorization to give or modify removal credits at any time.

(4) Contents of the Application. An application for authorization to give removal credits must be supported by the following information:

(i) List of pollutants. A list of pollutants for which removal credits are proposed.

(ii) Consistent Removal Data. The data required pursuant to paragraph (b) of this section.

(iii) Calculation of revised discharge limits. Proposed revised discharge limits for each affected subcategory of Industrial Users calculated in accordance with paragraph (a)(4) of this section.

(iv) Local Pretreatment Program Certification. A certification that the POTW has an approved local pretreatment program or qualifies for the exception to this requirement found at paragraph (d) of this section.

(v) Sludge Management Certification. A specific description of the POTW's current methods of using or disposing of its sludge and a certification that the granting of removal credits will not cause a violation of the sludge requirements identified in paragraph (a)(3)(iv) of this section.

(vi) NPDES Permit Limit Certification. A certification that the granting of removal credits will not cause a violation of the POTW's NPDES permit limits and conditions as required in paragraph (a)(3)(v) of this section.

(5) Department Review. The Department shall review the POTW's application for authorization to give or modify removal credits in accordance with the procedures of section 403.11 and shall, in no event, have more than 180 days from public notice of an application to complete review.

(6) EPA review of State removal credit approvals. The Regional Administrator may agree in the Memorandum of Agreement under 40 CFR Part 123.24(d) to waive the right to review and object to submissions for authority to grant removal credits. Such an agreement shall not restrict the Regional Administrator's right to comment upon or object to permits issued to POTW's except to the extent R.61-9.122.24(d) allows such restriction.

(7) Nothing in these regulations precludes an Industrial User or other interested party from assisting the POTW in preparing and presenting the information necessary to apply for authorization.

(f) Continuation and withdrawal of authorization.

(1) Effect of authorization.

(i) Once a POTW has received authorization to grant removal credits for a particular pollutant regulated in a categorical Pretreatment Standard, it may automatically extend that removal credit to the same pollutant when it is regulated in other categorical standards, unless granting the removal credit will cause the POTW to violate the sludge requirements identified in (a)(3)(iv) of this section or its NPDES permit limits and conditions as required by (a)(3)(v). If a POTW elects at a later time to extend removal credits to a certain categorical Pretreatment Standard, industrial subcategory or one or more Industrial Users that initially were not granted removal credits, it must notify the Department.

(ii) [Reserved]

(2) Inclusion in POTW permit. Once authority is granted, the removal credits shall be included in the POTW's NPDES Permit as soon as possible and shall become an enforceable requirement of the POTW's NPDES permit. The removal credits will remain in effect for the term of the POTW's NPDES permit, provided the POTW maintains compliance with the conditions specified in paragraph (f)(4) of this section.

(3) Compliance monitoring. Following authorization to give removal credits, a POTW shall continue to monitor and report on (at such intervals as may be specified by the Department, but in no case less than once per year) the POTW's removal capabilities. A minimum of one representative sample per month during the reporting period is required, and all sampling data must be included in the POTW's compliance report.

(4) Modification or withdrawal of removal credits.

(i) Notice of POTW. The Department shall notify the POTW if, on the basis of pollutant removal capability reports received pursuant to paragraph (f)(3) of this section or other relevant information available to it, the Department determines:

(A) That one or more of the discharge limit revisions made by the POTW itself, no longer meets the requirements of this section, or

(B) That such discharge limit revisions are causing a violation of any conditions or limits contained in the POTW's NPDES Permit.

(ii) Corrective Action. If appropriate corrective action is not taken within a reasonable time, not to exceed 60 days unless the POTW or the affected Industrial Users demonstrate that a longer time period is reasonably necessary to undertake the appropriate corrective action, the Department shall either withdraw such discharge limits or require modifications in the revised discharge limits.

(iii) Public notice of withdrawal or modification. The Department shall not withdraw or modify revised discharge limits unless it shall first have notified the POTW and all Industrial Users to whom revised discharge limits have been applied, and made public, in writing, the reasons for such withdrawal or modification, and an opportunity is provided for a hearing. Following such notice and withdrawal or modification, all Industrial Users to whom revised discharge limits has been applied, shall be subject to the modified discharge limits or the discharge limits prescribed in the applicable categorical Pretreatment Standards, as appropriate, and shall achieve compliance with such limits within a reasonable time (not to exceed the period of time prescribed in the applicable categorical Pretreatment Standard(s)) as may be specified by the Department.

(g) Removal credits in State-run pretreatment programs under section 403.10(e). Where the Department elects to implement a local pretreatment program in lieu of requiring the POTW to develop such a program (as provided in section 403.10(e)), the POTW will not be required to develop a pretreatment program as a precondition to obtaining authorization to give removal credits. The POTW will, however, be required to comply with the other conditions of paragraph (a)(3) of this section.

(h) Compensation for Overflow. "Overflow" means the intentional or unintentional diversion of flow from the POTW before the POTW Treatment Plant. POTW which at least once annually overflow untreated wastewater to receiving waters may claim Consistent Removal of a pollutant only by complying with either paragraphs (h)(1) or (h)(2) of this section. However, paragraph (h) of this section shall not apply where Industrial User(s) can demonstrate that Overflow does not occur between the Industrial User(s) and the POTW Treatment Plant;

(1) The Industrial User provides containment or otherwise ceases or reduces Discharges from the regulated processes which contain the pollutant for which an allowance is requested during all circumstances in which an Overflow event can reasonably be expected to occur at the POTW or at a sewer to which the Industrial User is connected. Discharges must cease or be reduced, or pretreatment must be increased, to the extent necessary to compensate for the removal not being provided by the POTW. Allowances under this provision will only be granted where the POTW submits to the Department evidence that:

(i) All Industrial Users to which the POTW proposes to apply this provision have demonstrated the ability to contain or otherwise cease or reduce, during circumstances in which an Overflow event can reasonably be expected to occur. Discharges from the regulated processes which contain pollutants for which an allowance is requested:

(ii) The POTW has identified circumstances in which an Overflow event can reasonably be expected to occur, and has a notification or other viable plan to insure that Industrial Users will learn of an impending Overflow in sufficient time to contain, cease, or reduce Discharging to prevent untreated Overflows from occurring. The POTW must also demonstrate that it will monitor and verify the data required in paragraph (h)(1)(iii) of this section, to insure that Industrial Users are containing, ceasing, or reducing operations during POTW System Overflow; and

(iii) All Industrial Users to which the POTW proposes to apply this provision have demonstrated the ability and commitment to collect and make available, upon request by the POTW, Department, or EPA Regional Administrator, daily flow reports or other data sufficient to

demonstrate that all Discharges from regulated processes containing the pollutant for which the allowance is requested were contained, reduced, or otherwise ceased, as appropriate, during all circumstances in which an Overflow event was reasonably expected to occur; or

(2)(i) The Consistent Removal claimed is reduced pursuant to the following equation:

$$r_c = r_m \frac{8760 - Z}{8760}$$

Where:

r_m = POTW's Consistent Removal rate for that pollutant as established under paragraphs (a)(1) and (b)(2) of this section

r_c = removal corrected by the Overflow factor

Z = hours per year that overflow occurred between the Industrial User(s) and the POTW Treatment Plant, the hours either to be shown in the POTW's current NPDES permit application or the hours, as demonstrated by verifiable techniques, that a particular Industrial User's Discharge overflows between the Industrial User and the POTW Treatment Plant; and

(ii) [Reserved.]

(iii) [Reserved.]

403.8. POTW Pretreatment Program Requirements: Development and Implementation by POTW.

(a) POTW's required to develop a pretreatment program.

(1) Any POTW (or combination of POTWs operated by the same authority) with a total design flow greater than 5 million gallons per day (mgd) and receiving from Industrial Users pollutants which Pass Through or Interfere with the operation of the POTW or are otherwise subject to Pretreatment Standards will be required to establish a POTW Pretreatment Program.

(2) [Reserved]

(3) The Department may require that a POTW with a design flow of 5 mgd or less develop a POTW Pretreatment Program if he or she finds that the nature or volume of the industrial influent, treatment process upsets, violations of POTW effluent limitations, contamination of municipal sludge, or other circumstances warrant in order to prevent Interference with the POTW or Pass Through.

(b) Deadline for Program Approval. A POTW which meets the criteria of paragraph (a) of this section shall develop and submit a program for approval as soon as possible, but in no case later than one year after written notification from the Department of such identification. The POTW Pretreatment Program shall meet the criteria set forth in paragraph (f) of this section and shall be administered by the POTW to ensure compliance by Industrial Users with applicable Pretreatment Standards and Requirements.

(c) Incorporation of approved programs in permits. A POTW may develop an appropriate POTW Pretreatment Program any time before the time limit set forth in paragraph (b) of this section. The POTW's NPDES Permit will be reissued or modified by the State to incorporate the approved Program as enforceable conditions of the Permit. The modification of a POTW's NPDES Permit for the purposes of incorporating a POTW Pretreatment Program approved in accordance with the procedure in section 403.11 shall be deemed a minor Permit modification subject to the procedures in R.61-9.122.63.

(d) Incorporation of compliance schedules in permits. If the POTW does not have an approved Pretreatment Program at the time the POTW's existing Permit is reissued or modified, the reissued or modified Permit will contain the shortest reasonable compliance schedule, for the approval of the legal authority, procedures and funding required by paragraph (f) of this section.

(e) Cause for reissuance or modification of Permits. Under the authority of section 402(b)(1)(C) of CWA, the Department may modify, or alternatively, revoke and reissue a POTW's Permit in order to:

(1) Put the POTW on a compliance schedule for the development of a POTW Pretreatment Program where the addition of pollutants into a POTW by an Industrial User or combination of

Industrial Users presents a substantial hazard to the functioning of the treatment works, quality of the receiving waters, human health, or the environment;

(2) [Reserved]

(3) Incorporate a modification of the permit approved under section 301(h) or 301(i) of CWA;

(4) Incorporate an approved POTW Pretreatment Program in the POTW Permit; or

(5) Incorporate a compliance schedule for the development of a POTW Pretreatment Program in the POTW Permit.

(6) Incorporate the removal credits (established under section 403.7) in the POTW Permit.

(f) POTW pretreatment requirements. A POTW Pretreatment Program must be based on the following legal authority and include the following procedures. These authorities and procedures shall at all times be fully and effectively exercised and implemented.

(1) Legal authority. The POTW shall operate pursuant to legal authority enforceable in Federal, State or local courts, which authorizes or enables the POTW to apply and to enforce the requirements of sections 307(b) and (c), and 402(b)(8) of CWA and any regulations implementing those sections. Such authority may be contained in a statute, ordinance, or series of contracts or joint powers agreements which the POTW is authorized to enact, enter into or implement, and which are authorized by State law. At a minimum, this legal authority shall enable the POTW to:

(i) Deny or condition new or increased contributions of pollutants, or changes in the nature of pollutants, to the POTW by Industrial Users where such contributions do not meet applicable Pretreatment Standards and Requirements or where such contributions would cause the POTW to violate its NPDES permit;

(ii) Require compliance with applicable Pretreatment Standards and Requirements by Industrial Users;

(iii) Control through Permit, order, or similar means, the contribution to the POTW by each Industrial User to ensure compliance with applicable Pretreatment Standards and Requirements. In the case of Industrial Users identified as significant under Section 403.3, this control shall be achieved through individual permits or equivalent individual control mechanisms issued to each such User except as follows.

(A) (1) At the discretion of the POTW and with prior Department approval, this control may include use of general control mechanisms if the following conditions are met. All of the facilities to be covered must:

(i) Involve the same or substantially similar types of operations;

(ii) Discharge the same types of wastes;

(iii) Require the same effluent limitations;

(iv) Require the same or similar monitoring; and

(v) In the opinion of the POTW, and with prior Department approval, are more appropriately controlled under a general control mechanism than under individual control mechanisms.

(2) To be covered by the general control mechanism, the Significant Industrial User must file a written request for coverage that identifies its contact information, production processes, the types of wastes generated, the location for monitoring all wastes covered by the general control mechanism, any requests in accordance with section 403.12(e)(2) for a monitoring waiver for a pollutant neither present nor expected to be present in the Discharge, and any other information the POTW deems appropriate. A monitoring waiver for a pollutant neither present nor expected to be present in the Discharge is not effective in the general control mechanism until after the POTW has provided written notice to the Significant Industrial User that, with prior Department approval, such a waiver request has been granted in accordance with section 403.12(e)(2). The POTW must retain a copy of the general control mechanism, documentation to support the POTW's determination that a specific Significant Industrial User meets the criteria in paragraphs (f)(1)(iii)(A)(1) through (5) of this section, and a copy of the User's written request for coverage for 3 years after the expiration of the general control mechanism. A POTW may not control a Significant Industrial User through a

general control mechanism where the facility is subject to production-based, categorical Pretreatment Standards or categorical Pretreatment Standards expressed as mass of pollutant discharged per day or for Industrial Users whose limits are based on the Combined Wastestream Formula or Net/Gross calculations (sections 403.6(f) and 403.15).

(B) Both individual and general control mechanisms must be enforceable and contain, at a minimum, the following conditions:

(1) Statement of duration (in no case more than five years);

(2) Statement of non-transferability without, at a minimum, prior notification to the POTW and provision of a copy of the existing control mechanism to the new owner or operator;

(3) Effluent limits, including Best Management Practices, based on applicable general Pretreatment Standards in S.C. R.61-9, part 403, categorical Pretreatment Standards, local limits, and State and local law;

(4) Self-monitoring, sampling, reporting, notification and recordkeeping requirements, including an identification of the pollutants to be monitored (including the process for seeking a waiver for a pollutant neither present nor expected to be present in the Discharge in accordance with section 403.12(e)(2), or a specific waived pollutant in the case of an individual control mechanism), sampling location, sampling frequency, and sample type, based on the applicable general Pretreatment Standards in part 403 of this chapter, categorical Pretreatment Standards, local limits, and State and local law;

(5) Statement of applicable civil and criminal penalties for violation of Pretreatment Standards and requirements, and any applicable compliance schedule. Such schedules may not extend the compliance date beyond applicable federal deadlines;

(6) Requirements to control Slug Discharges, if determined by the POTW to be necessary.

(iv)(A) Require the development of a compliance schedule by each Industrial User for the installation of technology required to meet applicable Pretreatment Standards and Requirements and

(B) require the submission of all notices and self-monitoring reports from Industrial Users as are necessary to assess and assure compliance by Industrial Users with Pretreatment Standards and Requirements, including but not limited to the reports required in section 403.12;

(v) Carry out all inspection, surveillance and monitoring procedures necessary to determine, independent of information supplied by Industrial Users, compliance or noncompliance with applicable Pretreatment Standards and Requirements by Industrial Users. Representatives of the POTW shall be authorized to enter any premises of any Industrial User in which a Discharge source or treatment system is located or in which records are required to be kept under section 403.12(o) to assure compliance with Pretreatment Standards. Such authority shall be at least as extensive as the authority provided under section 308 of CWA;

(vi)(A) Obtain remedies for noncompliance by any Industrial User with any Pretreatment Standard and Requirement. All POTWs shall be able to seek injunctive relief for noncompliance by Industrial Users with Pretreatment Standards and Requirements. All POTWs shall also have authority to seek or assess civil or criminal penalties in at least the amount of \$1,000 a day for each violation by Industrial Users of Pretreatment Standards and Requirements. POTWs whose approved Pretreatment Programs require modification to conform to the requirements of this paragraph shall submit a request for approval of a program modification in accordance with section 403.18.

(B) Pretreatment requirements which will be enforced through the remedies set forth in paragraph (f)(1)(vi)(A) of this section, will include but not be limited to, the duty to allow or carry out inspections, entry, or monitoring activities; any rules, regulations, or orders issued by the POTW; any requirements set forth in control mechanisms issued by the POTW; or any reporting requirements imposed by the POTW or these regulations in this part. The POTW shall have authority and procedures (after informal notice to the discharger) immediately and effectively to halt or prevent any Discharge of pollutants to the POTW which reasonably appears to present an imminent endangerment to the health or welfare of persons. The POTW shall also have authority and procedures (which shall include notice to the affected Industrial Users

and an opportunity to respond) to halt or prevent any Discharge to the POTW which presents or may present an endangerment to the environment or which threatens to interfere with the operation of the POTW. The Department shall have authority to seek judicial relief and may also use administrative penalty authority when the POTW has sought a monetary penalty which the Department believes to be insufficient.

(vii) Comply with the confidentiality requirements set forth in section 403.14.

(2) Procedures. The POTW shall develop and implement procedures to ensure compliance with the requirements of a Pretreatment Program. At a minimum, these procedures shall enable the POTW to:

(i) Identify and locate all possible Industrial Users which might be subject to the POTW Pretreatment Program. Any compilation, index or inventory of Industrial Users made under this paragraph shall be made available to the Regional Administrator or Department upon request;

(ii) Identify the character and volume of pollutants contributed to the POTW by the Industrial Users identified under paragraph (f)(2)(i) of this section. This information shall be made available to the Regional Administrator or Department upon request;

(iii) Notify Industrial Users identified under paragraph (f)(2)(i) of this section, of applicable Pretreatment Standards and any applicable requirements under sections 204(b) and 405 of CWA and Subtitles C and D of the Resource Conservation and Recovery Act. Within 30 days of approval pursuant to section 403.8(f)(6), of a list of significant industrial users, notify each significant industrial user of its status as such and of all requirements applicable, to it as a result of such status.

(iv) Receive and analyze self-monitoring reports and other notices submitted by Industrial Users in accordance with the self-monitoring requirements in section 403.12;

(v) Randomly sample and analyze the effluent from Industrial Users and conduct surveillance activities in order to identify, independent of information supplied by Industrial Users, occasional and continuing noncompliance with Pretreatment Standards. Inspect and sample the effluent from each Significant Industrial User at least once a year, except as otherwise specified below:

(A) Where the POTW has authorized the Industrial User subject to a categorical Pretreatment Standard to forego sampling of a pollutant regulated by a categorical Pretreatment Standard in accordance with section 403.12(e)(3), the POTW must sample for the waived pollutant(s) at least once during the term of the Categorical Industrial User's control mechanism. In the event that the POTW subsequently determines that a waived pollutant is present or is expected to be present in the Industrial User's wastewater based on changes that occur in the User's operations, the POTW must immediately begin at least annual effluent monitoring of the User's Discharge and inspection.

(B) Where the POTW has determined that an Industrial User meets the criteria for classification as a Non-Significant Categorical Industrial User, the POTW must evaluate, at least once per year, whether an Industrial User continues to meet the criteria in section 403.3(o)(2).

(C) In the case of Industrial Users subject to reduced reporting requirements under section 403.12(e)(3), the POTW must randomly sample and analyze the effluent from Industrial Users and conduct inspections at least once every two years. If the Industrial User no longer meets the conditions for reduced reporting in section 403.12(e)(3), the POTW must immediately begin sampling and inspecting the Industrial User at least once a year.

(vi) Evaluate whether each such Significant Industrial User needs a plan or other action to control Slug Discharges. For Industrial Users identified as significant prior to November 14, 2005, this evaluation must have been conducted at least once by October 14, 2006; additional Significant Industrial Users must be evaluated within 1 year of being designated a Significant Industrial User. For purposes of this subsection, a Slug Discharge is any discharge of a non-routine, episodic nature, including but not limited to an accidental spill or a non-customary batch discharge, which has a reasonable potential to cause interference or pass through, or in any other way violate the POTW's regulations, local limits or permit conditions. The results of such activities shall be available to the Department upon request. Significant Industrial Users are required to notify the POTW immediately of any changes at its facility affecting potential for a

Slug Discharge. If the POTW decides that a slug control plan is needed, the plan shall contain, at a minimum, the following elements:

(A) Description of discharge practices, including non-routine batch discharges;

(B) Description of stored chemicals;

(C) Procedures for immediately notifying the POTW of Slug Discharges, including any discharge that would violate a prohibition under section 403.5(b) with procedures for follow-up written notification within five days;

(D) If necessary, procedures to prevent adverse impact from accidental spills, including inspection and maintenance of storage areas, handling and transfer of materials, loading and unloading operations, control of plant site run-off, worker training, building of containment structures or equipment, measures for containing toxic organic pollutants (including solvents), and/or measures and equipment for emergency response;

(vii) Investigate instances of noncompliance with Pretreatment Standards and Requirements, as indicated in the reports and notices required under section 403.12, or indicated by analysis, inspection, and surveillance activities described in paragraph (f)(2)(v) of this section. Sample-taking and analysis and the collection of other information shall be performed with sufficient care to produce evidence admissible in enforcement proceedings or in judicial actions; and

(viii) Comply with the public participation requirements of 40 CFR part 25 in the enforcement of National Pretreatment Standards. These procedures shall include provision for at least annual public notification in a newspaper(s) of general circulation that provides meaningful public notice within the jurisdiction(s) served by the POTW of Industrial Users which, at any time during the previous 12 months, were in significant noncompliance with applicable Pretreatment requirements. For the purposes of this provision, a Significant Industrial User (or any Industrial User which violates paragraphs (f)(2)(viii)(C), (D), or (H) of this section) is in significant noncompliance if its violation meets one or more of the following criteria:

(A) Chronic violations of wastewater Discharge limits, defined here as those in which sixty-six percent or more of all of the measurements taken for the same pollutant parameter during a six-month period exceed (by any magnitude) a numeric Pretreatment Standard or Requirement, including instantaneous limits, as defined by 403.3;

(B) Technical Review Criteria (TRC) violations, defined here as those in which thirty-three percent or more of all of the measurements taken for the same pollutant parameter during a six-month period equal or exceed the product of the numeric Pretreatment Standard or Requirement including instantaneous limits, as defined by 403.3 multiplied by the applicable TRC (TRC = 1.4 for BOD, TSS, fats, oil, and grease, and 1.2 for all other pollutants except pH);

(C) Any other violation of a Pretreatment Standard or Requirement as defined by 403.3 (daily maximum, long-term average, instantaneous limit, or narrative Standard) that the POTW determines has caused, alone or in combination with other Discharges, interference or pass-through (including endangering the health of POTW personnel or the general public);

(D) Any discharge of a pollutant that has caused imminent endangerment to human health, welfare or to the environment or has resulted in the POTW's exercise of its emergency authority under paragraph (f)(1)(vi)(B) of this section to halt or prevent such a discharge;

(E) Failure to meet, within 90 days after the schedule date, a compliance schedule milestone contained in a local control mechanism or enforcement order for starting construction, completing construction, or attaining final compliance;

(F) Failure to provide, within 45 days after the due date, required reports such as baseline monitoring reports, 90-day compliance reports, periodic self-monitoring reports, and reports on compliance with compliance schedules;

(G) Failure to accurately report noncompliance;

(H) Any other violation or group of violations, which may include a violation of Best Management Practices, which the POTW determines will adversely affect the operation or implementation of the local Pretreatment program.

(3) Funding. The POTW shall have sufficient resources and qualified personnel to carry out the authorities and procedures described in paragraphs (f)(1) and (2) of this section. In some limited circumstances, funding and personnel may be delayed where (i) the POTW has adequate legal authority and procedures to carry out the Pretreatment Program requirements described in this section, and (ii) a limited aspect of the Program does not need to be implemented immediately. (See 403.9(b).)

(4) Local limits. The POTW shall develop local limits as required in section 403.5(c)(1) or demonstrate to the satisfaction of the Department that they are not necessary.

(5) The POTW shall develop and implement an enforcement response plan. This plan shall contain detailed procedures indicating how a POTW will investigate and respond to instances of industrial user noncompliance. The plan shall at a minimum:

(i) Describe how the POTW will investigate instances of noncompliance;

(ii) Describe the types of escalating enforcement responses the POTW will take in response to all anticipated types of industrial user violations and the time periods within which responses will take place;

(iii) Identify (by title) the official(s) responsible for each type of response;

(iv) Adequately reflect the POTW's primary responsibility to enforce all applicable pretreatment requirements and standards, as detailed in section 403.8(f)(1) and (f)(2).

(6) The POTW shall prepare and maintain a list of its Industrial Users meeting the criteria in section 403.3(o)(1). The list shall identify the criteria in section 403.3(o)(1) applicable to each Industrial User and, where applicable, shall also indicate whether the POTW has made a determination pursuant to Section 403.3(o)(3) that such Industrial User should not be considered a Significant Industrial User. The initial list shall be submitted to the Department pursuant to section 403.9 or as a non-substantial modification pursuant to section 403.18(d). Modifications to the list shall be submitted to the Department pursuant to section 403.12(i)(1).

403.9. POTW pretreatment programs and/or authorization to revise pretreatment standards: Submission for approval.

(a) Who approves Program. A POTW requesting approval of a POTW Pretreatment Program shall develop a program description which includes the information set forth in paragraphs (b)(1) through (4) of this section. This description shall be submitted to the Department which will make a determination on the request for program approval in accordance with the procedures described in section 403.11.

(b) Contents of POTW program submission. The program description must contain the following information:

(1) A statement from the City Solicitor or a city official acting in a comparable capacity (or the attorney for those POTWs which have independent legal counsel) that the POTW has authority adequate to carry out the programs described in section 403.8. This statement shall:

(i) Identify the provision of the legal authority under section 403.8(f)(1) which provides the basis for each procedure under section 403.8(f)(2);

(ii) Identify the manner in which the POTW will implement the program requirements set forth in section 403.8, including the means by which Pretreatment Standards will be applied to individual Industrial Users (e.g., by order, permit, ordinance, etc.); and,

(iii) Identify how the POTW intends to ensure compliance with Pretreatment Standards and Requirements, and to enforce them in the event of noncompliance by Industrial Users;

(2) A copy of any statutes, ordinances, regulations, agreements, or other authorities relied upon by the POTW for its administration of the Program. This Submission shall include a statement reflecting the endorsement or approval of the local boards or bodies responsible for supervising and/or funding the POTW Pretreatment Program if approved;

(3) A brief description (including organization charts) of the POTW organization which will administer the Pretreatment Program. If more than one agency is responsible for administration of the Program the responsible agencies should be identified, their respective responsibilities delineated, and their procedures for coordination set forth; and

(4) A description of the funding levels and full and part-time manpower available to implement the Program;

(c) Conditional POTW program approval. The POTW may request conditional approval of the Pretreatment Program pending the acquisition of funding and personnel for certain elements of the Program. The request for conditional approval must meet the requirements set forth in paragraph (b) of this section except that the requirements of paragraph (b) of this section may be relaxed if the Submission demonstrates that:

(1) A limited aspect of the Program does not need to be implemented immediately;

(2) The POTW had adequate legal authority and procedures to carry out those aspects of the Program which will not be implemented immediately; and

(3) Funding and personnel for the Program aspects to be implemented at a later date will be available when needed. The POTW will describe in the Submission the mechanism by which this funding will be acquired. Upon receipt of a request for conditional approval, the Department will establish a fixed date for the acquisition of the needed funding and personnel. If funding is not acquired by this date, the conditional approval of the POTW Pretreatment Program and any removal allowances granted to the POTW, may be modified or withdrawn.

(d) Content of removal allowance submission. The request for authority to revise categorical Pretreatment Standards must contain the information requested in section 403.7(d).

(e) Department action. Any POTW requesting POTW Pretreatment Program approval shall submit to the Department three copies of the Submission described in paragraph (b), and if appropriate, (d) of this section. Within 60 days after receiving the Submission, the Department shall make a preliminary determination of whether the Submission meets the requirements of paragraph (b) and (c) of this section. If the Department makes the preliminary determination that the Submission meets these requirements, the Department shall:

(1) Notify the POTW that the Submission has been received and is under review; and

(2) Commence the public notice and evaluation activities set forth in section 403.11.

(f) Notification where submission is defective. If, after review of the Submission as provided for in paragraph (e) of this section, the Department determines that the Submission does not comply with the requirements of paragraph (b) or (c) of this section, and, if appropriate, paragraph (d) of this section, the Department shall provide notice in writing to the applying POTW and each person who has requested individual notice. This notification shall identify any defects in the Submission and advise the POTW and each person who has requested individual notice of the means by which the POTW can comply with the applicable requirements of paragraphs (b), (c) of this section, and if appropriate, paragraph (d) of this section.

(g) Consistency with water quality management plans.

(1) In order to be approved the POTW Pretreatment Program shall be consistent with any approved water quality management plan developed in accordance with 40 CFR Parts 130 and 131, as revised, where such 208 plan includes Management Agency designations and addresses pretreatment in a manner consistent with 40 CFR Part 403 and this regulation. In order to assure such consistency, the Department shall solicit the review and comment of the appropriate 208 Planning Agency during the public comment period provided for in section 403.11(b)(1)(ii) prior to approval or disapproval of the Program.

(2) Where no 208 plan has been approved or where a plan has been approved but lacks Management Agency designations and/or does not address pretreatment in a manner consistent with this regulation, the Department shall nevertheless solicit the review and comment of the appropriate 208 planning agency.

403.10.

(a) [Reserved]

(b) [Reserved]

(c) [Reserved]

(d) [Reserved]

(e) State Program in lieu of POTW Program. Notwithstanding the provision of section 403.8(a), the State may assume responsibility for implementing the POTW Pretreatment Program requirements set forth in section 403.8(f) in lieu of requiring the POTW to develop a Pretreatment Program. However, this does not preclude POTWs from independently developing Pretreatment Programs.

403.11. Approval procedures for POTW pretreatment programs and POTW granting of removal credits.

The following procedures shall be adopted in approving or denying requests for approval of POTW Pretreatment Programs and applications for removal credit authorization:

(a) Deadline for review of submission. The Department shall have 90 days from the date of public notice of any Submission complying with the requirements of section 403.9(b) and, where removal credit authorization is sought with section 403.7(e) and section 403.9(d), to review the Submission. The Department shall review the Submission to determine compliance with the requirements of section 403.8(b) and (f), and, where removal credit authorization is sought, with section 403.7. The Department may have up to an additional 90 days to complete the evaluation of the Submission if the public comment period provided for in paragraph (b)(1)(ii) of this section is extended beyond 30 days or if a public hearing is held as provided for in paragraph (b)(2) of this section. In no event, however, shall the time for evaluation of the Submission exceed a total of 180 days from the date of public notice of a Submission meeting the requirements of section 403.9(b) and, in the case of a removal credit application, section 403.7(e) and section 403.9(b).

(b) Public notice and opportunity for hearing. Upon receipt of a Submission, the Department shall commence its review. After making a determination that a Submission meets the requirements of section 403.9(b) the Department shall:

(1) Issue a public notice of request for approval of the Submission;

(i) This public notice shall be circulated in a manner designed to inform interested and potentially interested persons of the Submission. Procedures for the circulation of public notice shall include:

(A) Mailing notices of the request for approval of the Submission to designated 208 planning agencies, Federal and State fish, shellfish, and wildlife resource agencies (unless such agencies have asked not to be sent the notices); and to any other person or group who has requested individual notice, including those on appropriate mailing lists; and

(B) Publication of a notice of request for approval of the Submission in a newspaper(s) of general circulation within the jurisdiction(s) served by the POTW that provides meaningful public notice.

(ii) The public notice shall provide a period of not less than 30 days following the date of the public notice during which time interested persons may submit their written views on the Submission.

(iii) All written comments submitted during the 30 day comment period shall be retained by the Department and considered in the decision on whether or not to approve the Submission. The period for comment may be extended at the discretion of the Department; and

(2) Provide an opportunity for the applicant, any affected State, any interested State or Federal agency, person or group of persons to request a public hearing with respect to the Submission.

(i) This request for public hearing shall be filed within the 30 day (or extended) comment period described in paragraph (b)(1)(ii) of this section and shall indicate the interest of the person filing such request and the reasons why a hearing is warranted.

(ii) The Department shall hold a hearing if the POTW so requests. In addition, a hearing will be held if there is a significant public interest in issues relating to whether or not the Submission should be approved. Instances of doubt should be resolved in favor of holding the hearing.

(iii) Public notice of a hearing to consider a Submission and sufficient to inform interested parties of the nature of the hearing and the right to participate shall be published in the same newspaper as the notice of the original request for approval of the Submission under paragraph (b)(1)(i)(B) of this section. In addition, notice of the hearing shall be sent to those persons requesting individual notice.

(c) Department decision. At the end of the 30 day (or extended) comment period and within the 90 day (or extended) period provided for in paragraph (a) of this section, the Department shall approve or deny the Submission based upon the evaluation in paragraph (a) of this section and taking into consideration comments submitted during the comment period and the record of the public hearing, if held. Where the Department makes a determination to deny the request, the Department shall so notify the POTW and each person who has requested individual notice. The notification shall include suggested modifications and the Department may allow the requestor additional time to bring the Submission into compliance with applicable requirements.

(d) EPA objection to Department's decision. No POTW pretreatment program shall be approved by the Department if following the 30 day (or extended) evaluation period provided for in paragraph (b)(1)(ii) of this section and any hearing held pursuant to paragraph (b)(2) of this section the Regional Administrator sets forth in writing objections to the approval of such Submission and the reasons for such objections. A copy of the Regional Administrator's objections shall be provided to the applicant, and each person who has requested individual notice. The Regional Administrator shall provide an opportunity for written comments and may convene a public hearing on his or her objections. Unless retracted, the Regional Administrator's objections shall constitute a final ruling to deny approval of a POTW pretreatment program 90 days after the date of the objections are issued.

(e) Notice of decision. The Department shall notify those persons who submitted comments and participated in the public hearing, if held, of the approval or disapproval of the Submission. In addition, the Department shall cause to be published a notice of approval or disapproval in the same newspapers as the original notice of request for approval of the Submission was published.

(f) Public access to submission. The Department shall ensure that the Submission and any comments upon such Submission are available to the public for inspection and copying.

403.12. Reporting requirements for POTW's and industrial users.

(a) [Reserved.]

(b) Reporting requirements for industrial users upon effective date of categorical pretreatment standard-baseline report. Within 180 days after the effective date of a categorical Pretreatment Standard, or 180 days after the final administrative decision made upon a category determination submission under section 403(6)(a)(4), whichever is later, existing Industrial Users subject to such categorical Pretreatment Standards and currently discharging to or scheduled to discharge to a POTW shall be required to submit to the Control Authority, a report which contains the information listed in paragraph (b)(1)-(7) of this section. At least 90 days prior to commencement of discharge, new Sources, and sources that become Industrial Users subsequent to the promulgation of an applicable categorical Standard, shall be required to submit to the Control Authority a report which contains the information listed in paragraphs (b)(1)-(5) of this section. New sources shall also be required to include in this report information on the method of pretreatment the source intends to use to meet applicable pretreatment standards. New Sources shall give estimates of the information requested in paragraphs (b)(4) and (5) of this section:

(1) Identifying information. The User shall submit the name and address of the facility including the name of the operator and owners;

(2) Permits. The User shall submit a list of any environmental control permits held by or for the facility;

(3) Description of operations. The User shall submit a brief description of the nature, average rate of production, and Standard Industrial Classification of the operation(s) carried out by such Industrial User. This description should include a schematic process diagram which indicates points of Discharge to the POTW from the regulated processes.

(4) Flow measurement. The User shall submit information showing the measured average daily and maximum daily flow, in gallons per day, to the POTW from each of the following:

(i) Regulated process streams; and

(ii) Other streams as necessary to allow use of the combined waste stream formula of section 403.6(f). (See paragraph (b)(5)(iv) of this section.)

The Control Authority may allow for verifiable estimates of these flows where justified by cost or feasibility considerations.

(5) Measurement of pollutants.

(i) The user shall identify the Pretreatment Standards applicable to each regulated process;

(ii) In addition, the User shall submit the results of sampling and analysis identifying the nature and concentration (or mass, where required by the Standard or Control Authority) of regulated pollutants in the Discharge from each regulated process. Both daily maximum and average concentration (or mass, where required) shall be reported. The sample shall be representative of daily operations. In cases where the Standard requires compliance with a Best Management Practice or pollution prevention alternative, the User shall submit documentation as required by the Control Authority or the applicable Standards to determine compliance with the Standard;

(iii) The User shall take a minimum of one representative sample to compile that data necessary to comply with the requirements of this paragraph.

(iv) Samples should be taken immediately downstream from pretreatment facilities if such exist or immediately downstream from the regulated process if no pretreatment exists. If other wastewaters are mixed with the regulated wastewater prior to pretreatment, the User should measure the flows and concentrations necessary to allow use of the combined waste stream formula of section 403.6(f), in order to evaluate compliance with the Pretreatment Standards. Where an alternate concentration or mass limit has been calculated in accordance with section 403.6(f) this adjusted limit along with supporting data shall be submitted to the Control Authority;

(v) Sampling and analysis shall be performed in accordance with the techniques prescribed in 40 CFR Part 136 and amendments thereto. Where 40 CFR Part 136 does not contain sampling or analytical techniques for the pollutant in question, or where the Administrator or Department determines that the Part 136 sampling and analytical techniques are inappropriate for the pollutant in question, sampling and analysis shall be performed by using validated analytical methods or any other applicable sampling and analytical procedures, including procedures suggested by the POTW or other parties, approved by the Administrator or Department.

(vi) The Control authority may allow the submission of a baseline report which utilizes only historical data so long as the data provides information sufficient to determine the need for industrial pretreatment measures;

(vii) The baseline report shall indicate the time, date and place, of sampling, and methods of analysis, and shall certify that such sampling and analysis is representative of normal work cycles and expected pollutant Discharges to the POTW;

(6) Certification. A statement, reviewed by an authorized representative of the Industrial User (as defined in paragraph (l) of this section) and certified by a qualified professional, indicating whether Pretreatment Standards are being met on a consistent basis, and, if not, whether additional operation and maintenance (O and M) and/or additional Pretreatment is required for the Industrial User to meet the Pretreatment Standards and Requirements; and

(7) Compliance schedule. If additional pretreatment and/or O and M will be required to meet the Pretreatment Standards: the shortest schedule by which the Industrial User will provide such additional pretreatment and/or O & M. The completion date in this schedule shall not be later than the compliance date established for the applicable Pretreatment Standard.

(i) Where the Industrial User's categorical Pretreatment Standard has been modified by the combined waste stream formula (section 403.6(f)), and/or a Fundamentally Different Factors variance (section 403.13) at the time the User submits the report required by paragraph (b) of this section, the information required by paragraphs (b)(6) and (7) of this section shall pertain to the modified limits.

(ii) If the categorical Pretreatment Standard is modified by a removal allowance (section 403.7), the combined waste stream formula (section 403.6(f)), and/or a Fundamentally Different Factors variance (section 403.13) at the time the User submits the report required by paragraph (b) of this section, the information required by paragraphs (b)(6) and (7) of this section shall be submitted by the Industrial User to the Control Authority within 60 days after the modified limit is approved.

(c) Compliance schedule for meeting categorical Pretreatment Standards. The following conditions shall apply to the schedule required by paragraph (b)(7) of this section:

(1) The schedule shall contain increments of progress in the form of dates for the commencement and completion of major events leading to the construction and operation of additional pretreatment required for the Industrial User to meet the applicable categorical Pretreatment Standards (e.g., hiring an engineer, completing preliminary plans, completing final plans, executing contract for major components, commencing construction, completing construction, etc.).

(2) No increment referred to in paragraph (c)(1) of this section shall exceed 9 months.

(3) Not later than 14 days following each date in the schedule and the final date for compliance, the Industrial User shall submit a progress report to the Control Authority including, at a minimum, whether or not it complied with the increment of progress to be met on such date and, if not, the date on which it expects to comply with this increment of progress, the reason for delay, and the steps being taken by the Industrial User to return the construction to the schedule established. In no event shall more than 9 months elapse between such progress reports to the Control Authority.

(d) Report on compliance with categorical pretreatment standard deadline. Within 90 days following the date for final compliance with applicable categorical Pretreatment Standards or in the case of a New Source following commencement of the introduction of wastewater into the POTW, any Industrial User subject to Pretreatment Standards and Requirements shall submit to the Control Authority a report containing the information described in paragraphs (b)(4)-(6) of this section. For Industrial Users subject to equivalent mass or concentration limits established by the Control Authority in accordance with the procedures in section 403.6(d), this report shall contain a reasonable measure of the User's long term production rate. For all other Industrial Users subject to categorical Pretreatment Standards expressed in terms of allowable pollutant discharge per unit of production (or other measure of operation), this report shall include the User's actual production during the appropriate sampling period.

(e) Periodic reports on continued compliance.

(1) Any Industrial User subject to a categorical Pretreatment Standard (except a Non-Significant Categorical User as defined in section 403.3(o)(2)), after the compliance date of such Pretreatment Standard, or, in the case of a New Source, after commencement of the discharge into the POTW, shall submit to the Control Authority during the months of June and December, unless required more frequently in the Pretreatment Standard or by the Control Authority or the Department, a report indicating the nature and concentration of pollutants in the effluent which are limited by such categorical Pretreatment Standards. In addition, this report shall include a record of measured or estimated average and maximum daily flows for the reporting period for the Discharge reported in paragraph (b)(4) of this section, except that the Control Authority may require more detailed reporting of flows. In cases where the Pretreatment Standard requires compliance with a Best Management Practice (or pollution prevention alternative), the User shall submit documentation required by the Control Authority or the Pretreatment Standard necessary to determine the compliance status of the User. At the discretion of the Control Authority and in consideration of such factors as local high or low flow rates, holidays, budget cycles, etc., the Control Authority may modify the months during which the above reports are to be submitted. For Industrial Users for which EPA or the authorized State, tribe, or territory is the Control Authority, as of December 21, 2020, all reports submitted in compliance with this section must be submitted electronically by the industrial user to the Control Authority or initial recipient, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), 40 CFR 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, the Industrial Users for which EPA or the authorized State, tribe, or territory is the Control Authority may be required to report electronically if specified by a particular control mechanism or if required to do so by State law.

(2) The Control Authority may with prior Department approval authorize the Industrial User subject to a categorical Pretreatment Standard to forego sampling of a pollutant regulated by a categorical Pretreatment Standard if the Industrial User has demonstrated through sampling and other technical factors that the pollutant is neither present nor expected to be present in the Discharge, or is present only at background levels from intake water and without any increase in the pollutant due to activities of the Industrial User. This authorization is subject to the following conditions:

(i) The Control Authority may with prior Department approval authorize a waiver where a pollutant is determined to be present solely due to sanitary wastewater discharged from the facility provided that the sanitary wastewater is not regulated by an applicable categorical Standard and otherwise includes no process wastewater and the POTW does not have an effluent NPDES limit for this pollutant.

(ii) The monitoring waiver is valid only for the duration of the effective period of the Permit or other equivalent individual control mechanism, but in no case longer than 5 years. The User must submit a new request for the waiver before the waiver can with prior Department approval be granted for each subsequent control mechanism.

(iii) In making a demonstration that a pollutant is not present, the Industrial User must provide data from at least one sampling of the facility's process wastewater prior to any treatment present at the facility that is representative of all wastewater from all processes. The request for a monitoring waiver must be signed in accordance with paragraph (l) of this section and include the certification statement in section 403.6(b)(2)(ii). Non-detectable sample results may only be used as a demonstration that a pollutant is not present if the EPA approved method from 40 CFR part 136 with the lowest minimum detection level for that pollutant was used in the analysis, or at the lowest Practical Quantitation Limit specified by the Department, whichever is lower.

(iv) Any grant of the monitoring waiver by the Control Authority must be included as a condition in the User's control mechanism. The reasons supporting the waiver and any information submitted by the User in its request for the waiver must be maintained by the Control Authority for 3 years after expiration of the waiver.

(v) Upon approval of the monitoring waiver and revision of the User's control mechanism by the Control Authority, the Industrial User must certify on each report with the statement below, that there has been no increase in the pollutant in its wastestream due to activities of the Industrial User:

Based on my inquiry of the person or persons directly responsible for managing compliance with the Pretreatment Standard for 40 CFR _____ [specify applicable National Pretreatment Standard part(s)], I certify that, to the best of my knowledge and belief, there has been no increase in the level of _____ [list pollutant(s)] in the waste streams due to the activities at the facility since filing of the last periodic report under S.C. R.61-9.403.12(e)(1).

(vi) In the event that a waived pollutant is found to be present or is expected to be present based on changes that occur in the User's operations, the User must immediately: Comply with the monitoring requirements of paragraph (e)(1) of this section or other more frequent monitoring requirements imposed by the Control Authority; and notify the Control Authority and the Department.

(vii) This provision does not supersede certification processes and requirements established in categorical Pretreatment Standards, except as otherwise specified in the categorical Pretreatment Standard.

(3) The Control Authority may reduce the requirement in paragraph (e)(1) of this section to a requirement to report no less frequently than once a year, unless required more frequently in the Pretreatment Standard or by the Department, where the Industrial User meets all of the following conditions:

(i) The Industrial User's total categorical wastewater flow does not exceed any of the following:

(A) 0.01 percent of the design dry weather hydraulic capacity of the POTW, or 5,000 gallons per day, whichever is smaller, as measured by a continuous effluent flow monitoring device unless the Industrial User discharges in batches;

(B) 0.01 percent of the design dry weather organic treatment capacity of the POTW; and

(C) 0.01 percent of the maximum allowable headworks loading for any pollutant regulated by the applicable categorical Pretreatment Standard for which approved local limits were developed by a POTW in accordance with section 403.5(c) and paragraph (d) of this section;

(ii) The Industrial User has not been in significant noncompliance, as defined in section 403.8(f)(2)(vii), for any time in the past two years;

(iii) The Industrial User does not have daily flow rates, production levels, or pollutant levels that vary so significantly that decreasing the reporting requirement for this Industrial User would result in data that are not representative of conditions occurring during the reporting period pursuant to paragraph (g)(3) of this section;

(iv) The Industrial User must notify the Control Authority immediately of any changes at its facility causing it to no longer meet conditions of paragraphs (e)(3)(i) or (ii) of this section. Upon notification, the Industrial User must immediately begin complying with the minimum reporting in paragraph (e)(1) of this section; and

(v) The Control Authority must retain documentation to support the Control Authority's determination that a specific Industrial User qualifies for reduced reporting requirements under paragraph (e)(3) of this section for a period of 3 years after the expiration of the term of the control mechanism.

(4) For Industrial Users subject to equivalent mass or concentration limits established by the Control Authority in accordance with the procedures in section 403.6(d), the report required by paragraph (e)(1) shall contain a reasonable measure of the User's long term production rate. For all other Industrial Users subject to categorical Pretreatment Standards expressed only in terms of allowable pollutant discharge per unit of production (or other measure of operation), the report required by paragraph (e)(1) shall include the User's actual average production rate for the reporting period.

(f) Notice of potential problems, including slug loading. All categorical and non-categorical Industrial Users shall notify the POTW immediately of all discharges that could cause problems to the POTW, including any slug loadings, as defined by section 403.5(b), by the Industrial User.

(g) Monitoring and analysis to demonstrate continued compliance.

(1) Except in the case of Non-Significant Categorical Users, the reports required in paragraphs (b), (d), (e), and (h) of this section shall contain the results of sampling and analysis of the Discharge, including the flow and the nature and concentration, or production and mass where requested by the Control Authority, of pollutants contained therein which are limited by the applicable Pretreatment Standards. This sampling and analysis may be performed by the Control Authority in lieu of the Industrial User. Where the POTW performs the required sampling and analysis in lieu of the Industrial User, the User will not be required to submit the compliance certification required under section 403.12(b)(6) and section 403.12(d). In addition, where the POTW itself collects all the information required for the report, including flow data, the Industrial User will not be required to submit the report.

(2) If sampling performed by an Industrial User indicates a violation, the User shall notify the Control Authority within 24 hours of becoming aware of the violation. The User shall also repeat the sampling and analysis and submit the results of the repeat analysis to the Control Authority within 30 days after becoming aware of the violation. Where the Control Authority has performed the sampling and analysis in lieu of the Industrial User, the Control Authority must perform the repeat sampling and analysis unless it notifies the User of the violation and requires the User to perform the repeat analysis. Resampling is not required if:

(i) The Control Authority performs sampling at the Industrial User at a frequency of at least once per month; or

(ii) The Control Authority performs sampling at the User between the time when the initial sampling was conducted and the time when the User or the Control Authority receives the results of this sampling.

(3) The reports required in paragraphs (b), (d), (e), and (h) of this section must be based upon data obtained through appropriate sampling and analysis performed during the period covered by the report, which data are representative of conditions occurring during the reporting period. The Control Authority shall require that frequency of monitoring necessary to assess and assure compliance by Industrial Users with applicable Pretreatment Standards and Requirements. Grab samples must be used for pH, cyanide, total phenols, oil and grease, sulfide, and volatile organic compounds. For all other pollutants, 24-hour composite samples must be obtained through flow-proportional composite sampling techniques, unless time-proportional composite sampling or grab sampling is authorized by the Control Authority. Where time-proportional composite sampling or

grab sampling is authorized by the Control Authority with approval by the Department, the samples must be representative of the discharge and the decision to allow the alternative sampling must be documented in the Industrial User file for that facility or facilities. Using protocols (including appropriate preservation) specified in 40 CFR part 136 and appropriate EPA guidance, multiple grab samples collected during a 24-hour period may be composited prior to the analysis as follows: For cyanide, total phenols, and sulfides, the samples may be composited in the laboratory or in the field; for volatile organics and oil & grease, the samples may be composited in the laboratory. Composite samples for other parameters unaffected by the compositing procedures as documented in approved EPA methodologies may be authorized by the Control Authority, as appropriate.

(4) For sampling required in support of baseline monitoring and 90-day compliance reports required in paragraphs (b) and (d) of this section, a minimum of four (4) grab samples must be used for pH, cyanide, total phenols, oil and grease, sulfide and volatile organic compounds for facilities for which historical sampling data do not exist; for facilities for which historical sampling data are available, the Control Authority may with approval by the Department authorize a lower minimum. For the reports required by paragraphs (e) and (h) of this section, the Control Authority shall require the number of grab samples necessary to assess and assure compliance by Industrial Users with Applicable Pretreatment Standards and Requirements.

(5) All analyses shall be performed in accordance with procedures established by the Administrator pursuant to section 304(h) of CWA contained in 40 CFR Part 136 and amendments thereto or with any other test procedures approved by the Administrator. (See, section 136.4 and section 136.5) Sampling shall be performed in accordance with the techniques approved by the Department. Where 40 CFR Part 136 does not include sampling or analytical techniques for the pollutants in question, or where the Administrator determines that the Part 136 sampling and analytical techniques are inappropriate for the pollutant in question, sampling and analyses shall be performed using validated analytical methods or any other sampling and analytical procedures, including procedures suggested by the POTW or other parties, approved by the administrator.

(6) If an Industrial User subject to the reporting requirement in paragraph (e) or (h) of this section monitors any regulated pollutant at the appropriate sampling location more frequently than required by the Control Authority, using the procedures prescribed in paragraph (g)(5) of this section, the results of this monitoring shall be included in the report.

(h) Reporting requirements for Industrial Users not subject to categorical Pretreatment Standards. The Control Authority must require appropriate reporting from those Industrial Users with Discharges that are not subject to categorical Pretreatment Standards. Significant Non-categorical Industrial Users must submit to the Control Authority at least once every six (6) months (on dates specified by the Control Authority) a description of the nature, concentration, and flow of the pollutants required to be reported by the Control Authority. In cases where a local limit requires compliance with a Best Management Practice or pollution prevention alternative, the User must submit documentation required by the Control Authority to determine the compliance status of the User. These reports must be based on sampling and analysis performed in the period covered by the report, and in accordance with the techniques described in Part 136 and amendments thereto. This sampling and analysis may be performed by the Control Authority in lieu of the significant non-categorical Industrial User. For Industrial Users for which EPA or the authorized State, tribe, or territory is the Control Authority, as of December 21, 2020, all reports submitted in compliance with this section must be submitted electronically by the industrial user to the Control Authority or the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), 40 CFR 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, the Industrial Users for which EPA or the authorized State, tribe, or territory is the Control Authority may be required to report electronically if specified by a particular control mechanism or if required to do so by State law.

(i) Annual POTW reports. POTWs with approved Pretreatment Programs shall provide the Department with a report that briefly describes the POTW's program activities, including activities of all participating agencies, if more than one jurisdiction is involved in the local program. The report required by this section shall be submitted no later than one (1) year after approval of the POTW's Pretreatment Program, and at least annually thereafter, and shall include, at a minimum, the applicable required data in appendix A to 40 CFR Part 127. The report required by this section must also include a summary of changes to the POTW's pretreatment program that have not been

previously reported to the Department and any other relevant information requested by the Department. As of December 21, 2020, all annual reports submitted in compliance with this section must be submitted electronically by the POTW Pretreatment Program to the Department, as defined in 40 CFR 127.2(b), in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), 40 CFR 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, the Department may also require POTW Pretreatment Programs to electronically submit annual reports under this section if specified by a particular permit or if required to do so by State law.

(1) An updated list of the POTW's Industrial Users, including their names and addresses, or a list of deletions and additions keyed to a previously submitted list. The POTW shall provide a brief explanation of each deletion. This list shall identify which Industrial Users are subject to categorical Pretreatment Standards and specify which Standards are applicable to each Industrial User. The list shall indicate which Industrial Users are subject to local standards that are more stringent than the categorical Pretreatment Standards. The POTW shall also list the Industrial Users that are subject only to local Requirements. The list must also identify Industrial Users subject to categorical Pretreatment Standards that are subject to reduced reporting requirements under paragraph (e)(3), and identify which Industrial Users are Non-Significant Categorical Industrial Users;

(2) A summary of the status of Industrial User compliance over the reporting period;

(3) A summary of compliance and enforcement activities (including inspections) conducted by the POTW during the reporting period;

(4) A summary of changes to the POTW's pretreatment program that have not been previously reported to the Department; and

(5) Any other relevant information requested by the Department;

(j) Notification of changed Discharge. All Industrial Users shall promptly notify the Control Authority (and the POTW if the POTW is not the Control Authority) in advance of any substantial change in the volume or character of pollutants in their discharge, including the listed or characteristic hazardous wastes for which the Industrial User has submitted initial notification under section 403.12(p).

(k) Compliance schedule for POTW's. The following conditions and reporting requirements shall apply to the compliance schedule for development of an approvable POTW Pretreatment Program required by section 403.8.

(1) The schedule shall contain increments of progress in the form of dates for the commencement and completion of major events leading to the development and implementation of a POTW Pretreatment Program (e.g., acquiring required authorities, developing funding mechanisms, acquiring equipment);

(2) No increment referred to in paragraph (k)(1) of this section shall exceed nine months;

(3) Not later than 14 days following each date in the schedule and the final date for compliance, the POTW shall submit a progress report to the Department including, as a minimum, whether or not it complied with the increment of progress to be met on such date and, if not, the date on which it expects to comply with this increment of progress, the reason for delay, and the steps taken by the POTW to return to the schedule established. In no event shall more than nine months elapse between such progress reports to the Department.

(l) Signatory requirements for industrial user reports. The reports required by paragraphs (b), (d), and (e) of this section shall include the certification statement as set forth in section 403.6(b)(2)(ii), and shall be signed as follows:

(1) By a responsible corporate officer, if the Industrial User submitting the reports required by paragraphs (b), (d), and (e) of this section is a corporation. For the purpose of this paragraph, a responsible corporate officer means:

(i) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy- or decision-making functions for the corporation, or

(ii) The manager of one or more manufacturing, production, or operating facilities, provided the manager is authorized to make management decisions which govern the operation of the

regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiate and direct other comprehensive measures to assure long-term environmental compliance with environmental laws and regulations; can ensure that the necessary systems are established or actions taken to gather complete and accurate information for control mechanism requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

(2) By a general partner or proprietor if the Industrial User submitting the reports required by paragraphs (b), (d), and (e) of this section is a partnership or sole proprietorship, respectively.

(3) By a duly authorized representative of the individual designated in paragraph (l)(1) or (l)(2) of this section if:

(i) The authorization is made in writing by the individual described in paragraph (l)(1) or (l)(2);

(ii) The authorization specifies either an individual or a position having responsibility for the overall operation of the facility from which the Industrial Discharge originates, such as the position of plant manager, operator of a well, or well field superintendent, or a position of equivalent responsibility, or having overall responsibility, for environmental matters for the company; and

(iii) The written authorization is submitted to the Control Authority.

(4) If an authorization under paragraph (l)(3) of this section is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, or overall responsibility for environmental matters for the company, a new authorization satisfying the requirements of paragraph (l)(3) of this section must be submitted to the Control Authority prior to or together with any reports to be signed by an authorized representative.

(m) Signatory requirements for POTW reports. Reports submitted to the Department by the POTW in accordance with paragraph (i) of this section must be signed by a principal executive officer, ranking elected official, or other duly authorized employee. The duly authorized employee must be an individual or position having responsibility for the overall operation of the facility or the Pretreatment Program. This authorization must be made in writing by the principal executive officer or ranking elected official, and submitted to the Department prior to or together with the report being submitted.

(n) Provisions Governing Fraud and False Statements: the reports and other documents required to be submitted or maintained under this section shall be subject to:

(1) The provisions of 18 U.S.C. section 1001 relating to fraud and false statements;

(2) The provisions of section 309(c)(4) of CWA, as amended, governing false statements, representation or certification; and

(3) The provisions of section 309(c)(6) regarding responsible corporate officers.

(o) Record-keeping requirements.

(1) Any Industrial User and POTW subject to the reporting requirements established in this section shall maintain records of all information resulting from any monitoring activities required by this section, including documentation associated with Best Management Practices. Such records shall include for all samples:

(i) The date, exact place, method, and time of sampling and the names of the person or persons taking the samples;

(ii) The dates analyses were performed;

(iii) Who performed the analyses;

(iv) The analytical techniques/methods used; and

(v) The results of such analyses.

(2) Any Industrial User or POTW subject to the reporting requirements established in this section (including documentation associated with Best Management Practices) shall be required to retain for a minimum of 3 years any records of monitoring activities and results (whether or not such monitoring activities are required by this section) and shall make such records available for inspection and copying by the Department and the Regional Administrator (and POTW in the case of an Industrial User). This period of retention shall be extended during the course of any

unresolved litigation regarding the discharge of pollutants by the Industrial User or the operation of the POTW Pretreatment Program or when requested by the Department or the Regional Administrator.

(3) Any POTW to which reports are submitted by an Industrial User pursuant to paragraphs (b), (d), (e) and (h) of this section shall retain such reports for a minimum of 3 years and shall make such reports available for inspection and copying by the Department and the Regional Administrator. This period of retention shall be extended during the course of any unresolved litigation regarding the discharge of pollutants by the Industrial User or the operation of the POTW Pretreatment Program or when requested by the Department or the Regional Administrator.

(p) Provisions governing hazardous waste.

(1) The Industrial User shall notify the POTW, the EPA Regional Waste Management Division Director, and State hazardous waste authorities in writing of any discharge into the POTW of a substance, which, if otherwise disposed of, would be a hazardous waste under 40 CFR Part 261. Such notification must include the name of the hazardous waste as set forth in 40 CFR Part 261, the EPA hazardous waste number, and the type of discharge (continuous, batch, or other). If the Industrial User discharges more than 100 kilograms of such waste per calendar month to the POTW, the notification shall also contain the following information to the extent such information is known and readily available to the Industrial User. An identification of the hazardous constituents contained in the wastes, an estimation of the mass and concentration of such constituents in the waste stream discharged during that calendar month, and an estimation of the mass of constituents in the waste stream expected to be discharged during the following twelve months. All notifications must take place within 180 days of the effective date of this regulation. Industrial users who commence discharging after the effective date of this regulation shall provide the notification no later than 180 days after the discharge of the listed or characteristic hazardous waste. Any notification under this paragraph need be submitted only once for each hazardous waste discharged. However, notifications of changed discharges must be submitted under section 403.12(j). The notification requirement in this section does not apply to pollutants already reported under the self-monitoring requirements of section 403.12(b), (d), and (e).

(2) Dischargers are exempt from the requirements of paragraph (p)(1) of this section during a calendar month in which they discharge no more than fifteen kilograms of hazardous wastes, unless the wastes are acute hazardous wastes as specified in 40 CFR 261.30(d) and 261.33(e). Discharge of more than fifteen kilograms of non-acute hazardous wastes in a calendar month, or of any quantity of acute hazardous wastes as specified in 40 CFR 261.30(d) and 261.33(e), requires a one-time notification. Subsequent months during which the Industrial User discharges more than such quantities of any hazardous waste do not require additional notification.

(3) In the case of any new regulations under section 3001 of RCRA identifying additional characteristics of hazardous waste or listing any additional substance as a hazardous waste, the Industrial User must notify the POTW, the EPA Regional Waste Management Waste Division Director, and State hazardous waste authorities of the discharge of such substance within 90 days of the effective date of such regulations.

(4) In the case of any notification made under paragraph (p) of this section, the Industrial User shall certify that it has a program in place to reduce the volume and toxicity of hazardous wastes generated to the degree it has determined to be economically practical.

(q) Annual certification by Non-Significant Categorical Industrial Users. A facility determined to be a Non-Significant Categorical Industrial User pursuant to section 403.3(o)(2) must annually submit the following certification statement, signed in accordance with the signatory requirements in paragraph (l) of this section. This certification must accompany any alternative report required by the Control Authority:

Based on my inquiry of the person or persons directly responsible for managing compliance with the categorical Pretreatment Standards under 40 CFR ____ I certify that, to the best of my knowledge and belief that during the period from _____, _____ to _____, _____ [month, day, year]:

(a) The facility described as _____ [facility name] met the definition of a non-significant categorical Industrial User as described in section 403.3(o)(2); (b) the facility complied with all applicable Pretreatment Standards and requirements during this reporting period; and (c) the

facility never discharged more than a total of 100 gallons of categorical wastewater on any given day during this reporting period. This compliance certification is based upon the following information:

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

403.13. Variances from categorical pretreatment standards for fundamentally different factors.

(a) Definition. The term “Requester” means an Industrial User or a POTW or other interested person seeking a variance from the limits specified in a categorical Pretreatment Standard.

(b) Purpose and scope. In establishing categorical Pretreatment Standards for existing sources, the EPA will take into account all the information it can collect, develop and solicit regarding the factors relevant to pretreatment standards under section 307(b). In some cases, information which may affect these Pretreatment Standards will not be available or, for other reasons, will not be considered during their development. As a result, it may be necessary on a case-by-case basis to adjust the limits in categorical Pretreatment Standards, making them either more or less stringent, as they apply to a certain Industrial User within an industrial category or subcategory. This will only be done if data specific to that Industrial User indicates it presents factors fundamentally different from those considered by EPA in developing the limit at issue. Any interested person believing that factors relating to an Industrial User are fundamentally different from the factors considered during development of a categorical Pretreatment Standard applicable to that User and further, that the existence of those factors justifies a different discharge limit than specified in the applicable categorical Pretreatment Standard, may request a fundamentally different factors variance under this section or such a variance request may be initiated by the EPA.

(c) Criteria.

(1) General criteria. A request for a variance based upon fundamentally different factors shall be approved only if:

(i) There is an applicable categorical Pretreatment Standard which specifically controls the pollutant for which alternative limits have been requested; and

(ii) Factors relating to the discharge controlled by the categorical Pretreatment Standards are fundamentally different from the factors considered by EPA in establishing the Standards; and

(iii) The request for a variance is made in accordance with the procedural requirements in paragraphs (g) and (h) of this section.

(2) Criteria applicable to less stringent limits. A variance request for the establishment of limits less stringent than required by the Standard shall be approved only if:

(i) The alternative limit requested is no less stringent than justified by the fundamental difference;

(ii) The alternative limit will not result in a violation of prohibitive discharge standards prescribed by or established under section 403.5;

(iii) The alternative limit will not result in a non-water quality environmental impact (including energy requirements) fundamentally more adverse than the impact considered during development of the Pretreatment Standards; and

(iv) Compliance with the Standards (either by using the technologies upon which the Standards are based or by using other control alternatives) would result in either:

(A) A removal cost (adjusted for inflation) wholly out of proportion to the removal cost considered during development of the Standards; or

(B) A non-water quality environmental impact (including energy requirements) fundamentally more adverse than the impact considered during development of the Standards.

(3) Criteria applicable to more stringent limits. A variance request for the establishment of limits more stringent than required by the Standards shall be approved only if:

- (i) The alternative limit request is no more stringent than justified by the fundamental difference; and
- (ii) Compliance with the alternative limit would not result in either:
 - (A) A removal cost (adjusted for inflation) wholly out of proportion to the removal cost considered during development of the Standards; or
 - (B) A non-water quality environmental impact (including energy requirements) fundamentally more adverse than the impact considered during development of the Standards.
- (d) Factors considered fundamentally different. Factors which may be considered fundamentally different are:
 - (1) The nature or quality of pollutants contained in the raw waste load of the User's process wastewater;
 - (2) The volume of the User's process wastewater and effluent discharged;
 - (3) Non-water quality environmental impact of control and treatment of the User's raw waste load;
 - (4) Energy requirements of the application of control and treatment technology;
 - (5) Age, size, land availability, and configuration as they relate to the User's equipment or facilities; processes employed; process changes; and engineering aspects of the application of control technology;
 - (6) Cost of compliance with required control technology.
- (e) Factors which will not be considered fundamentally different. A variance request or portion of such a request under this section may not be granted on any of the following grounds:
 - (1) The feasibility of installing the required waste treatment equipment within the time CWA allows;
 - (2) The assertion that the Standards cannot be achieved with the appropriate waste treatment facilities installed, if such assertion is not based on factors listed in paragraph (d) of this section;
 - (3) The User's ability to pay for the required waste treatment; or
 - (4) The impact of a Discharge on the quality of the POTW's receiving waters.
- (f) State or local law. Nothing in this section shall be construed to impair the right of the State of South Carolina or any locality under section 510 of CWA to impose more stringent limitations than required by Federal law.
- (g) Application deadline.
 - (1) Requests for a variance and supporting information must be submitted in writing to the Department or to the Administrator (or his delegate), as appropriate.
 - (2) In order to be considered, a request for a variance must be submitted no later than 180 days after the date on which a categorical Pretreatment Standard is published in the Federal Register.
 - (3) Where the User has requested a categorical determination pursuant to section 403.6(b), the User may elect to await the results of the category determination before submitting a variance request under this section. Where the User so elects, he or she must submit the variance request within 30 days after a final decision has been made on the categorical determination pursuant to section 403.6(b)(4).
- (h) Contents submission. Written submissions for variance requests, whether made to the Administrator (or his delegate) or the Department, must include:
 - (1) The name and address of the person making the request;
 - (2) Identification of the interest of the Requester which is affected by the categorical Pretreatment Standard for which the variance is requested;
 - (3) Identification of the POTW currently receiving the waste from the Industrial User for which alternative discharge limits are requested;
 - (4) Identification of the categorical Pretreatment Standards which are applicable to the Industrial User;
 - (5) A list of each pollutant or pollutant parameter for which an alternative discharge limit is sought;

(6) The alternative discharge limits proposed by the Requester for each pollutant or pollutant parameter identified in paragraph (h)(5) of this section;

(7) A description of the Industrial User's existing water pollution control facilities;

(8) A schematic flow representation of the Industrial User's water system including water supply, process wastewater systems, and points of Discharge; and

(9) A Statement of facts clearly establishing why the variance request should be approved, including detailed support data, documentation, and evidence necessary to fully evaluate the merits of the request, e.g., technical and economic data collected by the EPA and used in developing each pollutant discharge limit in the Pretreatment Standard.

(i) Deficient requests. The Administrator (or his delegate) or the Department will only act on written requests for variances that contain all of the information required. Persons who have made incomplete submissions will be notified by the Administrator (or his delegate) or the Department that their requests are deficient and unless the time period is extended, will be given up to thirty days to remedy the deficiency. If the deficiency is not corrected within the time period allowed by the Administrator (or his delegate) or the Department, the request for a variance shall be denied.

(j) Public notice. Upon receipt of a complete request, the Administrator (or his delegate) or the Department will provide notice of receipt, opportunity to review the submission, and opportunity to comment.

(1) The public notice shall be circulated in a manner designed to inform interested and potentially interested persons of the request. Procedures for the circulation of public notice shall include mailing notices to:

(i) The POTW into which the Industrial User requesting the variance discharges;

(ii) Adjoining States whose waters may be affected; and

(iii) Designated 208 planning agencies, Federal and State fish, shellfish and wildlife resource agencies; and to any other person or group who has requested individual notice, including those on appropriate mailing lists.

(2) The public notice shall provide for a period not less than 30 days following the date of the public notice during which time interested persons may review the request and submit their written views on the request.

(3) Following the comment period, the Administrator (or his delegate) or the Department will make a determination on the request taking into consideration any comments received. Notice of this final decision shall be provided to the requester (and the Industrial User for which the variance is requested if different), the POTW into which the Industrial User discharges and all persons who submitted comments on the request.

(k) Review of requests by state.

(1) Where the Department finds that fundamentally different factors do not exist, he may deny the request and notify the requester (and Industrial User where they are not the same) and the POTW of the denial.

(2) Where the Department finds that fundamentally different factors do exist, he shall forward the request, with a recommendation that the request be approved, to the Administrator (or his delegate).

(l) Review of requests by EPA.

(1) Where the Administrator (or his delegate) finds that fundamentally different factors do not exist, he shall deny the request for a variance and send a copy of his determination to the Department, to the POTW, and to the requester (and to the Industrial User, where they are not the same).

(2) Where the Administrator (or his delegate) finds that fundamentally different factors do exist, and that a partial or full variance is justified, he will approve the variance. In approving the variance, the Administrator (or his delegate) will:

(i) Prepare recommended alternative discharge limits for the Industrial User either more or less stringent than those prescribed by the applicable categorical Pretreatment Standards to the extent warranted by the demonstrated fundamentally different factors;

(ii) Provide the following information in his written determination:

- (A) The recommended alternative discharge limits for the Industrial User concerned;
 - (B) The rationale for the adjustment of the Pretreatment Standard (including the reasons for recommending that the variance be granted) and an explanation of how the recommended alternative discharge limits were derived;
 - (C) The supporting evidence submitted to the Administrator (or his delegate); and
 - (D) Other information considered by the Administrator (or his delegate) in developing the recommended alternative discharge limits;
- (iii) Notify the Department and the POTW of his determination; and
 - (iv) Send the information described in paragraphs (l)(2)(i) and (ii) of this section to the Requester (and to the Industrial User where they are not the same).
- (m) Request for hearing.

(1) Within 30 days following the date of receipt of the notice of the decision of the Administrator's delegate on a variance request, the requester or any other interested person may submit a petition to the Regional Administrator for a hearing to reconsider or contest the decision. If such a request is submitted by a person other than the Industrial User, the person shall simultaneously serve a copy of the request on the Industrial User.

(2) If the Regional Administrator declines to hold a hearing and the Regional Administrator affirms the findings of the Administrator's delegate, the requester may submit a petition for a hearing to the Environmental Appeals Board (which is described in section 1.25 of 40 CFR Part 1.25) within 30 days of the Regional Administrator's decision.

403.14. Confidentiality.

(a) EPA authorities. In accordance with 40 CFR Part 2, any information submitted to EPA pursuant to these regulations may be claimed as confidential by the submitter. Any such claim must be asserted at the time of submission in the manner prescribed on the application form or instructions, or, in the case of other submissions, by stamping the words "confidential business information" on each page containing such information. If no claim is made at the time of submission, EPA may make the information available to the public without further notice. If a claim is asserted, the information will be treated in accordance with the procedures in 40 CFR Part 2 (Public Information).

(b) Effluent data. Information and data provided to the Control Authority pursuant to this part which is effluent data shall be available to the public without restriction.

(c) State or POTW. All other information which is submitted to the State of South Carolina or the POTW shall be available to the public at least to the extent provided by 40 CFR 2.302 and S.C. Code Ann. 30-4-10 *et seq.*

403.15. Net/gross calculation.

(a) Application. Categorical Pretreatment Standards may be adjusted to reflect the presence of pollutants in the Industrial User's intake water in accordance with this section. Any Industrial User wishing to obtain credit for intake pollutants must make application to the Control Authority. Upon request of the Industrial User, the applicable Standard will be calculated on a "net" basis (i.e., adjusted to reflect credit for pollutants in the intake water) if the requirements of paragraph (b) of this section are met.

(b) Criteria.

(1) Either:

(i) The applicable categorical Pretreatment Standards contained in 40 CFR subchapter N specifically provide that they shall be applied on a net basis or

(ii) The Industrial User demonstrates that the control system it proposes or uses to meet applicable categorical Pretreatment Standards would, if properly installed and operated, meet the Standards in the absence of pollutants in the intake waters.

(2) Credit for generic pollutants such as biochemical oxygen demand (BOD), total suspended solids (TSS), and oil and grease should not be granted unless the Industrial User demonstrates that the constituents of the generic measure in the User's effluent are substantially similar to the

constituents of the generic measure in the intake water or unless appropriate additional limits are placed on process water pollutants either at the outfall or elsewhere.

(3) Credit shall be granted only to the extent necessary to meet the applicable categorical Pretreatment Standard(s), up to a maximum value equal to the influent value. Additional monitoring may be necessary to determine eligibility for credits and compliance with Standard(s) adjusted under this section.

(4) Credit shall be granted only if the User demonstrates that the intake water is drawn from the same body of water as that into which the POTW discharges. The Control Authority may waive this requirement if it finds that no environmental degradation will result.

403.16. Upset provision.

(a) Definition. For the purposes of this section, "Upset" means an exceptional incident in which there is unintentional and temporary noncompliance with categorical Pretreatment Standards because of factors beyond the reasonable control of the Industrial User. An Upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventive maintenance, or careless or improper operation.

(b) Effect of an upset. An Upset shall constitute an affirmative defense to an action brought for noncompliance with categorical Pretreatment Standards if the requirements of paragraph (c) are met.

(c) Conditions necessary for a demonstration of upset. An Industrial User who wishes to establish the affirmative defense of Upset shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence that:

(1) An Upset occurred and the Industrial User can identify the cause(s) of the Upset;

(2) The facility was at the time being operated in a prudent and workmanlike manner and in compliance with applicable operation and maintenance procedures;

(3) The Industrial User has submitted the following information to the POTW and Control Authority within 24 hours of becoming aware of the Upset (if this information is provided orally, a written submission must be provided within five days):

(i) A description of the Indirect Discharge and cause of noncompliance;

(ii) The period of noncompliance, including exact dates and times or, if not corrected, the anticipated time the noncompliance is expected to continue;

(iii) Steps being taken and/or planned to reduce, eliminate and prevent recurrence of the noncompliance.

(d) Burden of proof. In any enforcement proceeding the Industrial User seeking to establish the occurrence of an Upset shall have the burden of proof.

(e) Reviewability of agency consideration of claims of upset. In the usual exercise of prosecutorial discretion, Agency enforcement personnel should review any claims that non-compliance was caused by an Upset. No determinations made in the course of the review constitute final Agency action subject to judicial review. Industrial Users will have the opportunity for a judicial determination on any claim of Upset only in an enforcement action brought for noncompliance with categorical Pretreatment Standards.

(f) User responsibility in case of upset. The Industrial User shall control production or all Discharges to the extent necessary to maintain compliance with categorical Pretreatment Standards upon reduction, loss, or failure of its treatment facility until the facility is restored or an alternative method of treatment is provided. This requirement applies in the situation where, among other things, the primary source of power of the treatment facility is reduced, lost or fails.

403.17. Bypass.

(a) Definitions.

(1) "Bypass" means the intentional diversion of waste streams from any portion of an Industrial User's treatment facility.

(2) "Severe property damage" means substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of

natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.

(b) Bypass not violating applicable Pretreatment Standards or Requirements. An Industrial User may allow any bypass to occur which does not cause Pretreatment Standards or Requirements to be violated, but only if it also is for essential maintenance to assure efficient operation. These bypasses are not subject to the provision of paragraphs (c) and (d) of this section.

(c) Notice.

(1) If an Industrial User knows in advance of the need for a bypass, it shall submit prior notice to the Control Authority, if possible at least ten days before the date of the bypass.

(2) An Industrial User shall submit oral notice of an unanticipated bypass that exceeds applicable Pretreatment Standards to the Control Authority within 24 hours from the time the Industrial User becomes aware of the bypass. A written submission shall also be provided within 5 days of the time the Industrial User becomes aware of the bypass. The written submission shall contain a description of the bypass and its cause; the duration of the bypass, including exact dates and times, and, if the bypass has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent recurrence of the bypass. The Control Authority may waive the written report on a case-by-case basis if the oral report has been received within 24 hours.

(d) Prohibition of bypass.

(1) Bypass is prohibited, and the Control Authority may take enforcement action against an Industrial User for a bypass, unless;

(i) Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;

(ii) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass which occurred during normal periods of equipment downtime or preventative maintenance; and

(iii) The Industrial User submitted notices as required under paragraph (c) of this section.

(2) The Control Authority may approve an anticipated bypass, after considering its adverse effects, if the Control Authority determines that it will meet the three conditions listed in paragraph (d)(1) of this section.

403.18. Modification of POTW Pretreatment Programs.

(a) General. Either the Department or a POTW with an approved POTW Pretreatment Program may initiate program modification at any time to reflect changing conditions at the POTW. Program modification is necessary whenever there is a significant change in the operation of a POTW Pretreatment Program that differs from the information in the POTW's Submission, as approved under section 403.11.

(b) Substantial modifications defined. Substantial modifications include:

(1) Modifications that relax POTW legal authorities [as described in section 403.8(f)(1)], except for modifications that directly reflect a revision to this Part 403 or to 40 CFR chapter I, subchapter N, and are reported pursuant to paragraph (d) of this section;

(2) Modifications that relax local limits, except for the modifications to local limits for pH and reallocations of the Maximum Allowable Industrial Loading of a pollutant that do not increase the total industrial loadings for the pollutant, which are reported pursuant to paragraph (d) of this section. Maximum Allowable Industrial Loading means the total mass of a pollutant that all Industrial Users of a POTW (or a subgroup of Industrial Users identified by the POTW) may discharge pursuant to limits developed under section 403.5(c);

(3) Changes to the POTW's control mechanism, as described in section 403.8(f)(1)(iii);

(4) A decrease in the frequency of self-monitoring or reporting required of industrial users;

(5) A decrease in the frequency of industrial user inspections or sampling by the POTW;

(6) Changes to the POTW's confidentiality procedures; and

(7) Other modifications designated as substantial modifications by the Department on the basis that the modification could have a significant impact on the operation of the POTW's Pretreatment Program; could result in an increase in pollutant loadings at the POTW; or could result in less-stringent requirements being imposed on Industrial Users of the POTW.

(c) Approval procedures for substantial modifications.

(1) The POTW shall submit to the Department a statement of the basis for the desired program modification, a modified program description [see section 403.9(b)], or such other documents the Department determines to be necessary under the circumstances.

(2) The Department shall approve or disapprove the modification based on the requirements of section 403.8(f) and using the procedures in sections 403.11(b) through (f), except as provided in paragraphs (c)(3) and (4) of this section. The modification shall become effective upon approval by the Department.

(3) The Department need not publish a notice of decision under section 403.11(e) provided the notice of request for approval under section 403.11(b)(1) states that the request will be approved if no comments are received by a date specified in the notice; no substantive comments are received; and the request is approved without change.

(4) Notices required by section 403.11 may be performed by the POTW provided that the Department finds that the POTW notice otherwise satisfies the requirements of section 403.11.

(d) Approval procedures for non-substantial modifications.

(1) The POTW shall notify the Department of any non-substantial modification at least 45 days prior to implementation by the POTW, in a statement similar to that provided for in paragraph (c)(1) of this section.

(2) Within 45 days after the submission of the POTW's statement, the Department shall notify the POTW of its decision to approve or disapprove the non-substantial modification.

(3) If the Department does not notify the POTW within 45 days of its decision to approve or deny the modification, or to treat the modification as substantial under paragraph (b)(7) of this section, the POTW may implement the modification.

(e) Incorporation in permit. All modifications shall be incorporated into the POTW's NPDES permit upon approval. The permit will be modified to incorporate the approved modification in accordance with section R.61-9.122.63(g).

APPENDIX B. 65 TOXIC POLLUTANTS

Acenaphthene
Acrolein
Acrylonitrile
Aldrin/Dieldrin
Antimony and compounds
Arsenic and compounds
Asbestos
Benzene
Benzidine
Beryllium and compounds
Cadmium and compounds
Carbon tetrachloride
Chlordane (technical mixture and metabolites)
Chlorinated benzenes (other than dichlorobenzenes)
Chlorinated ethanes (including 1,2-dichloroethane, 1,1,1-trichloroethane, and hexachloroethane)
Chloroalkyl ethers (chloroethyl and mixed ethers)
Chlorinated naphthalene
Chlorinated phenols (other than those listed elsewhere; includes trichlorophenols and chlorinated cresols)
Chloroform
2-chlorophenol
Chromium and compounds
Copper and compounds
Cyanides
DDT and metabolites
Dichlorobenzenes (1,2-, 1,3-, and 1,4-dichlorobenzenes)
Dichlorobenzidine
Dichloroethylenes (1,1- and 1,2-dichloroethylene)
2,4-dichlorophenol
Dichloropropane and dichloropropene 2,4-dimethylphenol
Dinitrotoluene
Diphenylhydrazine
Endosulfan and metabolites
Endrin and metabolites
Ethylbenzene
Fluoranthene
Haloethers (other than those listed elsewhere; includes chlorophenylphenyl ethers, bromophenylphenyl ether, bis-(dichloroisopropyl) ether, bis-(chloroethoxy) methane and polychlorinated diphenyl ethers)
Halomethanes (other than those listed elsewhere; includes methylene chloride, methylchloride, methylbromide, bromoform, dichlorobromomethane)
Heptachlor and metabolites
Hexachlorobutadiene
Hexachlorocyclohexane

Hexachlorocyclopentadiene
Isophorone
Lead and compounds
Mercury and compounds
Naphthalene
Nickel and compounds
Nitrophenols (including 2,4-dinitrophenol, dinitroresol)
Nitrosamines
Pentachlorophenol
Phenol
Phthalate esters
Polychlorinated biphenyls (PCBs)
Polynuclear aromatic hydrocarbons (including benzantracenes, benzopyrenes, benzofluoranthene, chrysenes, dibenzanthracenes, and indenopyrenes)
Selenium and compounds
Silver and compounds
2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)
Tetrachloroethylene
Thallium and compounds
Toluene
Toxaphene
Trichloroethylene
Vinyl chloride
Zinc and compounds

APPENDIX C. INDUSTRIAL CATEGORIES SUBJECT TO NATIONAL CATEGORICAL PRETREATMENT STANDARDS

Aluminum Forming
Asbestos Manufacturing
Battery Manufacturing
Builder's Paper
Carbon Black
Cement Manufacturing
Centralized Waste Treatment
Coil Coating
Copper Forming
Dairy Products Processing
Electrical and Electronic Components
Electroplating
Feedlots
Ferroalloy Manufacturing
Fertilizer Manufacturing
Fruits and Vegetables Processing Manufacturing
Glass Manufacturing
Grain Mills
Ink Formulating
Inorganic Chemicals
Iron and Steel Manufacturing
Leather Tanning and Finishing
Meat Processing
Metal Finishing
Metal Molding and Casting
Nonferrous Metals Forming and Metal Powders
Nonferrous Metals Manufacturing
Oil and Gas Extraction
Organic Chemicals, Plastics, and Synthetic Fibers
Paint Formulating
Paving and Roofing (Tars and Asphalt)
Pesticides
Petroleum Refining
Pharmaceuticals
Phosphate Manufacturing
Plastics Molding and Forming
Porcelain Enameling
Pulp, Paper, and Paperboard
Rubber Manufacturing
Seafood Processing
Soaps and Detergents Manufacturing
Steam Electric

Sugar Processing

Textile Mills

Timber Products Processing

Transportation Equipment Cleaning

Waste Combustors

APPENDIX D. SELECTED INDUSTRIAL SUBCATEGORIES CONSIDERED DILUTE FOR PURPOSES OF THE COMBINED WASTESTREAM FORMULA

The following industrial subcategories are considered to have dilute waste streams for purposes of the combined waste stream formula. They either were or could have been excluded from categorical pretreatment standards pursuant to paragraph 8 of the *Natural Resources Defense Council, Inc., et al. v. Costle* Consent Decree for one or more of the following four reasons:

- 1) The pollutants of concern are not detectable in the effluent from the industrial user (paragraph 8(a)(iii));
- 2) the pollutants of concern are present only in trace amounts and are neither causing nor likely to cause toxic effects (paragraph 8(a)(iii));
- 3) the pollutants of concern are present in amounts too small to be effectively reduced by technologies known to the Administrator (paragraph 8(a)(iii); or
- 4) the waste stream contains only pollutants which are compatible with the POTW (paragraph 8(b)(i)). In some instances, different rationales were given for exclusion under paragraph 8. However, EPA has reviewed these subcategories and has determined that exclusion could have occurred due to one of the four reasons listed above.

Auto and Other Laundries (40 CFR Part 444)

Carpet and Upholstery Cleaning

Coin-Operated Laundries and Dry Cleaning

Diaper Services

Dry Cleaning Plants except Rug Cleaning

Industrial Laundries

Laundry and Garment Services, Not Elsewhere Classified

Linen Supply

Power Laundries, Family and Commercial

Electrical and Electronic Components (40 CFR Part 469) (The Paragraph 8 exemption for the manufacture of products in the Electrical and Electronic Components Category is for operations not covered by Electroplating/ Metal Finishing pretreatment regulations (40 CFR Parts 413/433)).

Capacitors (Fluid Fill)

Carbon and Graphite Products

Dry Transformers

Ferrite Electronic Devices

Fixed Capacitors

Fluorescent Lamps

Fuel Cells

Incandescent Lamps

Magnetic Coatings

Mica Paper Dielectric

Motors, Generators, Alternators

Receiving and Transmitting Tubes

Resistance Heaters

Resistors

Switchgear

Transformer (Fluid Fill)

Metal Molding and Casting (40 CFR Part 464)

Nickel Casting

- Tin Casting
- Titanium Casting
- Gum and Wood Chemicals (40 CFR Part 454)
 - Char and Charcoal Briquets
- Inorganic Chemicals Manufacturing (40 CFR Part 415)
 - Ammonium Chloride
 - Ammonium Hydroxide
 - Barium Carbonate
 - Calcium Carbonate
 - Carbon Dioxide
 - Carbon Monoxide and Byproduct Hydrogen
 - Hydrochloric Acid
 - Hydrogen Peroxide (Organic Process)
 - Nitric Acid
 - Oxygen and Nitrogen
 - Potassium Iodide
 - Sodium Chloride (Brine Mining Process)
 - Sodium Hydrosulfide
 - Sodium Hydrosulfite
 - Sodium Metal
 - Sodium Silicate
 - Sodium Thiosulfate
 - Sulfur Dioxide
 - Sulfuric Acid
- Leather (40 CFR Part 425)
 - Gloves
 - Luggage
- Paving and Roofing (40 CFR Part 443)
 - Asphalt Concrete
 - Asphalt Emulsion
 - Linoleum
 - Printed Asphalt Felt
 - Roofing
- Pulp, Paper, and Paperboard, and Builders' Paper and Board Mills (40 CFR Parts 430 and 431)
 - Groundwood-Chemi-Mechanical
- Rubber Manufacturing (40 CFR Part 428)
 - Tire and Inner Tube Plants
 - Emulsion Crumb Rubber
 - Solution Crumb Rubber
 - Latex Rubber
 - Small-sized General Molded, Extruded & Fabricated Rubber Plants ¹
 - Medium-sized General Molded Extruded and Fabricated Rubber Plants ¹
 - Large-sized General Molded Extruded and Fabricated Rubber Plants ¹

¹ Except for production attributed to lead-sheathed hose manufacturing operations.

Wet Digestion Reclaimed Rubber
Pan, Dry Digestion, and Mechanical Reclaimed Rubber
Latex Dipped, Latex-Extruded, and Latex-Molded Rubber ²
Latex Foam ³

Soap and Detergent Manufacturing (40 CFR Part 417)

Soap Manufacture by Batch Kettle
Fatty Acid Manufacture by Fat Splitting
Soap Manufacture by Fatty Acid Neutralization
Glycerine Concentration
Glycerine Distillation
Manufacture of Soap Flakes and Powders
Manufacture of Bar Soaps
Manufacture of Liquid Soaps
Manufacture of Spray Dried Detergents
Manufacture of Liquid Detergents
Manufacture of Dry Blended Detergents
Manufacture of Drum Dried Detergents
Manufacture of Detergent Bars and Cakes

Textile Mills (40 CFR 410)

Apparel manufacturing
Cordage and Twine
Padding and Upholstery Filling

Timber Products Processing (40 CFR part 429)

Barking Process
Finishing Processes
Hardboard-Dry Process

² Except for production attributed to chromic acid form-cleaning operations.

³ Except for production that generates zinc as a pollutant in discharge.

APPENDIX E. SAMPLING PROCEDURES

I. COMPOSITE METHOD

A. It is recommended that influent and effluent operational data be obtained through 24-hour flow proportional composite samples. Sampling may be done manually or automatically, and discretely or continuously. If discrete sampling is employed, at least 12 aliquots should be composited. Discrete sampling may be flow proportioned either by varying the time interval between each aliquot or the volume of each aliquot. All composites should be flow proportional to either the stream flow at the time of collection of the influent aliquot or to the total influent flow since the previous influent aliquot. Volatile pollutant aliquots must be combined in the laboratory immediately before analysis.

B. Effluent sample collection need not be delayed to compensate for hydraulic detention unless the POTW elects to include detention time compensation or unless the Department requires detention time compensation. The Department may require that each effluent sample is taken approximately one detention time later than the corresponding influent sample when failure to do so would result in an unrepresentative portrayal of actual POTW operation. The detention period should be based on a 24-hour average daily flow value. The average daily flow should in turn be based on the average of the daily flows during the same month of the previous year.

II. GRAB METHOD

If composite sampling is not an appropriate technique, grab samples should be taken to obtain influent and effluent operational data. A grab sample is an individual sample collected over a period of time not exceeding 15 minutes. The collection of influent grab samples should precede the collection of effluent samples by approximately one detention period except that where the detention period is greater than 24 hours such staggering of the sample collection may not be necessary or appropriate. The detention period should be based on a 24-hour average daily flow value. The average daily flow should in turn be based upon the average of the daily flows during the same month of the previous year. Grab sampling should be employed where the pollutants being evaluated are those, such as cyanide and phenol, which may not be held for an extended period because of biological, chemical, or physical interactions which take place after sample collection and affect the results.

APPENDIX G. POLLUTANTS ELIGIBLE FOR A REMOVAL CREDIT

I. REGULATED POLLUTANTS IN R.61-9.503 ELIGIBLE FOR A REMOVAL CREDIT

Pollutants	Use or Disposal Practice		
	LA	Surface Disposal	I
		Unlined ¹	Lined ²
Arsenic	X	X	X
Beryllium			X
Cadmium	X		X
Chromium		X	X
Copper	X		
Lead	X		X
Mercury	X		X
Molybdenum	X		
Nickel	X	X	X
Selenium	X		
Zinc	X		
Total hydrocarbons			X(1)

KEY: LA - land application
SD - surface disposal site without a liner and leachate collection system
I - firing of sewage sludge in a sewage sludge incinerator

- (1) The following organic pollutants are eligible for a removal credit if the requirements for total hydrocarbons (or carbon monoxide) in subpart E in R.61–9.503 and other requirements in R.61–62 are met when sewage sludge is fired in a sewage sludge incinerator: Acrylonitrile, Aldrin/Dieldrin (total), Benzene, Benzidine, Benzo(a)pyrene, Bis(2-chloroethyl)ether, Bis(2-ethylhexyl)phthalate, Bromodichloromethane, Bromoethane, Bromoform, Carbon tetrachloride, Chlordane, Chloroform, Chloromethane, DDD,DDE,DDT, Dibromochloro- methane, Dibutyl phthalate, 1,2-dichloroethane, 1,1-dichloroethylene, 2,4-dichlorophenol, 1,3-dichloropropene, Diethyl phthalate, 2,4-dinitrophenol, 1,2-diphenylhydrazine, Di-n-butyl phthalate, Endosulfan, Endrin, Ethylbenzene, Heptachlor, Heptachlor epoxide, Hexachlorobutadiene, Alpha-hexachlorocyclohexane, Beta- hexachlorocyclohexane, Hexachlorocyclopentadiene, Hexachloroethane, Hydrogen cyanide, Isophorone, Lindane, Methylene chloride, Nitrobenzene, N-Nitrosodimethylamine, N-Nitrosodi-n-propylamine, Pentachlorophenol, Phenol, Polychlorinated biphenyls, 2,3,7,8- tetrachlorodibenzo-p-dioxin, 1,1,2,2,-tetrachloroethane, Tetrachloroethylene, Toluene, Toxaphene, Trichloroethylene, 1,2,4-Trichlorobenzene, 1,1,1-Trichloroethane, 1,1,2-Trichloro- ethane, and 2,4,6-Trichlorophenol.

II. ADDITIONAL POLLUTANTS ELIGIBLE FOR A REMOVAL CREDIT

(milligrams per kilogram—dry weight basis)

Pollutant	LA	SD		I
		Unlined ¹	Lined ²	
Arsenic	—	—	100 ³	—
Aldrin/Dieldrin (Total)	2.7	—	—	—
Benzene	16 ³	140	3400	—
Benzo(a)pyrene	15	100 ³	100 ³	—
Bis(2-ethylhexyl) phthalate	—	100 ³	100 ³	—
Cadmium	—	100 ³	100 ³	—
Chlordane	86	100 ³	100 ³	—
Chromium (total)	100 ³	—	100 ³	—
Copper	—	46 ³	100	1400
DDD, DDE, DDT (Total)	1.2	2000	2000	—

Pollutant	LA	SD		I
		Unlined ¹	Lined ²	
2,4 Dichlorophenoxy-acetic acid	—	7	7	—
Fluoride	730	—	—	—
Heptachlor	7.4	—	—	—
Hexachlorobenzene	29	—	—	—
Hexachlorobutadiene	600	—	—	—
Iron	78 ³	—	—	—
Lead	—	100 ³	100 ³	—
Lindane	84	28 ³	28 ³	—
Malathion	—	0.63	0.63	—
Mercury	—	100 ³	100 ³	—
Molybdenum	—	40	40	—
Nickel	—	—	100 ³	—
N-Nitrosodimethylamine	2.1	0.088	0.088	—
Pentachlorophenol	30	—	—	—
Phenol	—	82	82	—
Polychlorinated biphenyls	4.6	<50	<50	—
Selenium	—	4.8	4.8	4.8
Toxaphene	10	26 ³	26 ³	—
Trichloroethylene	10 ³	9500	10 ³	—
Zinc	—	4500	4500	4500

KEY: LA - land application
SD - surface disposal
I - incineration

1 - Active sewage sludge unit without a liner and leachate collection system.

2 - Active sewage sludge unit with a liner and leachate collection system.

3 - Value expressed in grams per kilogram - dry weight basis.

4 - Value to be determined on a case-by-case basis.

HISTORY: Added by State Register Volume 17, Issue No. 4, eff April 23, 1993; Amended by State Register Volume 20, Issue No. 6, eff June 28, 1996; State Register Volume 25, Issue No. 7, eff July 27, 2001; State Register Volume 32, Issue No. 5, Part 2, eff May 23, 2008.

61-9.503. STANDARDS FOR THE USE OR DISPOSAL OF SEWAGE SLUDGE.

Editor's Note

The following constitutes the history for 61-9.503, 503.1 through 503.50.

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001; State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003; State Register Volume 32, Issue No. 5, eff May 23, 2008.

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PART A

GENERAL PROVISIONS

503.1. Purpose and applicability.

(a) Purpose.

(1) This part establishes standards, which consist of general requirements, pollutant limits, management practices, and operational standards, for the final use or disposal of sewage sludge generated during the treatment of domestic sewage in a treatment works. Standards are included in this part for sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. Also included in this part are pathogen and alternative vector attraction reduction requirements for sewage sludge applied to the land or placed on a surface disposal site.

(2) In addition, the standards in this part include the frequency of monitoring and recordkeeping requirements when sewage sludge is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. Also included in this part are reporting requirements for Class I sludge management facilities, publicly owned treatment works (POTWs) with a design flow rate equal to or greater than one million gallons per day, POTWs that serve 10,000 people or more, and all sewage sludge disposal when sewage sludge is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator.

(b) Applicability.

(1) This part applies to any person who prepares sewage sludge, applies sewage sludge to the land, or fires sewage sludge in a sewage sludge incinerator and to the owner/operator of a surface disposal site.

(2) This part applies to sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator.

(3) This part applies to the exit gas from a sewage sludge incinerator stack.

(4) This part applies to land where sewage sludge is applied, to a surface disposal site, and to a sewage sludge incinerator.

(5) The requirements incorporated into this regulation pursuant to State Register Document 4444, including Appendix C, expire and are no longer effective five years from the State Register Document 4444 amendments' effective date.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

503.2. Compliance period.

(a) Compliance with the standards in this part shall be achieved as expeditiously as practicable, but in no case later than February 19, 1994. When compliance with the standards requires construction of new pollution control facilities, compliance with the standards shall be achieved as expeditiously as practicable, but in no case later than February 19, 1995.

(b) The requirements for frequency of monitoring, recordkeeping, and reporting in this part for total hydrocarbons in the exit gas from a sewage sludge incinerator are effective February 19, 1994 or, if compliance with the operational standard for total hydrocarbons in this part requires the construction of new pollution control facilities, February 19, 1995.

(c) All other requirements for frequency of monitoring, recordkeeping, and reporting in this part are effective on July 20, 1993.

(d) Unless otherwise specified in subpart E, compliance with the requirements in sections 503.41 (c) through (r), 503.43(c), (d), and (e), 503.45(a)(1) and (b) through (f), 503.46(a)(1), (a)(3), and (c), and 503.47(f) that were revised on September 3, 1999, shall be achieved as expeditiously as practicable, but in no case later than September 5, 2000. When new pollution control facilities must be constructed to comply with the revised requirements in subpart E, compliance with the revised requirements shall be achieved as expeditiously as practicable but no later than September 4, 2001.

(e) Compliance with 503 Appendix C-PCB, shall be required upon publication of the revised regulation in the South Carolina State Register.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

503.3. Permits.

(a) The requirements in this part shall be implemented through a permit, with the exception of 503 Appendix C-PCB in accordance with 503.3(b):

(1) issued to a "treatment works treating domestic sewage", as defined in R.61-9.122.2, in accordance with R.61-9.122, 124, and 505, by the State in accordance with 40 CFR 123 or,

(2) issued to any person who prepares, generates, or disposes of sewage sludge when the sewage sludge is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator, or

(3) issued under subtitle C of the Solid Waste Disposal Act; subpart C of the Safe Drinking Water Act; the Marine Protection, Research, and Sanctuaries Act of 1972; or the Clean Air Act. "Treatment works treating domestic sewage" shall submit a permit application in accordance with R.61-9.122.21.

(4) A person who derives a bulk or bag material from sewage sludge shall not be required to obtain a permit if: (1) the sewage sludge meets the ceiling concentrations in Table 1 of section 503.13; the pollutant concentration limits in Table 3 of section 503.13; the Class A pathogen requirements of section 503.32(a); one of the vector attraction reduction requirements in section

503.33(b)(1) through section 503.33(b)(8); and the requirements in 503 Appendix C-PCB, and (2) there is a permit in effect for either the preparer, generator and/or applier of the sewage sludge.

(b) Direct Enforceability. In addition to any other requirement of this regulation or a permit, sewage sludge use via land application shall be in accordance with Appendix C-PCB. This includes but is not limited to: bulk sewage sludge applied to agricultural land, forests or public contact sites; sewage sludge sold or given away in a bag or other container for application to the land; domestic septage; reclamation sites; or other materials mixed with sludge before application.

(c) The requirements under this part may be addressed in permits issued to land appliers.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

503.4. Relationship to other regulations.

(a) Disposal of sewage sludge in a municipal solid waste landfill unit, as defined in 40 CFR 258.2 and R.61-107, that complies with the requirements in 40 CFR Part 258 and R.61-107 constitutes compliance with section 405(d) of the CWA. Any person who prepares sewage sludge that is disposed in a municipal solid waste landfill unit shall ensure that the sewage sludge meets the requirements in 40 CFR Part 258 and R.61-107 concerning the quality of materials disposed in a municipal solid waste landfill unit.

(b) The disposal of sewage sludge involving the composting or co-composting of the sewage sludge with yard trash, land-clearing debris, or a combination of yard trash and land clearing debris shall comply with the requirements established in R.61-107. The submission and information requirements shall be determined by the Department.

(c) The disposal of sewage sludge utilizing an innovative and experimental solid waste management technology or process shall comply with the requirements addressed in R.61-107.

(d) The disposal of sewage sludge involving firing of sewage sludge in a sewage sludge incinerator or the heat drying/heat conditioning of the sewage sludge shall comply with the requirements addressed in 40 CFR Part 60, 40 CFR Part 61, and R.61-62.

(e) The processing of wastewater or the disposal of effluent from the processing of wastewater shall comply with the requirements addressed in R.61-62. Any activity covered by the Clean Air Amendments of 1990, shall comply within the time frame specified in the Clean Air Amendment or applicable federal regulations.

503.5. Additional or more stringent requirements.

(a) On a case-by-case basis, the Department may impose requirements for the use or disposal of sewage sludge in addition to or more stringent than the requirements in this part when necessary to protect public health and the environment from any adverse effect of a pollutant in the sewage sludge.

(b) Nothing in this part precludes a State or political subdivision thereof or interstate agency from imposing requirements for the use or disposal of sewage sludge more stringent than the requirements in this part or from imposing additional requirements for the use or disposal of sewage sludge.

(c) Sludge generated at an industrial facility. See R.61-9.504 for permit requirements for Industrial sludges.

(d) Commercial and mixed Domestic/Commercial septage. See R.61-9.504 for permit requirements.

503.6. Exclusions.

(a) Treatment processes. This part does not establish requirements for processes used to treat domestic sewage or for processes used to treat sewage sludge prior to final use or disposal, except as provided in section 503.32 and section 503.33.

(b) Selection of a use or disposal practice. This part does not require the selection of a sewage sludge use or disposal practice. The determination of the manner in which sewage sludge is used or disposed is a local determination.

(c) Co-firing of sewage sludge. This part does not establish requirements for sewage sludge co-fired in an incinerator with other wastes or for the incinerator in which sewage sludge and other wastes are co-fired.

(1) Domestic Sludge. Other wastes do not include auxiliary fuel, as defined in section 503.41(b), fired in a domestic sewage sludge incinerator.

(2) Industrial Sludge. See R.61-9.504 for permit requirements for Industrial sludges.

(d) Sludge generated at an industrial facility. This part (R.61-9.503) does not establish requirements for the use or disposal of sludge generated at an industrial facility during the treatment of industrial wastewater, including sewage sludge generated during the treatment of industrial wastewater combined with domestic sewage. See R.61-9.504 for permit requirements for Industrial sludges and industrial sewage sludge generated during the treatment of industrial wastewater combined with domestic sewage.

(e) Hazardous sewage sludge. This part does not establish requirements for the use or disposal of sewage sludge determined to be hazardous in accordance with 40 CFR Part 261.

(f) Sewage sludge with high PCB concentration. This part does not establish requirements and no land application of these materials may occur for the use or disposal of sewage sludge with a concentration of polychlorinated biphenyls (PCBs) equal to or greater than 50 milligrams per kilogram of total solids (dry weight basis). Requirements for land application of sludges (including sewage sludge, sludges and septage that may be mixed with grease trap waste) with PCB concentrations of less than 50 milligrams per kilogram (mg/kg dry weight basis) or less than 50 parts per million (ppm) are included in 503 Appendix C-PCB.

(g) Incinerator ash. This part does not establish requirements for the use or disposal of ash generated during the firing of sewage sludge in a sewage sludge incinerator.

(h) Grit and screenings. This part does not establish requirements for the use or disposal of grit (e.g., sand, gravel, cinders, or other materials with a high specific gravity) or screenings (e.g., relatively large materials such as rags) generated during preliminary treatment of domestic sewage in a treatment works.

(i) Drinking water treatment sludge. This part does not establish requirements for the use or disposal of sludge generated during the treatment of either surface water or ground water used for drinking water.

(j) Commercial and Industrial septage. This part (R.61-9.503) does not establish requirements for the use or disposal of commercial septage, industrial septage, a mixture of domestic septage and commercial septage, or a mixture of domestic septage and industrial septage. See R.61-9.504 for any permit requirements.

(k) Coal ash. This part does not establish requirements for the use or disposal of coal ash.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

503.7. Requirement for a person who prepares sewage sludge.

Any person who prepares sewage sludge shall ensure that the applicable requirements in this part are met when the sewage sludge is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator.

503.8. Sampling and analysis.

(a) Sampling. Representative samples of sewage sludge that is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator shall be collected and analyzed. The Department may establish minimum requirements in permits for the proper method of sampling and analysis of sewage sludge.

(b) Methods. The materials listed below are incorporated by reference in this part. The materials are incorporated as they exist on the date of approval, and notice of any change in these materials will be published in the Federal Register. They are available for inspection at the Office of the Federal Register, 7th Floor, suite 700, 800 North Capitol Street, NW, Washington, DC, and at the Office of Water Docket, room L-102, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC. Copies may be obtained from the standard producer or publisher listed in the regulation. Methods in the materials listed below shall be used to analyze samples of sewage sludge.

(1) Enteric viruses. ASTM Designation: D 4994-89, "Standard Practice for Recovery of Viruses From Wastewater Sludges", 1992 Annual Book of ASTM Standards: Section 11 -Water and Environmental Technology, ASTM, 1916 Race Street, Philadelphia, PA 19103-1187.

(2) Fecal coliform. Part 9221 C and E. or Part 9222 D., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW, Washington, DC, 20005.

(3) Helminth ova. Yanko, W.A., "Occurrence of Pathogens in Distribution and Marketing Municipal Sludges", EPA 600/1-87-014, 1987. National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (PB 88-154273/AS).

(4) Inorganic pollutants. "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods", EPA Publication SW-846, Second Edition (1982) with Updates I (April 1984) and II (April 1985) and Third Edition (November 1986) with Revision I (December 1987), II, IIA and IIB. Second Edition and Updates I and II are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (PB-87-120-291). Third Edition and Revision I are available from Superintendent of Documents, Government Printing Office, 941 North Capitol Street, NE., Washington, DC, 20002 (Document Number 955-001-00000-1).

(5) Salmonella sp. bacteria. Part 9260 D., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW, Washington, DC, 20005; or Kenner, B.A. and H.P. Clark, "Detection and enumeration of Salmonella and Pseudomonas aeruginosa", Journal of the Water Pollution Control Federation, Vol. 46, no. 9, September 1974, pp. 2163-2171. Water Environment Federation, 601 Wythe Street, Alexandria, Virginia 22314.

(6) Specific oxygen uptake rate. Part 2710 B., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW, Washington, DC, 20005.

(7) Total, fixed, and volatile solids. Part 2540 G., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW, Washington, DC, 20005.

503.9. General definitions.

All terms not defined herein have the meaning given them in R.61-9.122, R.61-9.124, R.61-9.129, R.61-9.133, R.61-9.403, or R.61-9.505.

(a) "Apply sewage sludge or sewage sludge applied to the land" means land application of sewage sludge.

(b) "Base flood" is a flood that has a one percent chance of occurring in any given year (i.e., a flood with a magnitude equalled once in 100 years).

(c) "Class I sludge management facility" is any publicly owned treatment works (POTW), as defined in 40 CFR 501.2, required to have an approved pretreatment program under R.61-9.403.8(a) (including any POTW located in a State that has elected to assume local program responsibilities pursuant to R.61-9.403.10(e)) and any treatment works treating domestic sewage, as defined in R.61-9.122.2, classified as a Class I sludge management facility by the EPA Regional Administrator, or, in the case of approved State programs, the Regional Administrator in conjunction with the Department, because of the potential for its sewage sludge use or disposal practice to affect public health and the environment adversely.

(d) "Cover crop" is a small grain crop, such as oats, wheat, or barley; grasses; or other crop grown for agronomic use.

(e) "CWA" see R.61-9.122.2(b) Definitions.

(f) "Domestic septage" is either liquid or solid material removed from a septic tank, cesspool, portable toilet, Type III marine sanitation device, or similar treatment works that receives only domestic sewage. Domestic septage does not include liquid or solid material removed from a septic tank, cesspool, or similar treatment works that receives either commercial wastewater or industrial wastewater and does not include grease removed from a grease trap at a restaurant.

(g) "Domestic sewage" is waste and wastewater from humans, or household operations that is discharged to or otherwise enters a treatment works.

(h) "Dry weight basis" means calculated on the basis of having been dried at 105 degrees Celsius until reaching a constant mass (i.e., essentially 100 percent solids content).

(i) "EPA" means the United States Environmental Protection Agency.

(j) "Feed crops" are crops produced primarily for consumption by animals.

(k) "Fiber crops" are crops such as flax and cotton.

(l) "Food crops" are crops consumed by humans. These include, but are not limited to, fruits, vegetables, and tobacco.

(m) "Ground water" is water below the land surface in the saturated zone.

(n) "Industrial wastewater" is wastewater generated in a commercial or industrial process. See R.61-9.504 for additional definitions.

(o) "Municipality" see R.61-9.122.2(b) Definitions. The definition includes under section 503 of this regulation a special district created under State law, such as a water district, sewer district, sanitary district, utility district, drainage district, or similar entity, or an integrated waste management facility as defined in section 201(e) of the CWA, as amended, that has as one of its principal responsibilities the treatment, transport, use, or disposal of sewage sludge.

(p) "Permitting authority" means the Department.

(q) "Person" see definition in R.61-9.122.2(b) Definitions.

(r) "Person who prepares sewage sludge" is either the person who generates sewage sludge during the treatment of domestic sewage in a treatment works or the person who derives a material from sewage sludge.

(s) "Place sewage sludge or sewage sludge placed" means disposal of sewage sludge on a surface disposal site.

(t) "Pollutant" is an organic substance, an inorganic substance, a combination of organic and inorganic substances, or a pathogenic organism that, after discharge and upon exposure, ingestion, inhalation, or assimilation into an organism either directly from the environment or indirectly by ingestion through the food chain, could, on the basis of information available to the Department, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunction in reproduction), or physical deformations in either organisms or offspring of the organisms.

(u) "Pollutant limit" is a numerical value that describes the amount of a pollutant allowed per unit amount of sewage sludge (e. g., milligrams per kilogram of total solids); the amount of a pollutant that can be applied to a unit area of land (e. g., kilograms per hectare); or the volume of a material that can be applied to a unit area of land (e.g., gallons per acre).

(v) "Runoff" is rainwater, leachate, or other liquid that drains overland on any part of a land surface and runs off of the land surface.

(w) "Sewage sludge" is solid, semi-solid, or liquid residue generated during the treatment of municipal wastewater or domestic sewage in a treatment works. Sewage sludge includes, but is not limited to, domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic or industrial sewage in a treatment works. See R.61-9.504 for Industrial sludge definition.

(x) "State" means the State of South Carolina.

(y) "Store or storage of sewage sludge" is the placement of sewage sludge on land on which the sewage sludge remains for two years or less. This does not include the placement of sewage sludge on land for treatment.

(z) "Treat or treatment of sewage sludge" is the preparation of sewage sludge for final use or disposal. This includes, but is not limited to, thickening, stabilization, and dewatering of sewage sludge. This does not include storage of sewage sludge.

(aa) "Treatment works" is either a Federally owned, publicly owned, or privately owned device or system used to treat (including recycle and reclaim) either domestic sewage or a combination of domestic sewage and industrial waste of a liquid nature.

(bb) "Wetlands" see R.61-9.122.2(b) Definitions.

(cc) [Reserved]

(dd) "Person who applies sewage sludge" may be the generator, preparer, or a land applier.

PART B
LAND APPLICATION

503.10. Applicability.

(a) This part applies to any person who prepares sewage sludge that is applied to the land, to any person who applies sewage sludge to the land, to sewage sludge applied to the land, and to the land on which sewage sludge is applied.

(b) Bulk sewage sludge.

(1) [Reserved]

(2) The Department, may apply any or all of the general requirements in section 503.12 and the management practices in section 503.14 to bulk sewage sludge meeting the pollutant concentrations in section 503.13(b)(3), the Class A pathogen requirements in section 503.32(a), and one of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8), on a case-by-case basis after determining that the general requirements or management practices are needed to protect public health and the environment from any reasonably anticipated adverse effect that may occur from any pollutant in the bulk sewage sludge.

(c)(1) [Reserved]

(2) The Department, may apply any or all of the general requirements in section 503.12 or the management practices in section 503.14 to derived bulk material meeting the pollutant concentrations in section 503.13(b)(3), the Class A pathogen requirements in section 503.32(a), and one of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8), on a case-by-case basis after determining that the general requirements or management practices are needed to protect public health and the environment from any reasonably anticipated adverse effect that may occur from any pollutant in the bulk sewage sludge.

(d) The requirements in this part may be applied by the Department, on a case-by-case basis, when a bulk material derived from sewage sludge is applied to the land if the sewage sludge from which the bulk material is derived meets the ceiling concentrations in Table 1 of section 503.13 and the pollutant concentrations in Table 3 of section 503.13; the Class A pathogen requirements in section 503.32(a); and one of the vector attraction reduction requirements in section 503.33(b)(1) through (b)(8).

(e) Sewage sludge sold or given away in a bag or other container for application to the land. The general requirements in section 503.12 and the management practices in section 503.14 do not apply, except for section 503.12(o), section 503.12(p), section 503.12(q), and section 503.14(e), when sewage sludge is sold or given away in a bag or other container for application to the land if the sewage sludge sold or given away in a bag or other container for application to the land meets the ceiling concentrations in Table 1 of section 503.13 and the pollutant concentrations in Table 3 of section 503.13; the Class A pathogen requirements in section 503.32(a); and one of the vector attraction reduction requirements in section 503.33(b)(1) through (b)(8).

(f) The general requirements in section 503.12 and the management practices in section 503.14 do not apply, except for section 503.12(o), section 503.12(p), section 503.12(q), and section 503.14(e), when a material derived from sewage sludge is sold or given away in a bag or other container for application to the land if the derived material meets the ceiling concentrations in Table 1 of section 503.13 and the pollutant concentrations in Table 3 of section 503.13; the Class A pathogen requirements in section 503.32(a); and one of the vector attraction reduction requirements in section 503.33(b)(1) through (b)(8).

(g) The requirements in this part do not apply, except for section 503.14(e), when a material derived from sewage sludge is sold or given away in a bag or other container for application to the

land if the sewage sludge from which the material is derived meets the ceiling concentrations in Table 1 of section 503.13 and the pollutant concentrations in Table 3 of section 503.13; the Class A pathogen requirements in section 503.32(a); and one of the vector attraction reduction requirements in section 503.33(b)(1) through (b)(8).

(h) If other materials are mixed with the sewage sludge, the final product must meet the applicable requirements related to pollution limits (in section 503.13), pathogen reduction (in section 503.15(a)), and vector attraction reduction (in section 503.15(c)) after the materials have been added to the sewage sludge.

503.11. Special definitions.

(a) "Agricultural land" is land on which a food crop, a feed crop, or a fiber crop is grown. This includes range land and land used as pasture.

(b) "Agronomic rate" is the whole sludge application rate (dry weight basis) designed: (1) to provide the amount of nitrogen needed by the food crop, feed crop, fiber crop, cover crop, or vegetation grown on the land and (2) to minimize the amount of nitrogen in the sewage sludge that passes below the root zone of the crop or vegetation grown on the land to the ground water and (3) to provide the amount of other organic and inorganic plant nutrients which promote crop or vegetative growth, such as calcium-carbonate equivalency.

(c) "Annual pollutant loading rate" is the maximum amount of a pollutant that can be applied to a unit area of land during a 365 day period.

(d) "Annual whole sludge application rate" is the maximum amount of sewage sludge (dry weight basis) that can be applied to a unit area of land during a 365 day period.

(e) "Bulk sewage sludge" is sewage sludge that is not sold or given away in a bag or other container for application to the land.

(f) "Cumulative pollutant loading rate" is the maximum amount of an inorganic pollutant that can be applied to an area of land.

(g) "Forest" is a tract of land thick with trees and underbrush.

(h) "Land application" is the spraying or spreading of sewage sludge onto the land surface; the injection of sewage sludge below the land surface; or the incorporation of sewage sludge into the soil so that the sewage sludge can either condition the soil or fertilize crops or vegetation grown in the soil.

(i) "Monthly average" is the arithmetic mean of all measurements taken during the month.

(j) "Other container" is either an open or closed receptacle. This includes, but is not limited to, a bucket, a box, a carton, and a vehicle or trailer with a load capacity of one metric ton or less.

(k) "Pasture" is land on which animals feed directly on feed crops such as legumes, grasses, grain stubble, or stover.

(l) "Public contact site" is land with a high potential for contact by the public. This includes, but is not limited to, public parks, ball fields, cemeteries, plant nurseries, turf farms, and golf courses.

(m) "Range land" is open land with indigenous vegetation.

(n) "Reclamation site" is drastically disturbed land that is reclaimed using sewage sludge. This includes, but is not limited to, strip mines and construction sites.

503.12. General requirements.

(a) No person shall apply sewage sludge to the land except in accordance with the requirements in this part.

(b) No person shall apply bulk sewage sludge subject to the cumulative pollutant loading rates in section 503.13(b)(2) to agricultural land, forest, a public contact site, or a reclamation site if any of the cumulative pollutant loading rates in section 503.13(b)(2) has been reached.

(c) No person shall apply domestic septage to agricultural land, forest, or a reclamation site during a 365 day period if the annual application rate in section 503.13(c) has been reached during that period.

(d) The person who prepares bulk sewage sludge that is applied to agricultural land, forest, a public contact site, or a reclamation site shall provide the person who applies the bulk sewage sludge written

notification of the concentration of total nitrogen (as N on a dry weight basis) in the bulk sewage sludge.

(e)(1) The person or the permittee who applies sewage sludge to the land shall obtain information needed to comply with the requirements in this part.

(2)(i) Before bulk sewage sludge subject to the cumulative pollutant loading rates in section 503.13(b)(2) is applied to the land, the person who proposes to apply the bulk sewage sludge shall contact the Department or the permitting authority for the State in which the bulk sewage sludge will be applied to determine whether bulk sewage sludge subject to the cumulative pollutant loading rates in section 503.13(b)(2) has been applied to the site.

(ii) If bulk sewage sludge subject to the cumulative pollutant loading rates in section 503.13(b)(2) has not been applied to the site, the cumulative amount for each pollutant listed in Table 2 of section 503.13 may be applied to the site in accordance with section 503.13(a)(2)(i).

(iii) If bulk sewage sludge subject to the cumulative pollutant loading rates in section 503.13(b)(2) has been applied to the site and the cumulative amount of each pollutant applied to the site in the bulk sewage sludge is known, the cumulative amount of each pollutant applied to the site shall be used to determine the additional amount of each pollutant that can be applied to the site in accordance with section 503.13(a)(2)(i).

(iv) If bulk sewage sludge subject to the cumulative pollutant loading rates in section 503.13(b)(2) has been applied to the site since July 20, 1993 and the cumulative amount of each pollutant applied to the site in the bulk sewage sludge since that date is not known, an additional amount of each pollutant shall not be applied to the site in accordance with section 503.13(a)(2)(i).

(f) When a person who prepares bulk sewage sludge provides the bulk sewage sludge to a person who applies the bulk sewage sludge to the land, the person who prepares the bulk sewage sludge shall provide the person who applies the sewage sludge notice and necessary information to comply with the requirements in this part.

(g) When a person who prepares sewage sludge provides the sewage sludge to another person who prepares the sewage sludge, the person who provides the sewage sludge shall provide the person who receives the sewage sludge notice and necessary information to comply with the requirements in this part.

(h) The person who applies bulk sewage sludge to the land shall provide the owner or lease holder of the land on which the bulk sewage sludge is applied notice and necessary information to comply with the requirements in this part.

(i) Any person who prepares bulk sewage sludge that is applied to land in a State other than the State in which the bulk sewage sludge is prepared shall provide written notice, prior to the initial application of bulk sewage sludge to the land application site by the applier, to the Department or the permitting authority for the State in which the bulk sewage sludge is proposed to be applied. The notice shall include:

- (1) The location, by either street address or latitude and longitude, of each land application site.
- (2) The approximate time period bulk sewage sludge will be applied to the site.
- (3) The name, address, telephone number, and National Pollutant Discharge Elimination System permit number (if appropriate) for the person who prepares the bulk sewage sludge.
- (4) The name, address, telephone number, and National Pollutant Discharge Elimination System permit number (if appropriate) for the person who will apply the bulk sewage sludge.

(j) Any person who applies bulk sewage sludge subject to the cumulative pollutant loading rates in section 503.13(b)(2) to the land shall provide written notice, prior to the initial application of bulk sewage sludge to a land application site by the applier, to the Department or permitting authority for the State in which the bulk sewage sludge will be applied and the Department or permitting authority for the State shall retain and provide access to the notice. The notice shall include:

- (1) The location, by either street address or latitude and longitude, of the land application site.
- (2) The name, address, telephone number, and National Pollutant Discharge Elimination System permit number (if appropriate) of the person who will apply the bulk sewage sludge.

(k) The Department may establish categories of land application sites and develop separate permitting requirements for each category as deemed necessary.

(1) The Department may establish requirements in permits for site selection regarding appropriate conditions for land application of sewage sludge.

(2) The Department may establish additional permitting restrictions based upon soil and groundwater conditions to insure protection of the groundwater and surface water of the State. Criteria may include but is not limited to soil permeability, clay content, and depth to groundwater.

(l) The Department may establish in permits the application buffer setbacks for property boundaries, roadways, residential developments, dwellings, water wells, drainageways, and surface water as deemed necessary to protect public health and the environment. Factors taken into consideration in the establishment of setbacks would indicate sludge application method, adjacent land usage, public access, aerosols, runoff prevention, and adjacent groundwater usage.

(m) The Department may establish permit conditions to require that sludge application remain consistent with the lime and fertilizer requirements for the cover, feed, food, and fiber crops based on published lime and fertilizer recommendations (such as "Nutrient Management for South Carolina", Cooperative Extension Service, Clemson University, EC 476).

(n) The Department may establish minimum requirements in permits for soil and/or groundwater monitoring, for bulk application sites, to verify compliance with this Regulation. Factors taken into consideration in the establishment of soil and groundwater monitoring will include groundwater depth, operation flexibility, application frequency, type of sludge, size of application area, and loading rate.

(1) The Department may establish pre-application and post-application site monitoring requirements in permits for limiting nutrients or limiting pollutants as determined by the Department.

(2) The Department may establish permit conditions which require the permittee to reduce, modify, or eliminate the sludge applications based on the results of this data.

(3) The Department may modify or revoke and reissue the permit based on this data.

(o) Any person who prepares bulk sewage sludge and applies it to the land, or provides the bulk sewage sludge to a person who applies the bulk sewage sludge, or provides the bulk sewage sludge to another person who treats or processes the bulk sewage sludge prior to land applying it, shall apply to the Department for a permit to land apply the bulk sewage sludge and shall receive an approved permit from the Department prior to the actual application. Any person who prepares sewage sludge and sells or gives it away in a bag or other container, or provides the sewage sludge to a person who sells or gives it away in a bag or other container, or provides the sewage sludge to another person who treats, mixes, alters or processes the sewage sludge for sale or gives it away in a bag or other container shall receive an approved permit from the Department prior to the sale or distribution of the material. The application for land applying, or bagging, or selling, or giving away sludges will be in the form of a report prepared by a qualified Professional Engineer, qualified soil scientist, qualified agronomist, or other qualified individual. This report shall at a minimum contain:

(1) Sludge generator information shall be included as follows:

(i) Facility name, address, telephone number, county, and NPDES or other permit number(if applicable).

(ii) Plant discharge capacity in millions of gallons per day (MGD) (if applicable), amount of sludge generated per year (dry weight basis), description of sludge storage and amount of stockpiled sludge (if applicable), description of sludge treatment, and current method of disposal.

(2) Sludge analysis information shall be included as follows:

(i) Test results or rationale that demonstrates the non-hazardous nature of the sludge to the satisfaction of the Department.

(ii) Name, address, lab certification number, and telephone number of the laboratory conducting the analyses.

(iii) Sludge shall be analyzed for:

(A) Total solids (mg/l) and volatile solids (mg/kg).

(B) Nutrients (on a dry weight basis).

- (1) Total Kjeldahl Nitrogen (mg/kg).
 - (2) Total inorganic nitrogen (mg/kg).
 - (3) Total ammonia nitrogen (mg/kg) and Total nitrate nitrogen (mg/kg).
 - (4) Total phosphorus (mg/kg).
 - (5) Total potassium (mg/kg).
 - (6) Calcium Carbonate Equivalency (if sewage sludge is alkaline stabilized).
- (C) Pollutants (on a dry weight basis).
- (1) Arsenic (mg/kg).
 - (2) Cadmium (mg/kg).
 - (3) Copper (mg/kg).
 - (4) Lead (mg/kg).
 - (5) Mercury (mg/kg).
 - (6) Molybdenum (mg/kg).
 - (7) Nickel (mg/kg).
 - (8) Selenium (mg/kg).
 - (9) Zinc (mg/kg).
 - (10) Other compounds required by the permit or any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required to be monitored for in the sewage sludge (if applicable).
- (D) If an analysis must be performed on the sludge to document compliance with pathogen reduction requirements and vector attraction reduction requirements, these analyses shall be submitted in the report along with an explanation.
- (iv) Sludge handling and application information shall be included as follows:
- (A) Description of method of transport (if applicable).
 - (B) The time of year of the sludge application and how it relates to crop planting and harvesting schedule (if applicable).
 - (C) Name, address, and telephone number of the contractor applying the sludge (if applicable).
 - (D) Type of equipment used to spread the sludge (if applicable).
- (v) Application site information shall be included (as appropriate):
- (A) Name and address of landowner and location of application site(s).
 - (B) Name and address of the party managing the site(s) (if different than the owner).
 - (C) Previous years when sludge was applied under permits by the Department and application amounts.
 - (D) Additional soil additives applied on the site(s).
 - (E) Description of method to control access to the site(s).
 - (F) Method of odor control (if applicable).
 - (G) Site location(s) on maps including:
 - (1) Topography and drainage characteristics.
 - (2) Adjacent land usage and location of inhabited dwellings.
 - (3) All water supply wells on adjacent property.
 - (4) Adjacent surface water bodies.
 - (5) Sludge use or disposal boundaries and buffer zones.
 - (6) Location of proposed groundwater monitoring wells (if applicable).
 - (7) Right-of-Ways

- (8) Soil test, description of soil types, and boring locations (if applicable).
- (vi) Site Monitoring Plan information shall be included as follows (when required):
 - (A) Groundwater monitoring information (if applicable).
 - (B) Soil monitoring methods and locations (if applicable).
 - (C) Surface water sampling methods and locations (if applicable).
 - (D) Metals testing, if required, due to previous application(s) (if applicable).
 - (E) Method to insure that the soil pH will remain within agronomic ranges during the life of the site (e.g. alkaline stabilized sludge projects).
- (vii) The Department, at its discretion, may identify specific application information that may be excluded from a submission if the applicant has an alternate permitted method of disposal for the bulk sewage sludge (e.g. a municipal solid waste landfill disposal permit). The Department, may allow an applicant to exclude application information from a submission of a modified application or addition to a previously permitted activity.
- (p) The Department, at its discretion, may request of an applicant any additional information deemed necessary to complete or correct deficiencies in the sludge disposal permit application before processing the application or issuing or denying the issuance of a permit.
- (q) Applicants for land application of sludge must submit their applications on permit application forms if designated by the Department.
- (r) If a deleterious impact to the groundwaters of the State from sewage sludge use or disposal practices is documented, through groundwater monitoring levels exceeding the standards set forth in R.61-68 or a significant adverse trend occurs, then it will be the obligation of the generator/preparer of the sewage sludge as directed by the Department to conduct an investigation to determine the vertical and horizontal extent of groundwater impact. The Department may require remediation of the groundwater to within acceptable levels for groundwater as set forth in R.61-68.

503.13. Pollutant limits.

(a) Sewage sludge.

(1) Bulk sewage sludge or sewage sludge sold or given away in a bag or other container shall not be applied to the land if the concentration of any pollutant in the sewage sludge exceeds the ceiling concentration for the pollutant in Table 1 of section 503.13.

(2) If bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site, either:

(i) the cumulative loading rate for each pollutant shall not exceed the cumulative pollutant loading rate for the pollutant in Table 2 of section 503.13; or

(ii) the concentration of each pollutant in the sewage sludge shall not exceed the concentration for the pollutant in Table 3 of section 503.13.

(3) If bulk sewage sludge is applied to a lawn or a home garden, the concentration of each pollutant in the sewage sludge shall not exceed the concentration for the pollutant in Table 3 of section 503.13.

(4) If sewage sludge is sold or given away in a bag or other container for application to the land, either:

(i) the concentration of each pollutant in the sewage sludge shall not exceed the concentration for the pollutant in Table 3 of section 503.13, or

(ii) the product of the concentration of each pollutant in the sewage sludge and the annual whole sludge application rate for the sewage sludge shall not cause the annual pollutant loading rate for the pollutant in Table 4 of section 503.13 to be exceeded. The procedure used to determine the annual whole sludge application rate is presented in appendix A of this part.

(b) Pollutant concentrations and loading rates –sewage sludge.

(1) Ceiling concentrations.

TABLE 1 OF SECTION 503.13 – CEILING CONCENTRATIONS

Pollutant	Ceiling Concentration (milligrams per kilogram) Dry weight basis
Arsenic	75
Cadmium	85
Copper	4300
Lead	840
Mercury	57
Molybdenum	75
Nickel	420
Selenium	100
Zinc	7500

(2) Cumulative pollutant loading rates.

TABLE 2 OF SECTION 503.13 – CUMULATIVE POLLUTANT LOADING RATES

Pollutant	Cumulative Pollutant Loading Rate (kilograms per hectare)
Arsenic	41
Cadmium	39
Copper	1500
Lead	300
Mercury	17
Nickel	420
Selenium	100
Zinc	2800

(3) Pollutant concentrations.

TABLE 3 OF SECTION 503.13 – POLLUTANT CONCENTRATIONS

Pollutant	Monthly Average Concentrations (milligrams per kilogram) Dry weight basis
Arsenic	41
Cadmium	39
Copper	1500
Lead	300
Mercury	17
Nickel	420
Selenium	100
Arsenic	41
Zinc	2800

(4) Annual pollutant loading rates.

TABLE 4 OF SECTION 503.13 – ANNUAL POLLUTANT LOADING RATES

Pollutant	Annual Pollutant Loading Rate (kilograms per hectare per 365 day period)
Arsenic	2.0
Cadmium	1.9
Copper	75
Lead	15
Mercury	0.85
Nickel	21
Selenium	5.0
Zinc	140

(c) Domestic septage. The annual application rate for domestic septage applied to agricultural land, forest, or a reclamation site shall not exceed the annual application rate calculated using equation (1), or the agronomic rate.

$$\text{AAR} = \frac{\text{N}}{0.0026} \quad (\text{Equation 1})$$

Where:

AAR = Annual application rate in gallons per acre per 365 day period.

N = Amount of nitrogen in pounds per acre per 365 day period needed by the crop or vegetation grown on the land.

(d) Additional parameters may be required, from the application information or subsequent monitoring in a permit thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR 136; Subchapter N (40 CFR Part 400 through 402 and 404 through 471)) may be required (in a permit) to be monitored for in the sewage sludge.

503.14. Management practices.

(a) Bulk sewage sludge shall not be applied to the land if it is likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act or its designated critical habitat.

(b) Bulk sewage sludge shall not be applied to agricultural land, forest, a public contact site, or a reclamation site that is flooded, frozen, or snow-covered so that the bulk sewage sludge enters a wetland or other waters of the State, as defined in R.61-9.122.2, except as provided in a permit issued pursuant to section 402 or 404 of the CWA.

(c) Bulk sewage sludge shall not be applied to agricultural land, forest, or a reclamation site that is 10 meters or less from waters of the State, as defined in R.61-9.122.2, unless otherwise specified by the Department.

(d) Bulk sewage sludge shall be applied to agricultural land, forest, a public contact site, or a reclamation site at a whole sludge application rate that is equal to or less than the agronomic rate for the bulk sewage sludge, unless, in the case of a reclamation site, otherwise specified by the Department.

(e) Either a label shall be affixed to the bag or other container in which sewage sludge that is sold or given away for application to the land, or an information sheet shall be provided to the person who receives sewage sludge sold or given away in another container for application to the land. The label or information sheet shall contain the following information:

(1) The name and address of the person who prepared the sewage sludge that is sold or given away in a bag or other container for application to the land.

(2) A statement that application of the sewage sludge to the land is prohibited except in accordance with the instructions on the label or information sheet.

(3) The annual whole sludge application rate for the sewage sludge that does not cause any of the annual pollutant loading rates in Table 4 of section 503.13 to be exceeded.

(4) The annual whole sludge application rate for the sewage sludge that does not cause the agronomic rate for appropriate crops to be exceeded (to be presented in tons/acre or other units approved by the Department).

(f) Screening of septage is required prior to land application. The screenings must be disposed of properly (e.g. municipal waste landfill).

503.15. Operational standards – pathogens and vector attraction reduction.

(a) Pathogens –sewage sludge.

(1) The Class A pathogen requirements in section 503.32(a) or the Class B pathogen requirements and site restrictions in section 503.32(b) shall be met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site.

(2) The Class A pathogen requirements in section 503.32(a) shall be met when bulk sewage sludge is applied to a lawn or a home garden.

(3) The Class A pathogen requirements in section 503.32(a) shall be met when sewage sludge is sold or given away in a bag or other container for application to the land.

(b) Pathogens –domestic septage. The requirements in either section 503.32(c)(2), or section 503.32(c)(3) shall be met when domestic septage is applied to agricultural land, forest, or a reclamation site.

(c) Vector attraction reduction –sewage sludge.

(1) One of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(10) shall be met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site.

(2) One of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8) shall be met when bulk sewage sludge is applied to a lawn or a home garden.

(3) One of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8) shall be met when sewage sludge is sold or given away in a bag or other container for application to the land.

(d) Vector attraction reduction –domestic septage. The vector attraction reduction requirements in section 503.33(b)(9), section 503.33(b)(10), or section 503.33(b)(12) shall be met when domestic septage is applied to agricultural land, forest, or a reclamation site.

503.16. Frequency of monitoring.

(a) Sewage sludge.

(1) The frequency of monitoring for the pollutants listed in Table 1, Table 2, Table 3 and Table 4 of section 503.13; the pathogen density requirements in section 503.32(a) and in section 503.32(b)(2) and the vector attraction reduction requirements in section 503.33(b)(1) through (b)(4) and sections 503.33(b)(7) and (b)(8) shall be the frequency in Table 1 of section 503.16. Facilities which generate less than 290 metric tons of sludge per year and dispose of the sludge once per year or less, may request a reduction in monitoring to a frequency of once per year. The Department will review these requests on a case-by-case basis.

TABLE 1 OF SECTION 503.16 – FREQUENCY OF MONITORING – LAND APPLI-
CATION

<u>Amount of sewage sludge¹</u> (metric tons per 365-day period)	<u>Frequency</u>
Greater than zero but less than 1,500.	Once per quarter (four times per year)
Equal to or greater than 1,500 but less than 15,000.	Once per 60 days (six times per year)
Equal to or greater than 15,000.	Once per month (12 times per year)

¹ Either the amount of bulk sewage sludge applied to the land or the amount of sewage sludge prepared for sale or give-away in a bag or other container for application to the land (dry weight basis).

(2) After the sewage sludge has been monitored for two years at the frequency in Table 1 of section 503.16, the Department may reduce the frequency of monitoring for pollutant concentrations and for the pathogen density requirements in section 503.32(a)(5)(ii) and (a)(5)(iii), but in no case shall the frequency of monitoring be less than once per year when sewage sludge is applied to the land.

(b) Domestic septage. If either the pathogen requirements in section 503.32(c)(1) and section 503.32(c)(2) or section 503.32(c)(3), and the vector attraction reduction requirements in section 503.33(b)(12) are met when domestic septage is applied to agricultural land, forest, or a reclamation site, each container of domestic septage applied to the land shall be monitored for compliance with those requirements.

503.17. Recordkeeping.

(a) Sewage sludge.

(1) The person who prepares the sewage sludge in section 503.10(b)(2) or in section 503.10(e) shall develop the following information and shall retain the information for five years:

(i) The concentration of each pollutant listed in Table 3 of section 503.13 in the sewage sludge.

(ii) The following certification statement: "I certify, under penalty of law, that the information that will be used to determine compliance with the Class A pathogen requirements in section 503.32(a) and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in section 503.33(b)(1) through 503.33(b)(8)] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(iii) A description of how the Class A pathogen requirements in section 503.32(a) are met.

(iv) A description of how one of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8) is met.

(2) The person who derives the material in section 503.10(c)(2) or in section 503.10(f) shall develop the following information and shall retain the information for five years:

(i) The concentration of each pollutant listed in Table 3 of section 503.13 in the material.

(ii) The following certification statement: "I certify, under penalty of law, that the information that will be used to determine compliance with the Class A pathogen requirements in section 503.32(a) and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in section 503.33(b)(1) through (b)(8)] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(iii) A description of how the Class A pathogen requirements in section 503.32(a) are met.

(iv) A description of how one of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8) is met.

(3) If the pollutant concentrations in section 503.13(b)(3), the Class A pathogen requirements in section 503.32(a), and the vector attraction reduction requirements in either section 503.33(b)(9) or section 503.33(b)(10) are met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site:

(i) The person who prepares the bulk sewage sludge shall develop the following information and shall retain the information for five years.

(A) The concentration of each pollutant listed in Table 3 of section 503.13 in the bulk sewage sludge.

(B) The following certification statement: "I certify, under penalty of law, that the information that will be used to determine compliance with the Class A pathogen requirements in section 503.32(a) was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this informa-

tion. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(C) A description of how the pathogen requirements in section 503.32(a) are met.

(ii) The person who applies the bulk sewage sludge shall develop the following information and shall retain the information for five years.

(A) The following certification statement: “I certify, under penalty of law, that the information that will be used to determine compliance with the management practices in section 503.14 and the vector attraction reduction requirement in [insert either section 503.33(b)(9) or (b)(10)] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(B) A description of how the management practices in section 503.14 are met for each site on which bulk sewage sludge is applied.

(C) A description of how the vector attraction reduction requirements in either section 503.33(b)(9) or section 503.33(b)(10) are met for each site on which bulk sewage sludge is applied.

(4) If the pollutant concentrations in section 503.13(b)(3) and the Class B pathogen requirements in section 503.32(b) are met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site:

(i) The person who prepares the bulk sewage sludge shall develop the following information and shall retain the information for five years:

(A) The concentration of each pollutant listed in Table 3 of section 503.13 in the bulk sewage sludge.

(B) The following certification statement: “I certify, under penalty of law, that the information that will be used to determine compliance with the Class B pathogen requirements in section 503.32(b) and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in section 503.33(b)(1) through (b)(8), if one of those requirements is met] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(C) A description of how the Class B pathogen requirements in section 503.32(b) are met.

(D) When one of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8) is met, a description of how the vector attraction reduction requirement is met.

(ii) The person who applies the bulk sewage sludge shall develop the following information and shall retain the information for five years.

(A) The following certification statement: “I certify, under penalty of law, that the information that will be used to determine compliance with the management practices in section 503.14, the site restrictions in section 503.32(b)(5), and the vector attraction reduction requirements in [insert either section 503.33(b)(9) or (b)(10), if one of those requirements is met] was prepared for each site on which bulk sewage sludge is applied under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(B) A description of how the management practices in section 503.14 are met for each site on which bulk sewage sludge is applied.

(C) A description of how the site restrictions in section 503.32(b)(5) are met for each site on which bulk sewage sludge is applied.

(D) When the vector attraction reduction requirement in either section 503.33(b)(9) or section 503.33(b)(10) is met, a description of how the vector attraction reduction requirement is met.

(E) The date bulk sewage sludge is applied to each site.

(5) If the requirements in section 503.13(a)(2)(i) are met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site:

(i) The person who prepares the bulk sewage sludge shall develop the following information and shall retain the information for five years.

(A) The concentration of each pollutant listed in Table 1 of section 503.13 in the bulk sewage sludge.

(B) The following certification statement: "I certify, under penalty of law, that the information that will be used to determine compliance with the pathogen requirements in [insert either section 503.32(a) or 503.32(b)] and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in section 503.33(b)(1) through (b)(8), if one of those requirements is met] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(C) A description of how the pathogen requirements in either section 503.32(a) or section 503.32(b) are met.

(D) When one of the vector attraction requirements in section 503.33(b)(1) through section 503.33(b)(8) is met, a description of how the vector attraction requirement is met.

(ii) The person who applies the bulk sewage sludge shall develop the following information, retain the information in section 503.17(a)(5)(ii)(A) through section 503.17(a)(5)(ii)(G) indefinitely, and retain the information in section 503.17(a)(5)(ii)(H) through section 503.17(a)(5)(ii)(M) for five years.

(A) The location, by either street address or latitude and longitude, of each site on which bulk sewage sludge is applied.

(B) The number of hectares in each site on which bulk sewage sludge is applied.

(C) The date bulk sewage sludge is applied to each site.

(D) The cumulative amount of each pollutant (i.e., kilograms) listed in Table 2 of section 503.13 in the bulk sewage sludge applied to each site, including the amount in section 503.12(e)(2)(iii).

(E) The amount of sewage sludge (i.e., metric tons) applied to each site.

(F) The following certification statement: "I certify, under penalty of law, that the information that will be used to determine compliance with the requirements to obtain information in section 503.12(e)(2) was prepared for each site on which bulk sewage sludge was applied under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(G) A description of how the requirements to obtain information in section 503.12(e)(2) are met.

(H) The following certification statement: "I certify, under penalty of law, that the information that will be used to determine compliance with the management practices in section 503.14 was prepared for each site on which bulk sewage sludge was applied under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(I) A description of how the management practices in section 503.14 are met for each site on which bulk sewage sludge is applied.

(J) The following certification statement when the bulk sewage sludge meets the Class B pathogen requirements in section 503.32(b): "I certify, under penalty of law, that the information that will be used to determine compliance with the site restrictions in section 503.32(b)(5) for each site on which Class B sewage sludge was applied was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly

gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(K) A description of how the site restrictions in section 503.32(b)(5) are met for each site on which Class B bulk sewage sludge is applied.

(L) The following certification statement when the vector attraction reduction requirement in either section 503.33(b)(9) or (b)(10) is met: “I certify, under penalty of law, that the information that will be used to determine compliance with the vector attraction reduction requirement in [insert either section 503.33(b)(9) or 503.33(b)(10)] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(M) If the vector attraction reduction requirements in either section 503.33(b)(9) or section 503.33(b)(10) are met, a description of how the requirements are met.

(6) If the requirements in section 503.13(a)(4)(ii) are met when sewage sludge is sold or given away in a bag or other container for application to the land, the person who prepares the sewage sludge that is sold or given away in a bag or other container shall develop the following information and shall retain the information for five years:

(i) The annual whole sludge application rate for the sewage sludge that does not cause the annual pollutant loading rates in Table 4 of section 503.13 to be exceeded.

(ii) The concentration of each pollutant listed in Table 4 of section 503.13 in the sewage sludge.

(iii) The following certification statement: “I certify, under penalty of law, that the information that will be used to determine compliance with the management practice in section 503.14(e), the Class A pathogen requirement in section 503.32(a), and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8)] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(iv) A description of how the Class A pathogen requirements in section 503.32(a) are met.

(v) A description of how one of the vector attraction requirements in section 503.33(b)(1) through section 503.33(b)(8) is met.

(b) Domestic septage. When domestic septage is applied to agricultural land, forest, or a reclamation site, the person who applies the domestic septage shall develop the following information and shall retain the information for five years:

(1) The location, by either street address or latitude and longitude, of each site on which domestic septage is applied.

(2) The number of acres in each site on which domestic septage is applied.

(3) The date domestic septage is applied to each site.

(4) The nitrogen requirement for the crop or vegetation grown on each site during a 365 day period.

(5) The rate, in gallons per acre per 365 day period, at which domestic septage is applied to each site.

(6) The following certification statement: “I certify, under penalty of law, that the information that will be used to determine compliance with the pathogen requirements in [insert either section 503.32(c)(1) or section 503.32(c)(2)] and the vector attraction reduction requirements in [insert section 503.33(b)(9), section 503.33(b)(10), or section 503.33(b)(12)] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(7) A description of how the pathogen requirements in either section 503.32(c)(1) or (c)(2) are met.

(8) A description of how the vector attraction reduction requirements in section 503.33(b)(9), section 503.33(b)(10), or section 503.33(b)(12) are met.

503.18. Reporting.

(a) Any generator of sewage sludge that is applied to the land, any person who prepares sewage sludge that is applied to the land, or any person who applies sewage sludge to the land, including Class I sludge management facilities, POTWs (as defined in 40 CFR 501.2) with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more shall submit a report on February 19 of each year. As of December 21, 2020, all reports submitted in compliance with this section must be submitted electronically in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), 40 CFR 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to the start dates for electronic reporting (see Table 1 in 40 CFR 127.16), the Department may also require operators to electronically submit annual reports under this section if required to do so by State law.

(1) The information in section 503.17(a), except the information in section 503.17(a)(3)(ii), section 503.17(a)(4)(ii) and in section 503.17(a)(5)(ii), for the appropriate requirements on or before February 19 of each year, for the period of January 1 through December 31 of the previous calendar year.

(2) The information in section 503.17(a)(5)(ii)(A) through (a)(5)(ii)(G) on or before February 19th of each year, for the period of January 1 through December 31 of the previous calendar year when 90 percent or more of any of the cumulative pollutant loading rates in Table 2 of section 503.13 is reached at a land application site.

(b) [Reserved]

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

PART C SURFACE DISPOSAL

503.20. Applicability.

(a) This part applies to any person who prepares sewage sludge that is placed on a surface disposal site, to the owner/operator of a surface disposal site, to sewage sludge placed on a surface disposal site, and to a surface disposal site.

(b) This part does not apply to sewage sludge stored on the land or to the land on which sewage sludge is stored. It also does not apply to sewage sludge that remains on the land for longer than two years when the person who prepares the sewage sludge demonstrates that the land on which the sewage sludge remains is not an active sewage sludge unit. The demonstration shall include the following information, which shall be retained by the person who prepares the sewage sludge for the period that the sewage sludge remains on the land:

(1) The name and address of the person who prepares the sewage sludge.

(2) The name and address of the person who either owns the land or leases the land.

(3) The location, by either street address or latitude and longitude, of the land.

(4) An explanation of why sewage sludge needs to remain on the land for longer than two years prior to final use or disposal.

(5) The approximate time period when the sewage sludge will be used or disposed.

(c) This part does not apply to sewage sludge treated on the land or to the land on which sewage sludge is treated.

503.21. Special definitions.

(a) “Active sewage sludge unit” is a sewage sludge unit that has not closed.

(b) “Aquifer” is a geologic formation, group of geologic formations, or a portion of a geologic formation capable of yielding ground water to wells or springs.

(c) “Contaminate an aquifer” means to introduce a substance that causes the maximum contaminant level for nitrate in 40 CFR 141.62(b) or R.61–68 (Water Classifications and Standards) to be exceeded

in the ground water or that causes the existing concentration of nitrate in ground water to increase when the existing concentration of nitrate in the ground water exceeds the maximum contaminant level for nitrate in 40 CFR 141.62(b) or R.61-68 (Water Classifications and Standards).

(d) "Cover" is soil or other material used to cover sewage sludge placed on an active sewage sludge unit.

(e) "Displacement" is the relative movement of any two sides of a fault measured in any direction.

(f) "Fault" is a fracture or zone of fractures in any materials along which strata on one side are displaced with respect to strata on the other side.

(g) "Final cover" is the last layer of soil or other material placed on a sewage sludge unit at closure.

(h) "Holocene time" is the most recent epoch of the Quaternary period, extending from the end of the Pleistocene epoch to the present.

(i) "Leachate collection system" is a system or device installed immediately above a liner that is designed, constructed, maintained, and operated to collect and remove leachate from a sewage sludge unit.

(j) "Liner" is soil or synthetic material that has a hydraulic conductivity of 1×10^7 centimeters per second or less.

(k) "Lower explosive limit" for methane gas is the lowest percentage of methane gas in air, by volume, that propagates a flame at 25 degrees Celsius and atmospheric pressure.

(l) "Qualified ground-water scientist" is an individual with a baccalaureate or post-graduate degree in the natural sciences or engineering who has sufficient training and experience in ground-water hydrology and related fields, as may be demonstrated by State registration, professional certification, or completion of accredited university programs, to make sound professional judgments regarding ground-water monitoring, pollutant fate and transport, and corrective action.

(m) "Seismic impact zone" is an area that has a 10 percent or greater probability that the horizontal ground level acceleration of the rock in the area exceeds 0.10 gravity once in 250 years.

(n) "Sewage sludge unit" is land on which only sewage sludge is placed for final disposal. This does not include land on which sewage sludge is either stored or treated. Land does not include waters of the State, as defined in R.61-9.122.2. Does not include beneficial use activities covered under Part B, which comply with agronomic rate requirements and metals limitations.

(o) "Sewage sludge unit boundary" is the outermost perimeter of an active sewage sludge unit.

(p) "Surface disposal site" is an area of land that contains one or more active sewage sludge units.

(q) "Unstable area" is land subject to natural or human-induced forces that may damage the structural components of an active sewage sludge unit. This includes, but is not limited to, land on which the soils are subject to mass movement.

503.22. General requirements.

(a) No person shall place sewage sludge on an active sewage sludge unit unless the requirements in this part are met.

(1) The following activities or conditions constitute surface disposal (unless the Department has issued a permit for the specific activity):

(i) Storage of sewage sludge, excluding sludge treatment, for more than two (2) years constitutes surface disposal.

(ii) The design storage capacity of sewage sludge will not be permitted to exceed two (2) years at the treatment plant design conditions, or

(iii) Accumulation of sewage sludge in a wastewater treatment unit to greater than fifty (50) percent of the capacity of the unit or to an average depth of greater than design depth constitutes surface disposal of sludge under this regulation, or

(iv) Storage of sewage sludge that adversely impacts the overall facility operation and maintenance or results in an excessive sludge inventory, may result in a facility being identified as a surface disposal site.

(2) For any facility, except a landfill or a sludge only monofill, meeting the definition of a surface disposal site on or after the date of this regulation, a report detailing the final closure of the site must be submitted to the Bureau of Water Pollution Control, Department of Health and Environmental Control, within one (1) year after the date of this regulation. The facility must be closed within five (5) years after the date of this regulation, and a plan must provide a schedule showing how the closure will be accomplished.

(3) Surface disposal of sewage sludge to existing active surface disposal facilities that are not permitted under R.61-258 must cease within three (3) years after the date of this regulation, or sufficient amounts of sludge must be removed from the facility in order to change the facility's classification.

(b) An active sewage sludge unit located within 60 meters of a fault that has displacement in Holocene time; located in an unstable area; or located in a wetland, except as provided in a permit issued pursuant to either section 402 or 404 of the CWA, shall close by March 22, 1994, unless, in the case of an active sewage sludge unit located within 60 meters of a fault that has displacement in Holocene time, otherwise specified by the Department.

(c) The owner/operator of an active sewage sludge unit shall submit a written closure and post closure plan to the Department 180 days prior to the date that the active sewage sludge unit closes. The plan shall describe how the sewage sludge unit will be closed and, at a minimum, shall include:

(1) A discussion of how the leachate collection system will be operated and maintained for three years after the sewage sludge unit closes if the sewage sludge unit has a liner and leachate collection system.

(2) A description of the system used to monitor for methane gas in the air in any structures within the surface disposal site and in the air at the property line of the surface disposal site, as required in section 503.24(j)(2).

(3) A discussion of how public access to the surface disposal site will be restricted for three years after the last sewage sludge unit in the surface disposal site closes.

(d) The owner of a surface disposal site shall provide written notification to the subsequent owner of the site that sewage sludge was placed on the land.

(e) Surface disposal of sludge in a landfill, including sludge only monofills, shall comply with State Solid Waste regulations and requirements in permits.

(f) Surface disposal of sludge by land application may be considered if the proposed application rates are at or below the agronomic rates as defined in section 503.11(b); additional requirements as defined in section 503.12 may be applied on a case-by-case basis.

(g) If a deleterious impact to the groundwaters of the State from sewage sludge use or disposal practices is documented, through groundwater monitoring levels exceeding the standards set forth in R.61-68 or a significant adverse trend occurs, then it will be the obligation of the generator/preparer of the sewage sludge as directed by the Department to conduct an investigation to determine the vertical and horizontal extent of groundwater impact. The Department may require remediation of the groundwater to within acceptable levels for groundwater as set forth in R.61-68.

503.23. Pollutant limits (other than domestic septage).

(a) Active sewage sludge unit without a liner and leachate collection system

(1) Except as provided in section 503.23(a)(2) and section 503.23(b), the concentration of each pollutant listed in Table 1 of section 503.23 in sewage sludge placed on an active sewage sludge unit shall not exceed the concentration for the pollutant in Table 1 of section 503.23.

TABLE 1 OF SECTION 503.23 – POLLUTANT CONCENTRATIONS – ACTIVE SEWAGE SLUDGE UNIT WITHOUT A LINER AND LEACHATE COLLECTION

Pollutant	Concentration (milligrams per kilograms) Dry weight basis
Arsenic	73
Chromium	600
Nickel	420

(2) Except as provided in section 503.23(b), the concentration of each pollutant listed in Table 1 of section 503.23 in sewage sludge placed on an active sewage sludge unit whose boundary is less than 150 meters from the property line of the surface disposal site shall not exceed the concentration determined using the following procedure.

(i) The actual distance from the active sewage sludge unit boundary to the property line of the surface disposal site shall be determined.

(ii) The concentration of each pollutant listed in Table 2 of section 503.23 in the sewage sludge shall not exceed the concentration in Table 2 of section 503.23 that corresponds to the actual distance in section 503.23(a)(2)(i).

TABLE 2 OF SECTION 503.23 – POLLUTANT CONCENTRATIONS – ACTIVE SEWAGE SLUDGE UNIT WITHOUT A LINER AND LEACHATE COLLECTION SYSTEM THAT HAS A UNIT BOUNDARY TO PROPERTY LINE DISTANCE LESS THAN 150 METERS

Unit boundary to property line distance. (meters)	Pollutant concentration (Dry weight Basis)		
	Arsenic (mg/kg)	Chromium (mg/kg)	Nickel (mg/kg)
0 to less than 25	30	200	210
25 to less than 50	34	220	240
50 to less than 75	39	260	270
75 to less than 100	46	300	320
100 to less than 125	53	360	390
125 to less than 150	62	450	420

(b) Active sewage sludge unit without a liner and leachate collection system –site-specific limits

(1) At the time of permit application, the owner/operator of a surface disposal site may request site-specific pollutant limits in accordance with section 503.23(b)(2) for an active sewage sludge unit without a liner and leachate collection system when the existing values for site parameters specified by the Department are different from the values for those parameters used to develop the pollutant limits in Table 1 of section 503.23 and when the Department determines that site-specific pollutant limits are appropriate for the active sewage sludge unit.

(2) The concentration of each pollutant listed in Table 1 of section 503.23 in sewage sludge placed on an active sewage sludge unit without a liner and leachate collection system shall not exceed either the concentration for the pollutant determined during a site-specific assessment, as specified by the Department, or the existing concentration of the pollutant in the sewage sludge, whichever is lower.

(c) Additional parameters may be required in the initial analysis and subsequent monitoring thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Sub Chapter N (40 CFR Part 400 through 402 and 404 through 471)) may be required (in a permit) to be monitored for in the sewage sludge.

503.24. Management practices.

(a) Sewage sludge shall not be placed on an active sewage sludge unit if it is likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act or its designated critical habitat.

(b) An active sewage sludge unit shall not restrict the flow of a base flood.

(c) When a surface disposal site is located in a seismic impact zone, an active sewage sludge unit shall be designed to withstand the maximum recorded horizontal ground level acceleration.

(d) An active sewage sludge unit shall be located 60 meters or more from a fault that has displacement in Holocene time, unless otherwise specified by the Department.

(e) An active sewage sludge unit shall not be located in an unstable area.

(f) An active sewage sludge unit shall not be located in a wetland, except as provided in a permit issued pursuant to section 402 or 404 of the CWA.

(g)(1) Run-off from an active sewage sludge unit shall be collected and shall be disposed in accordance with National Pollutant Discharge Elimination System permit requirements (see R.61-9.122 and 124) and any other applicable requirements.

(2) The run-off collection system for an active sewage sludge unit shall have the capacity to handle run-off from a 24-hour, 25-year storm event.

(h) The leachate collection system for an active sewage sludge unit that has a liner and leachate collection system shall be operated and maintained during the period the sewage sludge unit is active and for three years after the sewage sludge unit closes.

(i) Leachate from an active sewage sludge unit that has a liner and leachate collection system shall be collected and shall be disposed in accordance with the applicable requirements during the period the sewage sludge unit is active and for three years after the sewage sludge unit closes.

(j)(1) When a cover is placed on an active sewage sludge unit, the concentration of methane gas in air in any structure within the surface disposal site shall not exceed 25 percent of the lower explosive limit for methane gas during the period that the sewage sludge unit is active and the concentration of methane gas in air at the property line of the surface disposal site shall not exceed the lower explosive limit for methane gas during the period that the sewage sludge unit is active.

(2) When a final cover is placed on a sewage sludge unit at closure, the concentration of methane gas in air in any structure within the surface disposal site shall not exceed 25 percent of the lower explosive limit for methane gas for three years after the sewage sludge unit closes and the concentration of methane gas in air at the property line of the surface disposal site shall not exceed the lower explosive limit for methane gas for three years after the sewage sludge unit closes, unless otherwise specified by the Department.

(k) A food crop, a feed crop, or a fiber crop shall not be grown on an active sewage sludge unit, unless the owner/operator of the surface disposal site demonstrates to the Department that through management practices public health and the environment are protected from any reasonably anticipated adverse effects of pollutants in sewage sludge when crops are grown.

(l) Animals shall not be grazed on an active sewage sludge unit, unless the owner/operator of the surface disposal site demonstrates to the Department that through management practices public health and the environment are protected from any reasonably anticipated adverse effects of pollutants in sewage sludge when animals are grazed.

(m) Public access to a surface disposal site shall be restricted for the period that the surface disposal site contains an active sewage sludge unit and for three years after the last active sewage sludge unit in the surface disposal site closes.

(n)(1) Sewage sludge placed on an active sewage sludge unit shall not contaminate an aquifer.

(2) Results of a ground-water monitoring program developed by a qualified ground-water scientist or a certification by a qualified ground-water scientist shall be used to demonstrate that sewage sludge placed on an active sewage sludge unit does not contaminate an aquifer.

503.25. Operational standards – pathogens and vector attraction reduction.

(a) Pathogens –sewage sludge (other than domestic septage). The Class A pathogens requirements in section 503.32(a) or one of the Class B pathogen requirements in section 503.32(b)(2) through section 503.32(b)(4) shall be met when sewage sludge is placed on an active sewage sludge unit, unless the vector attraction reduction requirement in section 503.33(b)(11) is met.

(b) Vector attraction reduction –sewage sludge (other than domestic septage). One of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(11) shall be met when sewage sludge is placed on an active sewage sludge unit.

(c) Vector attraction reduction –domestic septage. One of the vector attraction reduction requirement in section 503.33(b)(9) through section 503.33(b)(12) shall be met when domestic septage is placed on an active sewage sludge unit.

503.26. Frequency of monitoring.

(a) Sewage sludge (other than domestic septage).

(1) The frequency of monitoring for the pollutants in Tables 1 and 2 of section 503.23; the pathogen density requirements in section 503.32(a) and in section 503.32(b)(2); and the vector attraction reduction requirements in section 503.33(b)(1) through (b)(4) and section 503.33(b)(7) and (b)(8) for sewage sludge placed on an active sewage sludge unit shall be the frequency in Table 1 of section 503.26. Facilities which generate less than 290 metric tons of sludge per year and dispose of the sludge once a year or less, may request a reduction in monitoring to a frequency of once per year. The department will review these requests on a case-by-case basis.

TABLE 1 OF SECTION 503.26 – FREQUENCY OF MONITORING – SURFACE DISPOSAL

Amount of sewage sludge ¹ (metric tons per 365 day period)	Frequency
Greater than zero but less than 1,500.	Once per quarter (four times per year)
Equal to or greater than 1,500 but less than 15,000.	Once per 60 days (six times per year)
Equal to or greater than 15,000.	Once per month (12 times per year)

¹ Amount of sewage sludge placed on an active sewage sludge unit (dry weight basis).

(2) After the sewage sludge has been monitored for two years at the frequency in Table 1 of this section, the Department may reduce the frequency of monitoring for pollutant concentrations and for the pathogen density requirements in section 503.32(a)(5)(ii) and (a)(5)(iii), but in no case shall the frequency of monitoring be less than once per year when sewage sludge is placed on an active sewage sludge unit.

(b) Domestic septage. If the vector attraction reduction requirements in section 503.33(b)(12) are met when domestic septage is placed on an active sewage sludge unit, each container of domestic septage shall be monitored for compliance with those requirements.

(c) Air. Air in structures within a surface disposal site and at the property line of the surface disposal site shall be monitored continuously for methane gas during the period that the surface disposal site contains an active sewage sludge unit on which the sewage sludge is covered and for three years after a sewage sludge unit closes when a final cover is placed on the sewage sludge.

503.27. Recordkeeping.

(a) When sewage sludge (other than domestic septage) is placed on an active sewage sludge unit:

(1) The person who prepares the sewage sludge shall develop the following information and shall retain the information for five years.

(i) The concentration of each pollutant listed in Table 1 of section 503.23 in the sewage sludge when the pollutant concentrations in Table 1 of section 503.23 are met.

(ii) The following certification statement: “I certify, under penalty of law, that the information that will be used to determine compliance with the pathogen requirements in [insert section 503.32(a), section 503.32(b)(2), section 503.32(b)(3), or section 503.32(b)(4), when one of those requirements is met] and the vector attraction reduction requirements in [insert one of the vector attraction reduction requirements in section 503.33(b)(1) through (b)(8), if one of those requirements is met] was prepared under my direction and supervision in accordance with the system

designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(iii) A description of how the pathogen requirements in section 503.32(a), section 503.32(b)(2), section 503.32(b)(3), or section 503.32(b)(4) are met when one of those requirements is met.

(iv) A description of how one of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8) is met when one of those requirements is met.

(2) The owner/operator of the surface disposal site shall develop the following information and shall retain that information for five years.

(i) The concentration of each pollutant listed in Table 2 of section 503.23 in the sewage sludge when the pollutant concentrations in Table 2 of section 503.23 are met or when site-specific pollutant limits in section 503.23(b) are met.

(ii) The following certification statement: “I certify, under penalty of law, that the information that will be used to determine compliance with the management practices in section 503.24 and the vector attraction reduction requirement in [insert one of the requirements in section 503.33(b)(9) through section 503.33(b)(11), if one of those requirements is met] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(iii) A description of how the management practices in section 503.24 are met.

(iv) A description of how the vector attraction reduction requirements in section 503.33(b)(9) through section 503.33(b)(11) are met if one of those requirements is met.

(b) When domestic septage is placed on a surface disposal site:

(1) If the vector attraction reduction requirements in section 503.33(b)(12) are met, the person who places the domestic septage on the surface disposal site shall develop the following information and shall retain the information for five years:

(i) The following certification statement: “I certify, under penalty of law, that the information that will be used to determine compliance with the vector attraction reduction requirements in section 503.33(b)(12) was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment.”

(ii) A description of how the vector attraction reduction requirements in section 503.33(b)(12) are met.

(2) The owner/operator of the surface disposal site shall develop the following information and shall retain that information for five years:

(i) The following certification statement: “I certify, under penalty of law, that the information that will be used to determine compliance with the management practices in section 503.24 and the vector attraction reduction requirements in [insert section 503.33(b)(9) through section 503.33(b)(11), if one of those requirements is met] was prepared under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate this information. I am aware that there are significant penalties for false certification including the possibility of fine or imprisonment.”

(ii) A description of how the management practices in section 503.24 are met.

(iii) A description how the vector attraction reduction requirements in section 503.33(b)(9) through section 503.33(b)(11) are met if one of those requirements is met.

503.28. Reporting.

(a) Any generator of sewage sludge disposed of at a surface disposal site, any person who prepares sewage sludge that is disposed of at a surface disposal site, or any person who disposes of sewage sludge at a surface disposal site, including Class I sludge management facilities, POTWs (as defined in 40 CFR 501.2) with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more shall submit a report with the information in section

503.27(a) to the Department on or before February 19 of each year, for the period of January 1 through December 31 of the previous calendar year. As of December 21, 2020, all reports submitted in compliance with this section must be submitted electronically in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), 40 CFR 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to the start dates for electronic reporting (see Table 1 in 40 CFR 127.16), the Department may also require operators to electronically submit annual reports under this section if required to do so by State law.

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

PART D

PATHOGENS AND VECTOR ATTRACTION REDUCTION

503.30. Scope.

- (a) This part contains the requirements for a sewage sludge to be classified either Class A or Class B with respect to pathogens.
- (b) This part contains the site restrictions for land on which a Class B sewage sludge is applied.
- (c) This part contains the pathogen requirements for domestic septage applied to agricultural land, forest, or a reclamation site.
- (d) This part contains alternative vector attraction reduction requirements for sewage sludge that is applied to the land or placed on a surface disposal site.

503.31. Special definitions.

- (a) “Aerobic digestion” is the biochemical decomposition of organic matter in sewage sludge into carbon dioxide and water by microorganisms in the presence of air.
- (b) “Anaerobic digestion” is the biochemical decomposition of organic matter in sewage sludge into methane gas and carbon dioxide by microorganisms in the absence of air.
- (c) “Density of microorganisms” is the number of microorganisms per unit mass of total solids (dry weight) in the sewage sludge.
- (d) “Land with a high potential for public exposure” is land that the public uses frequently. This includes, but is not limited to, a public contact site and a reclamation site located in a populated area (e.g., a construction site located in a city).
- (e) “Land with a low potential for public exposure” is land that the public uses infrequently. This includes, but is not limited to, agricultural land, forest, and a reclamation site located in an unpopulated area (e.g., a strip mine located in a rural area).
- (f) “Pathogenic organisms” are disease-causing organisms. These include, but are not limited to, certain bacteria, protozoa, viruses, and viable helminth ova.
- (g) “pH” means the logarithm of the reciprocal of the hydrogen ion concentration measured at twenty-five degrees Centigrade or measured at another temperature and then converted to an equivalent value at twenty-five degrees Centigrade.
- (h) “Specific oxygen uptake rate (SOUR)” is the mass of oxygen consumed per unit time per unit mass of total solids (dry weight basis) in the sewage sludge.
- (i) “Total solids” are the materials in sewage sludge that remain as residue when the sewage sludge is dried at 103 to 105 degrees Celsius.
- (j) “Unstabilized solids” are organic materials in sewage sludge that have not been treated in either an aerobic or anaerobic treatment process to include extended aeration, activated sludge or other treatment processes approved by the Department.
- (k) “Vector attraction” is the characteristic of sewage sludge that attracts rodents, flies, mosquitos, or other organisms capable of transporting infectious agents.
- (l) “Volatile solids” is the amount of the total solids in sewage sludge lost when the sewage sludge is combusted at 550 degrees Celsius in the presence of excess air.

503.32. Pathogens.

(a) Sewage sludge –Class A.

(1) The requirement in section 503.32(a)(2) and the requirements in either section 503.32(a)(3), section 503.32(a)(4), section 503.32(a)(5), section 503.32(a)(6), section 503.32(a)(7), or section 503.32(a)(8) shall be met for a sewage sludge to be classified Class A with respect to pathogens.

(2) The Class A pathogen requirements in section 503.32(a)(3) through section 503.32(a)(8) shall be met either prior to meeting or at the same time the vector attraction reduction requirements in section 503.33, except the vector attraction reduction requirements in section 503.33(b)(6) through section 503.33(b)(8), are met.

(3) Class A –Alternative 1.

(i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in section 503.10(b), section 503.10(c), section 503.10(e), or section 503.10(f).

(ii) The temperature of the sewage sludge that is used or disposed shall be maintained at a specific value for a period of time.

(A) When the percent solids of the sewage sludge is seven percent or higher, the temperature of the sewage sludge shall be 50 degrees Celsius or higher; the time period shall be 20 minutes or longer; and the temperature and time period shall be determined using equation (2), except when small particles of sewage sludge are heated by either warmed gases or an immiscible liquid.

$$D = \frac{131,700,000}{10^{0.1400t}} \text{ (Equation 2)}$$

Where,

D = time in days.

t = temperature in degrees Celsius.

TABLE 1 OF SECTION 503.32 – If the sewage sludge is 7% solids or higher.

Temperature (Celsius)	Time
50.0 (minimum)	13.17 days
60.0	12 hours 43 minutes
65.0	2 hours 39 minutes
70.0	30 minutes
71.3	20 minutes (minimum)

(B) When the percent solids of the sewage sludge is seven percent or higher and small particles of sewage sludge are heated by either warmed gases or an immiscible liquid, the temperature of the sewage sludge shall be 50 degrees Celsius or higher; the time period shall be 15 seconds or longer; and the temperature and time period shall be determined using equation (2).

TABLE 2 OF SECTION 503.32 – If the sewage sludge is 7% solids or higher and small particles of sewage sludge are heated by warm gases or an immiscible liquid.

Temperature (Celsius)	Time
50.0 (minimum)	13.17 days
65.0	2 hours 39 minutes
71.3	20 minutes
80.0	1 minute 12 seconds
84.9	15 seconds (minimum)

(C) When the percent solids of the sewage sludge is less than seven percent and the time period is at least 15 seconds, but less than 30 minutes, the temperature and time period shall be determined using equation (2).

TABLE 3 OF SECTION 503.32 – If the sewage sludge is less than 7% solids and the time period is at least 15 seconds, but less than 30 minutes.

Temperature (Celsius)	Time
70.0	30 minutes (Maximum time. See (D) for greater than 30 minutes)
71.3	20 minutes
75.0	6 minutes
80.0	1 minute 12 seconds
84.9	15 seconds (minimum)

(D) When the percent solids of the sewage sludge is less than seven percent; the temperature of the sewage sludge is 50 degrees Celsius or higher; and the time period is 30 minutes or longer, the temperature and time period shall be determined using equation (3).

$$D = \frac{50,070,000}{10^{0.1400t}} \text{ (Equation 3)}$$

Where,

D = time in days.

t = temperature in degrees Celsius.

TABLE 4 OF SECTION 503.32 - If the sewage sludge is less than 7% solids and the temperature of the sewage sludge is 50 degrees Celsius or higher; and the time period is 30 minutes or longer.

Temperature (Celsius)	Time
50.0 (minimum)	5.0 days
55.0	1.0 day
60.0	4 hours 48 minutes
65.0	58 minutes
67.0	30 minutes (minimum)

(iii) The temperature used in equation (2) and equation (3) will be the lowest, continuously measured temperature within the reaction vessel during a 24-hour period or the lowest measured temperature during any 24-hour period, if a continuous treatment process is used. If a batch treatment process is used, the temperature used in the equation (2) and equation (3) will be the lowest temperature measured during the batch treatment.

(iv) For design temperatures measuring greater than 70 degrees Celsius, continuous temperature monitoring shall be required.

(4) Class A –Alternative 2.

(i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in section 503.10(b), section 503.10(c), section 503.10(e), or section 503.10(f).

(ii)(A) The pH of the sewage sludge that is used or disposed shall be raised to above 12 and shall remain above 12 for 72 hours.

(B) The temperature of the sewage sludge shall be above 52 degrees Celsius for 12 hours or longer during the period that the pH of the sewage sludge is above 12.

(C) At the end of the 72 hour period during which the pH of the sewage sludge is above 12, the sewage sludge shall be air dried to achieve a percent solids in the sewage sludge greater than 50 percent.

(5) Class A –Alternative 3.

(i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella sp. bacteria in sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in section 503.10(b), section 503.10(c), section 503.10(e), or section 503.10(f).

(ii)(A) The sewage sludge shall be analyzed prior to pathogen treatment to determine whether the sewage sludge contains enteric viruses.

(B) When the density of enteric viruses in the sewage sludge prior to pathogen treatment is less than one Plaque-forming Unit per four grams of total solids (dry weight basis), the sewage sludge is Class A with respect to enteric viruses until the next monitoring episode for the sewage sludge.

(C) When the density of enteric viruses in the sewage sludge prior to pathogen treatment is equal to or greater than one Plaque-forming Unit per four grams of total solids (dry weight basis), the sewage sludge is Class A with respect to enteric viruses when the density of enteric viruses in the sewage sludge after pathogen treatment is less than one Plaque-forming Unit per four grams of total solids (dry weight basis) and when the values or ranges of values for the operating parameters for the pathogen treatment process that produces the sewage sludge that meets the enteric virus density requirement are documented.

(D) After the enteric virus reduction in paragraph (a)(5)(ii)(C) of this subsection is demonstrated for the pathogen treatment process, the sewage sludge continues to be Class A with respect to enteric viruses when the values for the pathogen treatment process operating parameters are consistent with the values or ranges of values documented in paragraph (a)(5)(ii)(C) of this subsection.

(iii)(A) The sewage sludge shall be analyzed prior to pathogen treatment to determine whether the sewage sludge contains viable helminth ova.

(B) When the density of viable helminth ova in the sewage sludge prior to pathogen treatment is less than one per four grams of total solids (dry weight basis), the sewage sludge is Class A with respect to viable helminth ova until the next monitoring episode for the sewage sludge.

(C) When the density of viable helminth ova in the sewage sludge prior to pathogen treatment is equal to or greater than one per four grams of total solids (dry weight basis), the sewage sludge is Class A with respect to viable helminth ova when the density of viable helminth ova in the sewage sludge after pathogen treatment is less than one per four grams of total solids (dry weight basis) and when the values or ranges of values for the operating parameters for the pathogen treatment process that produces the sewage sludge that meets the viable helminth ova density requirement are documented.

(D) After the viable helminth ova reduction in paragraph (a)(5)(iii)(C) of this subsection is demonstrated for the pathogen treatment process, the sewage sludge continues to be Class A with respect to viable helminth ova when the values for the pathogen treatment process operating parameters are consistent with the values or ranges of values documented in paragraph (a)(5)(iii)(C) of this subsection.

(6) Class A –Alternative 4.

(i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the

land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in section 503.10(b), section 503.10(c), section 503.10(e), or section 503.10(f).

(ii) The density of enteric viruses in the sewage sludge shall be less than one Plaque-forming Unit per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in section 503.10(b), section 503.10(c), section 503.10(e), or section 503.10(f), unless otherwise specified by the Department.

(iii) The density of viable helminth ova in the sewage sludge shall be less than one per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in section 503.10(b), section 503.10(c), section 503.10(e), or section 503.10(f), unless otherwise specified by the Department.

(7) Class A –Alternative 5.

(i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella, sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in section 503.10(b), section 503.10(c), section 503.10(e), or section 503.10(f).

(ii) Sewage sludge that is used or disposed shall be treated in one of the Processes to Further Reduce Pathogens described in appendix B of this part.

(8) Class A –Alternative 6.

(i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella, sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in section 503.10(b), section 503.10(c), section 503.10(e), or section 503.10(f).

(ii) Sewage sludge that is used or disposed shall be treated in a process that is equivalent to a Process to Further Reduce Pathogens, as determined by the Department.

(b) Sewage sludge –Class B.

(1)(i) The requirements in either section 503.32(b)(2), section 503.32(b)(3), or section 503.32(b)(4) shall be met for a sewage sludge to be classified Class B with respect to pathogens.

(ii) The site restrictions in section 503.32(b)(5) shall be met when sewage sludge that meets the Class B pathogen requirements in section 503.32(b)(2), section 503.32(b)(3), or section 503.32(b)(4) is applied to the land.

(2) Class B –Alternative 1.

(i) Seven representative samples of the sewage sludge that is used or disposed shall be collected.

(ii) The geometric mean of the density of fecal coliform in the samples collected in (b)(2)(i) of this subsection shall be less than either 2,000,000 Most Probable Number per gram of total solids (dry weight basis) or 2,000,000 Colony Forming Units per gram of total solids (dry weight basis).

(3) Class B –Alternative 2. Sewage sludge that is used or disposed shall be treated in one of the Processes to Significantly Reduce Pathogens described in appendix B of this part.

(4) Class B –Alternative 3. Sewage sludge that is used or disposed shall be treated in a process that is equivalent to a Process to Significantly Reduce Pathogens, as determined by the Department.

(5) Site Restrictions.

(i) Food crops with harvested parts that touch the sewage sludge/soil mixture and are totally above the land surface shall not be harvested for 14 months after application of sewage sludge.

(ii) Food crops with harvested parts below the surface of the land shall not be harvested for 20 months after application of sewage sludge when the sewage sludge remains on the land surface for four months or longer prior to incorporation into the soil.

(iii) Food crops with harvested parts below the surface of the land shall not be harvested for 38 months after application of sewage sludge when the sewage sludge remains on the land surface for less than four months prior to incorporation into the soil.

(iv) Food crops, feed crops, and fiber crops shall not be harvested for 30 days after application of sewage sludge.

(v) Animals shall not be grazed on the land for 30 days after application of sewage sludge.

(vi) Turf grown on land where sewage sludge is applied shall not be harvested for one year after application of the sewage sludge when the harvested turf is placed on either land with a high potential for public exposure or a lawn, unless otherwise specified by the Department.

(vii) Public access to land with a high potential for public exposure shall be restricted for one year after application of sewage sludge.

(viii) Public access to land with a low potential for public exposure shall be restricted for 30 days after application of sewage sludge.

(ix) The Department may establish in permits the required application buffer setbacks for property boundaries, roadways, residential developments, dwellings, water wells, drainageways, and surface water as deemed necessary to protect public health.

(x) The Department may establish minimum requirements in permits for soil and/or groundwater monitoring, for bulk application sites, to verify compliance with the Regulation.

(c) Domestic septage.

(1) [Reserved]

(2) The pH of domestic septage applied to agricultural land, forest, or a reclamation site shall be raised to 12 or higher by alkali addition and, without the addition of more alkali, shall remain at 12 or higher for 30 minutes and the site restrictions in section 503.32(b)(5)(i) through section 503.32(b)(5)(iv) shall be met.; or

(3) Any pathogen reduction process described in appendix B of this part and the site restrictions in section 503.32(b)(5)(i) through section 503.32(b)(5)(iv) shall be met.

503.33. Vector attraction reduction.

(a)(1) One of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(10) shall be met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site.

(2) One of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8) shall be met when bulk sewage sludge is applied to a lawn or a home garden.

(3) One of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(8) shall be met when sewage sludge is sold or given away in a bag or other container for application to the land.

(4) One of the vector attraction reduction requirements in section 503.33(b)(1) through section 503.33(b)(11) shall be met when sewage sludge (other than domestic septage) is placed on an active sewage sludge unit.

(5) One of the vector attraction reduction requirements in section 503.33(b)(9), section 503.33(b)(10), or section 503.33(b)(12) shall be met when domestic septage is applied to agricultural land, forest, or a reclamation site and one of the vector attraction reduction requirements in section 503.33(b)(9) through section 503.33(b)(12) shall be met when domestic septage is placed on an active sewage sludge unit.

(6) [Reserved]

(b)(1) The mass of volatile solids in the sewage sludge shall be reduced by a minimum of 38 percent (see calculation procedure in “Environmental Regulations and Technology-Control of Pathogens and Vector Attraction in Sewage Sludge”, EPA-625/R-92/013, 1992, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268).

(2) When the 38 percent volatile solids reduction requirement in section 503.33(b)(1) cannot be met for an anaerobically digested sewage sludge, vector attraction reduction can be demonstrated by digesting a portion of the previously digested sewage sludge anaerobically in the laboratory in a bench-scale unit for 40 additional days at a temperature between 30 and 37 degrees Celsius. When at the end of the 40 days, the volatile solids in the sewage sludge at the beginning of that period is reduced by less than 17 percent, vector attraction reduction is achieved.

(3) When the 38 percent volatile solids reduction requirement in section 503.33(b)(1) cannot be met for an aerobically digested sewage sludge, vector attraction reduction can be demonstrated by digesting a portion of the previously digested sewage sludge that has a percent solids of two percent or less aerobically in the laboratory in a bench-scale unit for 30 additional days at 20 degrees Celsius. When at the end of the 30 days, the volatile solids in the sewage sludge at the beginning of that period is reduced by less than 15 percent, vector attraction reduction is achieved.

(4) The specific oxygen uptake rate (SOUR) for sewage sludge treated in an aerobic process shall be equal to or less than 1.5 milligrams of oxygen per hour per gram of total solids (dry weight basis) at a temperature of 20 degrees Celsius.

(5) Sewage sludge shall be treated in an aerobic process for 14 days or longer. During that time, the temperature of the sewage sludge shall be higher than 40 degrees Celsius and the average temperature of the sewage sludge shall be higher than 45 degrees Celsius.

(6) The pH of sewage sludge shall be raised to 12 or higher by alkali addition and, without the addition of more alkali, shall remain at 12 or higher for two hours and then at 11.5 or higher for an additional 22 hours.

(7) The percent solids of sewage sludge that does not contain unstabilized solids generated in a primary wastewater treatment process shall be equal to or greater than 75 percent based on the moisture content and total solids prior to mixing with other materials.

(8) The percent solids of sewage sludge that contains unstabilized solids generated in a primary wastewater treatment process shall be equal to or greater than 90 percent based on the moisture content and total solids prior to mixing with other materials.

(9)(i) Sewage sludge shall be injected below the surface of the land.

(ii) No significant amount of the sewage sludge shall be present on the land surface within one hour after the sewage sludge is injected.

(iii) When the sewage sludge that is injected below the surface of the land is Class A with respect to pathogens, the sewage sludge shall be injected below the land surface within eight hours after being discharged from the pathogen treatment process.

(10)(i) Sewage sludge applied to the land surface or placed on an active sewage sludge unit shall be incorporated into the soil within six hours after application to or placement on the land, unless otherwise specified by the Department.

(ii) When sewage sludge that is incorporated into the soil is Class A with respect to pathogens, the sewage sludge shall be applied to or placed on the land within eight hours after being discharged from the pathogen treatment process.

(11) Sewage sludge placed on an active sewage sludge unit shall be covered with soil or other material at the end of each operating day.

(12) The pH of domestic septage shall be raised to 12 or higher by alkali addition and, without the addition of more alkali, shall remain at 12 or higher for 30 minutes.

(13) The vector attraction reduction requirement may be met through an alternative method to be determined by the Department on a case-by-case basis, if the sludge is not covered by 40 CFR 503.

PART E
INCINERATION

503.40. Applicability.

- (a) This part applies to a person who fires sewage sludge in a sewage sludge incinerator, to a sewage sludge incinerator, and to sewage sludge fired in a sewage sludge incinerator.
- (b) This part applies to the exit gas from a sewage sludge incinerator stack.

503.41. Special definitions.

- (a) "Air pollution control device" is one or more processes used to treat the exit gas from a sewage sludge incinerator stack.
- (b) "Auxiliary fuel" is fuel used to augment the fuel value of sewage sludge. This includes, but is not limited to, natural gas, fuel oil, coal, gas generated during anaerobic digestion of sewage sludge, and municipal solid waste (not to exceed 30 percent of the dry weight of sewage sludge and auxiliary fuel together). Hazardous wastes are not auxiliary fuel.
- (c) "Average daily concentration" is the arithmetic mean of the concentrations of a pollutant in milligrams per kilogram of sewage sludge (dry weight basis) in the samples collected and analyzed in a month.
- (d) "Control efficiency" is the mass of a pollutant in the sewage sludge fed to an incinerator minus the mass of that pollutant in the exit gas from the incinerator stack divided by the mass of the pollutant in the sewage sludge fed to the incinerator.
- (e) "Dispersion factor" is the ratio of the increase in the ground level ambient air concentration for a pollutant at or beyond the property line of the site where the sewage sludge incinerator is located to the mass emission rate for the pollutant from the incinerator stack.
- (f) "Fluidized bed incinerator" is an enclosed device in which organic matter and inorganic matter in sewage sludge are combusted in a bed of particles suspended in the combustion chamber gas.
- (g) "Hourly average" is the arithmetic mean of all measurements taken during an hour. At least two measurements must be taken during the hour.
- (h) "Incineration" is the combustion of organic matter and inorganic matter in sewage sludge by high temperatures in an enclosed device.
- (i) "Incinerator operating combustion temperature" is the arithmetic mean of the temperature readings in the hottest zone of the furnace recorded in a day (24 hours) when the temperature is averaged and recorded at least hourly during the hours the incinerator operates in a day.
- (j) "Monthly average" is the arithmetic mean of the hourly averages for the hours a sewage sludge incinerator operates during the month.
- (k) "Performance test combustion temperature" is the arithmetic mean of the average combustion temperatures in the hottest zone of the furnace for each of the runs in a performance test.
- (l) "Risk specific concentration" is the allowable increase in the average daily ground level ambient air concentration for a pollutant from the incineration of sewage sludge at or beyond the property line of the site where the sewage sludge incinerator is located.
- (m) "Sewage sludge feed rate" is either the average daily amount of sewage sludge fired in all sewage sludge incinerators within the property line of the site where the sewage sludge incinerators are located for the number of days in a 365 day period that each sewage sludge incinerator operates, or the average daily design capacity for all sewage sludge incinerators within the property line of the site where the sewage sludge incinerators are located.
- (n) "Sewage sludge incinerator" is an enclosed device in which only sewage sludge and auxiliary fuel are fired.
- (o) "Stack height" is the difference between the elevation of the top of a sewage sludge incinerator stack and the elevation of the ground at the base of the stack when the difference is equal to or less than 65 meters. When the difference is greater than 65 meters, stack height is the creditable stack height determined in accordance with 40 CFR 51.100 (ii).

(p) “Total hydrocarbons” means the organic compounds in the exit gas from a sewage sludge incinerator stack measured using a flame ionization detection instrument referenced to propane.

(q) “Wet electrostatic precipitator” is an air pollution control device that uses both electrical forces and water to remove pollutants in the exit gas from a sewage sludge incinerator stack.

(r) “Wet scrubber” is an air pollution control device that uses water to remove pollutants in the exit gas from a sewage sludge incinerator stack.

503.42. General Requirements.

No person shall fire sewage sludge in a sewage sludge incinerator except in compliance with the requirements in this part.

503.43. Pollutant limits.

(a) Firing of sewage sludge in a sewage sludge incinerator shall not violate the requirements in the National Emission Standard for Beryllium in subpart C of 40 CFR Part 61.

(b) Firing of sewage sludge in a sewage sludge incinerator shall not violate the requirements in the National Emission Standard for Mercury in subpart E of 40 CFR Part 61.

(c) Pollutant limit –lead.

(1) The average daily concentration for lead in sewage sludge fed to a sewage sludge incinerator shall not exceed the concentration calculated using Equation (4).

$$C = \frac{0.1 \times \text{NAAQS} \times 86,400}{\text{DF} \times (1 - \text{CE}) \times \text{SF}} \quad (\text{Equation 4})$$

Where:

C = Average daily concentration of lead in sewage sludge.

NAAQS = National Ambient Air Quality Standard for lead in micrograms per cubic meter.

DF = Dispersion factor in micrograms per cubic meter per gram per second.

CE = Sewage sludge incinerator control efficiency for lead in hundredths.

SF = Sewage sludge feed rate in metric tons per day (dry weight basis).

(2) The dispersion factor (DF) in equation (4) shall be determined from an air dispersion model in accordance with section 503.43(e).

(i) When the sewage sludge stack height is 65 meters or less, the actual sewage sludge incinerator stack height shall be used in the air dispersion model to determine the dispersion factor (DF) for equation (4).

(ii) When the sewage sludge incinerator stack height exceeds 65 meters, the creditable stack height shall be determined in accordance with 40 CFR 51.100 (ii) and the creditable stack height shall be used in the air dispersion model to determine the dispersion factor (DF) for equation (4).

(3) The control efficiency (CE) for equation (4) shall be determined from a performance test of the sewage sludge incinerator, in accordance with section 503.43(e).

(d) Pollutant limit – arsenic, cadmium, chromium, and nickel.

(1) The average daily concentration for arsenic, cadmium, chromium, and nickel in sewage sludge fed to a sewage sludge incinerator each shall not exceed the concentration calculated using equation (5).

$$C = \frac{\text{RSC} \times 86,400}{\text{DF} \times (1 - \text{CE}) \times \text{SF}} \quad (\text{Equation 5})$$

Where:

C = Average daily concentration of arsenic, cadmium, chromium, or nickel in sewage sludge.

CE = Sewage sludge incinerator control efficiency for arsenic, cadmium, chromium, or nickel in hundredths.

DF = Dispersion factor in micrograms per cubic meter per gram per second.

RSC = Risk-specific concentration for arsenic, cadmium, chromium, or nickel in micrograms per cubic meter.

SF = Sewage sludge feed rate in metric tons per day (dry weight basis).

(2) The risk specific concentrations for arsenic, cadmium, and nickel used in equation (5) shall be obtained from Table 1 of section 503.43.

TABLE 1 OF SECTION 503.43—RISK-SPECIFIC CONCENTRATION FOR ARSENIC, CADMIUM, AND NICKEL

Pollutant	Risk Specific Concentration (micrograms per cubic meter)
Arsenic	0.023
Cadmium	0.057
Nickel	2.0

(3) The risk specific concentration for chromium used in equation (5) shall be obtained from Table 2 of section 503.43 or shall be calculated using equation (6).

TABLE 2 OF SECTION 503.43—RISK-SPECIFIC CONCENTRATION FOR CHROMIUM

Type of Incinerator	Risk Specific Concentration (micrograms per cubic meter)
Fluidized bed with wet scrubber	0.65
Fluidized bed with wet scrubber and wet electrostatic precipitator	0.23
Other types with wet scrubber	0.064
Other types with wet scrubber and wet electrostatic precipitator	0.016

$$RSC = \frac{0.0085}{r} \text{ (Equation 6)}$$

Where:

RSC= risk specific concentration for chromium in micrograms per cubic meter used in equation (5).

r= decimal fraction of the hexavalent chromium concentration in the total chromium concentration measured in the exit gas from the sewage sludge incinerator stack in hundredths.

(4) The dispersion factor (DF) in equation (5) shall be determined from an air dispersion model in accordance with section 503.43(e).

(i) When the sewage sludge incinerator stack height is equal to or less than 65 meters, the actual sewage sludge incinerator stack height shall be used in the air dispersion model to determine the dispersion factor (DF) for equation (5).

(ii) When the sewage sludge incinerator stack height is greater than 65 meters, the creditable stack height shall be determined in accordance with 40 CFR 51.100 (ii) and the creditable stack height shall be used in the air dispersion model to determine the dispersion factor (DF) for equation (5).

(5) The control efficiency (CE) for equation (5) shall be determined from a performance test of the sewage sludge incinerator in accordance with section 503.43(e).

(e) Air dispersion modeling and performance testing.

(1) The air dispersion model used to determine the dispersion factor in section 503.43 (c)(2) and (d)(4) shall be appropriate for the geographical, physical, and population characteristics at the sewage sludge incinerator site. The performance test used to determine the control efficiencies in section 503.43(c)(3) and (d)(5) shall be appropriate for the type of sewage sludge incinerator.

(2) For air dispersion modeling initiated after September 3, 1999, the modeling results shall be submitted to the Department thirty (30) days after completion of the modeling. In addition to the modeling results, the submission shall include a description of the air dispersion model and the values used for the model parameters.

(3) The following procedures, at a minimum, shall apply in conducting performance tests to determine the control efficiencies in section 503.43(c)(3) and (d)(5) after September 3, 1999:

(i) The performance test shall be conducted under representative sewage sludge incinerator conditions at the highest expected sewage sludge feed rate within the design capacity of the sewage sludge incinerator.

(ii) The Department shall be notified at least thirty (30) days prior to any performance test so the Department may have the opportunity to observe the test. The notice shall include a test protocol with incinerator operating conditions and a list of test methods to be used.

(iii) Each performance test shall consist of three separate runs using the applicable test method. The control efficiency for a pollutant shall be the arithmetic mean of the control efficiencies for the pollutant from the three runs.

(4) The pollutant limits in section 503.43(c) and (d) of this section shall be submitted to the permitting authority no later than thirty (30) days after completion of the air dispersion modeling and performance test.

(5) Significant changes in geographical or physical characteristics at the incinerator site or in incinerator operating conditions require new air dispersion modeling or performance testing to determine a new dispersion factor or a new control efficiency that will be used to calculate revised pollutant limits.

(f) Additional parameters may be required in the initial analysis and subsequent monitoring thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required (in a permit) to be monitored in the sewage sludge.

503.44. Operational standard – total hydrocarbons.

(a) The total hydrocarbons concentration in the exit gas from a sewage sludge incinerator shall be corrected for zero percent moisture by multiplying the measured total hydrocarbons concentration by the correction factor calculated using equation (7).

$$\text{Correction factor (percent moisture)} = \frac{1}{(1 - X)} \quad (\text{Equation 7})$$

Where:

X= decimal fraction of the percent moisture in the sewage sludge incinerator exit gas in hundredths.

(b) The total hydrocarbons concentration in the exit gas from a sewage sludge incinerator shall be corrected to seven percent oxygen by multiplying the measured total hydrocarbons concentration by the correction factor calculated using equation (8).

$$\text{Correction factor (oxygen)} = \frac{14}{(21 - Y)} \quad (\text{Equation 8})$$

Where:

Y= Percent oxygen concentration in the sewage sludge incinerator stack exit gas(dry volume/dry volume).

(c) The monthly average concentration for total hydrocarbons in the exit gas from a sewage sludge incinerator stack, corrected for zero percent moisture using the correction factor from equation (7) and to seven percent oxygen using the correction factor from equation (8), shall not exceed 100 parts per million on a volumetric basis when measured using the instrument required by section 503.45(a).

503.45. Management practices.

(a)(1) An instrument that continuously measures and records the total hydrocarbons concentration in the sewage sludge incinerator stack exit gas shall be installed, calibrated, operated, and maintained for a sewage sludge incinerator.

- (2) The total hydrocarbons instrument shall employ a flame ionization detector; shall have a heated sampling line maintained at a temperature of 150 degrees Celsius or higher at all times; and shall be calibrated at least once every 24-hour operating period using propane.
- (b) An instrument that continuously measures and records the oxygen concentration in the sewage sludge incinerator stack exit gas shall be installed, calibrated, operated, and maintained for a sewage sludge incinerator.
- (c) An instrument that continuously measures and records information used to determine the moisture content in the sewage sludge incinerator stack exit gas shall be installed, calibrated, operated, and maintained for a sewage sludge incinerator.
- (d) An instrument that continuously measures and records combustion temperatures shall be installed, calibrated, operated, and maintained for a sewage sludge incinerator.
- (e) Operation of a sewage sludge incinerator shall not cause the operating combustion temperature for the sewage sludge incinerator to exceed the performance test combustion temperature by more than twenty (20) percent.
- (f) An air pollution control device shall be appropriate for the type of sewage sludge incinerator, and the operating parameters for the air pollution control device shall be adequate to indicate proper performance of the air pollution control device. For sewage sludge incinerators subject to the requirements in subpart O of 40 CFR part 60, operation of the air pollution control device shall not violate the requirements for the air pollution control device in subpart O of 40 CFR part 60. For all other sewage sludge incinerators, operation of the air pollution control device shall not cause a significant exceedance of the average value for the air pollution control device operating parameters from the performance test required by section 503.43(c)(3) and (d)(5).
- (g) Sewage sludge shall not be fired in a sewage sludge incinerator if it is likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act or its designated critical habitat.
- (h) The instruments required in section 503.45(a) through (d) shall be appropriate for the type of sewage sludge incinerator.

503.46. Frequency of monitoring.

- (a) Sewage sludge.
- (1) The frequency of monitoring for beryllium shall be as required in subpart C of 40 CFR part 61, and for mercury as required in subpart E of 40 CFR part 61.
- (2) The frequency of monitoring for arsenic, cadmium, chromium, lead, and nickel in sewage sludge fed to a sewage sludge incinerator shall be the frequency in Table 1 of section 503.46. Facilities which generate less than 290 metric tons of sludge per year and dispose of the sludge once per year or less, may request a reduction in monitoring to a frequency of once per year. The Department will review these requests on a case-by-case basis.

TABLE 1 OF SECTION 503.46—FREQUENCY OF MONITORING—INCINERATION

Amount of sewage sludge* (metric tons per 365 day period)	Frequency
Greater than zero but less than 1,500.	Once per quarter (four times per year)
Equal to or greater than 1,500 but less than 15,000.	Once per 60 days (six times per year)
Equal to or greater than 15,000.	Once per month (12 times per year)

* Amount of sewage sludge fired in a sewage sludge incinerator (dry weight basis).

- (3) After the sewage sludge has been monitored for two years at the frequency in Table 1 of section 503.46, the Department may reduce the frequency of monitoring for arsenic, cadmium, chromium, lead, and nickel.

(b) Total hydrocarbons, oxygen concentration, information to determine moisture content, and combustion temperatures. The total hydrocarbons concentration and oxygen concentration in the exit gas from a sewage sludge incinerator stack, the information used to measure moisture content in the exit gas, and the combustion temperatures for the sewage sludge incinerator shall be monitored continuously.

(c) Air pollution control device operating parameters. The frequency of monitoring for the sewage sludge incinerator air pollution control device operating parameters shall be specified by the Department.—For sewage sludge incinerators subject to the requirements in subpart O of 40 CFR part 60, the frequency of monitoring for the appropriate air pollution control device operating parameters shall be the frequency of monitoring in subpart O of 40 CFR part 60. For all other sewage sludge incinerators, the appropriate air pollution control device operating parameters shall be monitored at least daily.

503.47. Recordkeeping.

(a) The person who fires sewage sludge in a sewage sludge incinerator shall develop the information in section 503.47(b) through section 503.47(n) and shall retain that information for five years.

(b) The concentration of lead, arsenic, cadmium, chromium, and nickel in the sewage sludge fed to the sewage sludge incinerator.

(c) The total hydrocarbons concentrations in the exit gas from the sewage sludge incinerator stack.

(d) Information that indicates the requirements in the National Emission Standard for beryllium in subpart C of 40 CFR Part 61 are met.

(e) Information that indicates the requirements in the National Emission Standard for mercury in subpart E of 40 CFR Part 61 are met.

(f) The operating combustion temperatures for the sewage sludge incinerator.

(g) Values for the air pollution control device operating parameters.

(h) The oxygen concentration and information used to measure moisture content in the exit gas from the sewage sludge incinerator stack.

(i) The sewage sludge feed rate.

(j) The stack height for the sewage sludge incinerator.

(k) The dispersion factor for the site where the sewage sludge incinerator is located.

(l) The control efficiency for lead, arsenic, cadmium, chromium, and nickel for each sewage sludge incinerator.

(m) The risk specific concentration for chromium calculated using equation (6), if applicable.

(n) A calibration and maintenance log for the instruments used to measure the total hydrocarbons concentration and oxygen concentration in the exit gas from the sewage sludge incinerator stack, the information needed to determine moisture content in the exit gas, and the combustion temperatures.

503.48. Reporting.

(a) Any generator of sewage sludge when sewage sludge is incinerated, any person who prepares sewage sludge that is incinerated, or any person who incinerates sewage sludge, including Class I sludge management facilities, POTWs (as defined in 40 CFR 501.2) with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve a population of 10,000 people or greater shall submit the information in section 503.47(b) through section 503.47(h) to the Department on or before February 19 of each year, for the period of January 1 through December 31 of the previous calendar year. Reports required by this regulation do not exclude any person from submitting reports required by other Department regulations or by other applicable EPA regulations. As of December 21, 2020, all reports submitted in compliance with this section must be submitted electronically in compliance with this section and 40 CFR Part 3 (including, in all cases, subpart D to Part 3), 40 CFR 122.22, and 40 CFR Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to the start dates for electronic reporting (see Table 1 in 40 CFR 127.16), the Department may also require operators to electronically submit annual reports under this section if required to do so by State law.

HISTORY: Amended by SCSR 43–11 Doc. No. 4888, eff November 22, 2019.

503.50. Odor Control Requirements.

The permit holder shall use best management practices normally associated with the proper operation and maintenance of a sludge wastewater treatment site, any sludge storage or lagoon areas, transportation of sludges, and all individual activities permitted under R.61-9.503 to ensure that an undesirable level of odor does not exist.

(a) The permittee shall prepare an odor abatement plan for the sewage sludge treatment sites, any sludge storage or lagoon areas, and land application or surface disposal sites. Permittees that land-apply sludge must prepare the plan within 180 days of the effective date of this regulation (effective date of June 26, 2003). Permittees that have facilities described above that require plans have one (1) year from the June 26, 2003 effective date to prepare the plan. Odor abatement plans must be submitted for new projects with the submission of permit applications. The plan must include the following topics:

- (1) Operation and maintenance practices which are used to eliminate or minimize undesirable odor levels in the form of best management practices for odor control;
- (2) Use of treatment processes for the reduction of undesirable odors;
- (3) Use of setbacks; and
- (4) Contingency plans and methods to address odor problems for the different types of disposal/application methods used.

(b) Unless otherwise requested, prior to issuance of a new or expanded land application disposal permit (either NPDES or Land Application), the Department may review the odor abatement plan for compliance with this Part (503.50). The Department may require changes to the plan as appropriate.

(c) No permittee may cause, allow, or permit emission into the ambient air of any substance or combinations of substances in quantities that an undesirable level of odor is determined to result unless preventative measures of the type set out below are taken to abate or control the emission to the satisfaction of the Department. When an odor problem comes to the attention of the Department through field surveillance or specific complaints, the Department may determine, in accordance with section 48-1-120 of the Pollution Control Act, if the odor is at an undesirable level by considering the character and degree of injury or interference to:

- (1) The health or welfare of the people;
- (2) Plant, animal, freshwater aquatic, or marine life;
- (3) Property; or
- (4) Enjoyment of life or use of affected property.

(d) After determining that an undesirable level of odor exists, the Department may require:

- (1) the permittee to submit a corrective action plan to address the odor problem,
- (2) remediation of the undesirable level of odor within a reasonable timeframe, and
- (3) in an order, specific methods to address the problem.

(e) If the permittee fails to control or abate the odor problems addressed in this section within the specified timeframe, the Department may revoke disposal/application activities associated with the site or the specific aspect of the sludge management program.

APPENDIX A. PROCEDURE TO DETERMINE THE ANNUAL WHOLE SLUDGE APPLICATION RATE FOR A SEWAGE SLUDGE

Section 503.13(a)(4)(ii) requires that the product of the concentration for each pollutant listed in Table 4 of section 503.13 in sewage sludge sold or given away in a bag or other container for application to the land and the annual whole sludge application rate (AWSAR) for the sewage sludge not cause the annual pollutant loading rate for the pollutant in Table 4 of section 503.13 to be exceeded. This appendix contains the procedure used to determine the AWSAR for a sewage sludge that does not cause the annual pollutant loading rates in Table 4 of section 503.13 to be exceeded.

The relationship between the annual pollutant loading rate (APLR) for a pollutant and the annual whole sludge application rate (AWSAR) for a sewage sludge is shown in equation (1).

$$\text{APLR} = C \times \text{AWSAR} \times 0.001 \quad (1)$$

Where:

APLR= Annual pollutant loading rate in kilograms per hectare per 365 day period.

C= Pollutant concentration in milligrams per kilogram of total solids (dry weight basis).

AWSAR= Annual whole sludge application rate in metric tons per hectare per 365 day period (dry weight basis).

0.001= A conversion factor.

To determine the AWSAR, equation (1) is rearranged into equation (2):

$$\text{AWSAR} = \frac{\text{APLR}}{C \times 0.001} \quad (2)$$

The procedure used to determine the AWSAR for a sewage sludge is presented below.

PROCEDURE:

1. Analyze a sample of the sewage sludge to determine the concentration for each of the pollutants listed in Table 4 of section 503.13 in the sewage sludge.
2. Using the pollutant concentrations from Step 1 and the APLRs from Table 4 of section 503.13, calculate an AWSAR for each pollutant using equation (2) above.
3. The AWSAR for the sewage sludge is the lowest AWSAR calculated in Step 2.

APPENDIX B. PATHOGEN TREATMENT PROCESSES

A. PROCESSES TO SIGNIFICANTLY REDUCE PATHOGENS (PSRP)

1. Aerobic digestion. Sewage sludge is agitated with air or oxygen to maintain aerobic conditions for a specific mean cell residence time at a specific temperature. Values for the mean cell residence time and temperature shall be between 40 days at 20 degrees Celsius and 60 days at 15 degrees Celsius.

2. Air drying. Sewage sludge is dried on sand beds or on paved or unpaved basins. The sewage sludge dries for a minimum of three months. During two of the three months, the ambient average daily temperature is above zero degrees Celsius.

3. Anaerobic digestion. Sewage sludge is treated in the absence of air for a specific mean cell residence time at a specific temperature. Values for the mean cell residence time and temperature shall be between 15 days at 35 to 55 degrees Celsius and 60 days at 20 degrees Celsius.

4. Composting. Using either the within-vessel, static aerated pile, or windrow composting methods, the temperature of the sewage sludge is raised to 40 degrees Celsius or higher and remains at 40 degrees Celsius or higher for five days. For four hours during the five days, the temperature in the compost pile exceeds 55 degrees Celsius.

5. Lime stabilization. Sufficient lime is added to the sewage sludge to raise the pH of the sewage sludge to 12 after two hours of contact.

B. PROCESSES TO FURTHER REDUCE PATHOGENS (PFRP)

1. Composting. Using either the within-vessel composting method or the static aerated pile composting method, the temperature of the sewage sludge is maintained at 55 degrees Celsius or higher for three days.

Using the windrow composting method, the temperature of the sewage sludge is maintained at 55 degrees or higher for 15 days or longer. During the period when the compost is maintained at 55 degrees or higher, there shall be a minimum of five turnings of the windrow.

2. Heat drying. Sewage sludge is dried by direct or indirect contact with hot gases to reduce the moisture content of the sewage sludge to 10 percent or lower. Either the temperature of the sewage sludge particles exceeds 80 degrees Celsius or the wet bulb temperature of the gas in contact with the sewage sludge as the sewage sludge leaves the dryer exceeds 80 degrees Celsius.

3. Heat treatment. Liquid sewage sludge is heated to a temperature of 180 degrees Celsius or higher for 30 minutes.

4. Thermophilic aerobic digestion. Liquid sewage sludge is agitated with air or oxygen to maintain aerobic conditions and the mean cell residence time of the sewage sludge is 10 days at 55 to 60 degrees Celsius.

5. Beta ray irradiation. Sewage sludge is irradiated with beta rays from an accelerator at dosages of at least 1.0 megarad at room temperature (ca. 20 degrees Celsius).

6. Gamma ray irradiation. Sewage sludge is irradiated with gamma rays from certain isotopes, such as Cobalt 60 and Cesium 137, at dosages of at least 1.0 megarad at room temperature (ca. 20 degrees Celsius).

7. Pasteurization. The temperature of the sewage sludge is maintained at 70 degrees Celsius or higher for 30 minutes or longer.

HISTORY: Added by State Register Volume 20, Issue No. 6, eff June 28, 1996. Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001.

APPENDIX C. PCB. POLYCHLORINATED BIPHENYLS

(1) Beginning with the effective date of this appendix, sludges for land application (including sewage sludge, sludges and septage that may be mixed with grease trap waste) must be sampled at least quarterly (based on calendar year quarters) for PCBs using EPA SW-846 Method 8082A with an appropriate sample preparation method approved for use by the Department based on the matrix of the sample. This includes but is not limited to: bulk sewage sludge applied to agricultural land, forests or public contact sites; sewage sludge sold or given away in a bag or other container for application to the land; domestic septage; reclamation sites; or other materials mixed with sludge

before application. Reporting the above information, in addition to requirements specified later in this appendix, should be included in annual reports required by permits.

(2) If levels of PCBs are greater than or equal to one (1) milligram per kilogram (mg/kg dry weight basis), but less than ten (10) milligrams per kilogram (mg/kg dry weight basis), confirmation sludge sampling must be done as soon as practicable and the results provided to the Department within five (5) calendar days of receipt by the permittee.

(3) If levels of PCBs are greater than or equal to ten (10) milligrams per kilogram (mg/kg dry weight basis), confirmation sludge sampling must be done as soon as practicable and the results provided to the Department within five (5) calendar days of receipt of the results by the permittee. In addition, representative soil sampling of land application sites that may have received sludge during the monitoring period must be conducted within 30 days of knowledge of the confirmation sampling that confirms sludge PCB levels equal to or greater than ten (10) milligrams per kilogram (mg/kg dry weight basis). The results of the soil sampling must be provided to the Department within five (5) calendar days of receipt by the permittee. The Department may require any further action as deemed necessary and consistent with applicable laws.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

61-9.504. STANDARDS FOR THE USE OR DISPOSAL OF INDUSTRIAL SLUDGE.

Editor's Note

The following constitutes the history for 61-9.504, 504.1 through 504.50.

HISTORY: Amended by State Register Volume 25, Issue No. 7, eff July 27, 2001; State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003; State Register Volume 32, Issue No. 5, eff May 23, 2008.

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PART A
GENERAL PROVISIONS

504.1. Purpose and applicability.

(a) Purpose

(1) This part establishes standards, which consist of general requirements, pollutant limits, management practices, and operational standards, for the final use or disposal of industrial sludge generated during the treatment of industrial wastewater in a treatment works. Standards are included in this part for industrial sludge applied to the land. Also included in this part are pathogen and alternative vector attraction reduction requirements for industrial sludge applied to the land.

(2) In addition, the standards in this part include the frequency of monitoring and record-keeping requirements when industrial sludge is applied to the land. Also included in this part are reporting requirements for industrial sludge disposal when the sludge is applied to the land.

(b) Applicability

(1) This part applies to any person who prepares industrial sludge or applies industrial sludge to the land. This part also applies to any person who sells, or gives away industrial sludge or materials derived from industrial sludge.

(2) This part applies to industrial sludge applied to the land.

(3) [Reserved]

(4) This part applies to land where industrial sludge is applied and land disposal sites.

(5) The requirements incorporated into this regulation pursuant to State Register Document 4444, including Appendix C, expire and are no longer effective five years from the State Register Document 4444 amendments' effective date.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

504.2. Compliance period.

(a) Compliance with the standards in this part shall be implemented in permits issued subsequent to the effective date of the regulation.

(b) [Reserved]

(c) [Reserved]

(d) [Reserved]

(e) Compliance with 504 Appendix C-PCB, shall be required upon publication of the revised regulation in the South Carolina State Register.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

504.3. Permits.

(a) The requirements in this part shall be implemented through a permit, with the exception of 504 Appendix C-PCB in accordance with 504.3(b):

(1) [Reserved]

(2) issued to any person who prepares, generates, or disposes of industrial sludge when the industrial sludge is applied to land, or

(3) issued under subtitle C of the Solid Waste Disposal Act; subpart C of the Safe Drinking Water Act; the Marine Protection, Research, and Sanctuaries Act of 1972; or the Clean Air Act.

(4) [Reserved]

(b) Direct Enforceability. In addition to any other requirement of this regulation or a permit, industrial sludge use via land application shall be in accordance with Appendix C-PCB. This includes but is not limited to: bulk sludge applied to agricultural land, forests or public contact sites; sludge sold or given away in a bag or other container for application to the land; domestic septage; reclamation sites; or other materials mixed with sludge before application.

(c) The requirements under this part may be addressed in permits issued to land appliers.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

504.4. Relationship to other regulations.

(a) Disposal of industrial sludge in a municipal solid waste landfill unit permitted under R.61-107 constitutes compliance with this regulation. Any person who prepares industrial sludge that is disposed in a municipal solid waste landfill unit shall ensure that the industrial sludge meets the requirements in R.61-107 concerning the quality of materials disposed in a municipal solid waste landfill unit. Disposal of industrial sludge in an industrial solid waste landfill unit complying with State Solid Waste regulations and requirements in permits constitutes compliance with this regulation.

(b) The disposal of industrial sludge involving the composting or co-composting of the industrial sludge with yard trash, land-clearing debris, or a combination of yard trash and land clearing debris shall comply with the requirements established by the Department in R.61-107. The submission and information requirements shall be determined by the Department.

(c) The disposal of industrial sludge utilizing an innovative and experimental solid waste management technology or process shall be permitted under R.61-107.

(d) The disposal of industrial sludge involving firing of industrial sludge in an industrial sludge incinerator or the heat drying/heat conditioning of the industrial sludge shall be permitted under R.61-62.

(e) [Reserved]

504.5. Additional or more stringent requirements.

(a) On a case-by-case basis, the Department may impose requirements in permits for the use or disposal of industrial sludge in addition to or more stringent than the requirements in this part when necessary to protect public health and the environment from any adverse effect of a pollutant in the industrial sludge.

(b) [Reserved]

(c) [Reserved]

(d) [Reserved]

504.6. Exclusions.

(a) Treatment processes. This part does not establish requirements for processes used to treat industrial wastewater or for processes used to treat industrial sludge prior to final use or disposal, except as provided in section 504.32 and section 504.33.

(b) Selection of a use or disposal practice. This part does not require the selection of an industrial sludge use or disposal practice. The determination of the manner in which industrial sludge is used or disposed is a determination by the permittee.

(c) Incineration of industrial sludge. This part does not establish requirements for industrial sludge that is incinerated, including industrial sludge incinerated with other wastes, or with fuels or other materials or for the incinerator in which industrial sludge and other wastes are co-fired.

(1) [Reserved]

(2) [Reserved]

(d) [Reserved]

(e) Hazardous industrial sludge. This part does not establish requirements for the use or disposal of industrial sludge determined to be hazardous in accordance with 40 CFR Part 261.

(f) Industrial sludge with high PCB concentration. This part does not establish requirements and no land application of these materials may occur for the use or disposal of industrial sludge with a concentration of polychlorinated biphenyls (PCBs) equal to or greater than 50 milligrams per kilogram of total solids (dry weight basis). Requirements for land application of sludges (including industrial sludge, sludges and septage that may be mixed with grease trap waste) with PCB concentrations of less than 50 milligrams per kilogram (mg/kg dry weight basis) or less than 50 parts per million (ppm) are included in 504 Appendix C-PCB.

(g) Incinerator ash. This part does not establish requirements for the use or disposal of ash generated during the firing of industrial sludge in an industrial sludge incinerator.

(h) Grit and screenings. This part does not establish requirements for the use or disposal of grit (e.g., sand, gravel, cinders, or other materials with a high specific gravity) or screenings (e.g., relatively large materials such as rags) generated during preliminary treatment of industrial wastewater in a treatment works.

(i) Drinking water treatment sludge. This part does not establish requirements for the use or disposal of sludge generated during the treatment of either surface water or ground water used for drinking water.

(j) [Reserved]

(k) Coal ash. This part does not establish requirements for the use or disposal of coal ash.

(l) Grease. This part does not establish requirements for the use or disposal of grease removed from grease traps at restaurants or other similar establishments.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

504.7. Requirement for a person who prepares industrial sludge.

Any person who prepares industrial sludge shall ensure that the applicable requirements in this part are met when the industrial sludge is applied to the land.

504.8. Sampling and analysis.

(a) Sampling. Representative samples of industrial sludge that is applied to the land shall be collected and analyzed. The Department may establish minimum requirements in permits for the proper method of sampling and analysis of industrial sludge.

(b) Methods. The materials listed below are incorporated by reference in this part. The materials are incorporated as they exist on the date of approval, and notice of any change in these materials will be published in the Federal Register. Methods in the materials listed below shall be used to analyze samples of industrial sludge, as appropriate.

(1) Enteric viruses. ASTM Designation: D 4994-89, "Standard Practice for Recovery of Viruses From Wastewater Sludges", 1992 Annual Book of ASTM Standards: Section 11 -Water and Environmental Technology, ASTM, 1916 Race Street, Philadelphia, PA 19103-1187.

(2) Fecal coliform. Part 9221 C and E. or Part 9222 D., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW, Washington, DC, 20005.

(3) Helminth ova. Yanko, W.A., "Occurrence of Pathogens in Distribution and Marketing Municipal Sludges", EPA 600/1-87-014, 1987. National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (PB 88-154273/AS).

(4) Inorganic pollutants. "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods", EPA Publication SW-846, Second Edition (1982) with Updates I (April 1984) and II (April 1985) and Third Edition (November 1986) with Revision I (December 1987), II, IIA and IIB. Second Edition and Updates I and II are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (PB-87-120-291). Third Edition and Revision I are available from Superintendent of Documents, Government Printing Office, 941 North Capitol Street, NE., Washington, DC, 20002 (Document Number 955-001-00000-1).

(5) Salmonella sp. bacteria. Part 9260 D., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW, Washington, DC, 20005; or Kenner, B.A. and H.P. Clark, "Detection and enumeration of Salmonel-

la and *Pseudomonas aeruginosa*”, *Journal of the Water Pollution Control Federation*, Vol. 46, no. 9, September 1974, pp. 2163-2171. Water Environment Federation, 601 Wythe Street, Alexandria, Virginia 22314.

(6) Specific oxygen uptake rate. Part 2710 B., “Standard Methods for the Examination of Water and Wastewater”, 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW, Washington, DC, 20005.

(7) Total, fixed, and volatile solids. Part 2540 G., “Standard Methods for the Examination of Water and Wastewater”, 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW, Washington, DC, 20005.

504.9. General definitions.

All terms not defined herein have the meaning given them in R.61-9.122, R.61-9.124, R.61-9.129, R.61-9.133, R.61-9.403, or R.61-9.505.

(a) “Apply industrial sludge or industrial sludge applied to the land” means land application of industrial sludge. Disposal of industrial sludge in a permitted solid waste unit or in accordance with a wastewater facility closeout plan approved pursuant to Regulation 61–82 is not land application.

(b) “Base flood” is a flood that has a one percent chance of occurring in any given year (i.e., a flood with a magnitude equalled once in 100 years).

(c) “Cover crop” is a small grain crop, such as oats, wheat, or barley; grasses; or other crop grown for agronomic use.

(d) “CWA” see R.61–9.122.2(b) Definitions.

(e) “Domestic septage” is either liquid or solid material removed from a septic tank, portable toilet, Type III marine sanitation device, or similar treatment works that receives only domestic sewage. Domestic septage does not include liquid or solid material removed from a septic tank, cesspool, or similar treatment works that receives industrial wastewater and does not include grease removed from a grease trap at a restaurant.

(f) “Domestic sewage” is waste and wastewater from humans, which is generated from industrial, commercial, or household operations that is discharged to or otherwise enters a treatment works.

(g) “Dry weight basis” means calculated on the basis of having been dried at 105 degrees Celsius until reaching a constant mass (i.e., essentially 100 percent solids content).

(h) “EPA” means the United States Environmental Protection Agency.

(i) “Feed crops” are crops produced primarily for consumption by animals.

(j) “Fiber crops” are crops such as flax and cotton.

(k) “Food crops” are crops consumed by humans. These include, but are not limited to, fruits, vegetables, and tobacco.

(l) “Ground water” is water below the land surface in the saturated zone.

(m) “Industrial wastewater” is wastewater generated in a commercial or industrial process (including waste and wastewater from humans when combined with commercial or industrial wastewater). By definition, waste or wastewater from humans not combined with commercial or industrial wastewater will be considered domestic sewage covered under R.61-9.503.

(n) “Industrial Septage” is either liquid or solid material removed from a septic tank that receives industrial wastewater. This does not include grease removed from grease traps at restaurants or other similar establishments.

(o) “Industrial Sludge” is solid, semi-solid, or liquid residue generated during the treatment of industrial wastewater in a treatment works. Industrial sludge includes, but is not limited to, industrial septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from industrial sludge. Industrial sludge does not include ash generated during the firing of industrial sludge in an industrial sludge incinerator or grit and screenings generated during preliminary treatment of industrial wastewater in a treatment works. Industrial sludge by definition does not include sludge covered under 40 CFR Part 503 or R.61–9.503.

(p) “Municipality” see R.61–9.122.2(b) Definitions. The definition includes under R.61–9.503 a special district created under State law, such as a water district, sewer district, sanitary district, utility

district, drainage district, or similar entity, or an integrated waste management facility as defined in section 201(e) of the CWA, as amended, that has as one of its principal responsibilities the treatment, transport, use, or disposal of sewage sludge.

(q) "Permitting authority" means the Department.

(r) "Person" see definition in R.61-9.122.2(b) Definitions.

(s) "Person who prepares industrial sludge" is the person who generates industrial sludge during the treatment of industrial wastewater in a treatment works and/or the person who derives a material from industrial sludge when the industrial sludge does not meet the ceiling concentrations in Table 1 of section 504.13; the pollutant concentrations Table 3 of section 504.13; the Class A pathogen requirements in section 504.32(a); one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement (as determined by the Department), or the sludge contains other pollutants that may cause a public health or environmental problem.

(t) "Place industrial sludge or industrial sludge placed" means disposal of industrial sludge on a land disposal site.

(u) "Pollutant" is an organic substance, an inorganic substance, a combination of organic and inorganic substances, or a pathogenic organism that, after discharge and upon exposure, ingestion, inhalation, or assimilation into an organism either directly from the environment or indirectly by ingestion through the food chain, could, on the basis of information available to the Department, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunction in reproduction), or physical deformations in either organisms or offspring of the organisms.

(v) "Pollutant limit" is a numerical value that describes the amount of a pollutant allowed per unit amount of industrial sludge (e. g., milligrams per kilogram of total solids); the amount of a pollutant that can be applied to a unit area of land (e. g., kilograms per hectare); or the volume of a material that can be applied to a unit area of land (e.g., gallons per acre).

(w) "Runoff" is rainwater, leachate, or other liquid that drains overland on any part of a land surface and runs off of the land surface.

(x) "State" means the State of South Carolina.

(y) "Store or storage of industrial sludge" is the placement of industrial sludge on land on which the industrial sludge remains for two years or less. This does not include the placement of industrial sludge on land for treatment.

(z) "Treat or treatment of industrial sludge" is the preparation of industrial sludge for final use or disposal. This includes, but is not limited to, thickening, stabilization, and dewatering of industrial sludge. This does not include storage of industrial sludge.

(aa) "Treatment works" is either a commercially, or privately owned device or system used to treat (including recycle and reclaim) either industrial, commercial sewage or a combination of domestic sewage and industrial waste of a liquid nature.

(bb) "Wetlands" see R.61-9.122.2(b) Definitions.

(cc) "Commercial Wastewater" is any other wastewater (other than process wastewater) which is not included under industrial wastewater and does not include domestic sewage (e.g. centralized special waste collection and processing).

(dd) "Person who applies industrial sludge" may be the generator, preparer, or a land applier.

PART B

LAND APPLICATION

504.10. Applicability.

(a) This part applies to any person who prepares industrial sludge that is applied to the land, to any person who applies industrial sludge to the land, to industrial sludge applied to the land, and to the land on which industrial sludge is applied.

(b) Bulk industrial sludge

(1) [Reserved]

(2) The Department may apply any or all of the general requirements in section 504.12 and the management practices in section 504.14 to bulk industrial sludge meeting the ceiling concentrations in Table 1 of section 504.13 and the pollutant concentrations in Table 3 of section 504.13; the Class A pathogen requirements in section 504.32(a), and one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement (as determined by the Department), on a case-by-case basis after determining that the general requirements or management practices are needed to protect public health and the environment from any reasonably anticipated adverse effect that may occur from any pollutant in the bulk industrial sludge.

(c)(1) [Reserved]

(2) The Department may apply any or all of the general requirements in section 504.12 and the management practices in section 504.14 to a derived bulk material meeting the ceiling concentrations in Table 1 of section 504.13 and the pollutant concentrations in Table 3 of section 504.13; the Class A pathogen requirements in section 504.32(a) and one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement (as determined by the Department), on a case-by-case basis after determining that the general requirements or management practices are needed to protect public health and the environment from any reasonably anticipated adverse effect that may occur from any pollutant in the bulk industrial sludge.

(d) The requirements in this part may be applied by the Department, on a case-by-case basis, when a bulk material derived from industrial sludge is applied to the land if the industrial sludge from which the bulk material is derived meets the ceiling concentrations in Table 1 of section 504.13; the pollutant concentrations in Table 3 of section 504.13; the Class A pathogen requirements in section 504.32(a); one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement (as determined by the Department), and does not contain other pollutants that may cause a public health or environmental problem.

(e) Industrial sludge sold or given away in a bag or other container for application to the land. The general requirements in section 504.12 and the management practices in section 504.14 do not apply, except for section 504.12(o), section 504.12(p), section 504.12(q), and section 504.14(e), when industrial sludge is sold or given away in a bag or other container for application to the land if the industrial sludge sold or given away in a bag or other container for application to the land meets the ceiling concentrations in Table 1 of section 504.13; the pollutant concentrations Table 3 of section 504.13; the Class A pathogen requirements in section 504.32(a), and one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement (as determined by the Department).

(f) The general requirements in section 504.12 and the management practices in section 504.14 do not apply, except for section 504.12(o), section 504.12(p), section 504.12(q), and section 504.14(e), when a material derived from industrial sludge is sold or given away in a bag or other container for application to the land if the derived material meets the ceiling concentrations in Table 1 of section 504.13; the pollutant concentrations in Table 3 of section 504.13; the Class A pathogen requirements in section 504.32(a), and one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement (as determined by the Department).

(g) The requirements in this part do not apply, except for section 504.14(e), when a material derived from industrial sludge is sold or given away in a bag or other container for application to the land if the industrial sludge from which the material is derived meets the ceiling concentrations in Table 1 of section 504.13; the pollutant concentrations in Table 3 of section 504.13; the Class A pathogen requirements in section 504.32(a); one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement (as determined by the Department), and does not contain other pollutants that may cause a public health or environmental problem.

(h) If other materials are mixed with the industrial sludge, the final product must meet the applicable requirements related to pollution limits (in section 504.13), pathogen reduction (in section 504.15(a)) when pathogens are expected to be present and vector attraction reduction (in section

504.15(c)) when the industrial sludge is expected to attract vectors, after the materials have been added to the industrial sludge.

504.11. Special definitions.

(a) "Agricultural land" is land on which a food crop, a feed crop, or a fiber crop is grown. This includes range land and land used as pasture.

(b) "Agronomic rate" is the whole sludge application rate (dry weight basis) designed: (1) to provide the amount of nitrogen needed by the food crop, feed crop, fiber crop, cover crop, or vegetation grown on the land and (2) to minimize the amount of nitrogen in the industrial sludge that passes below the root zone of the crop or vegetation grown on the land to the ground water and (3) to provide the amount of other organic and inorganic plant nutrients which promote crop or vegetative growth, such as calcium-carbonate equivalency.

(c) "Annual pollutant loading rate" is the maximum amount of a pollutant that can be applied to a unit area of land during a 365 day period.

(d) "Annual whole sludge application rate" is the maximum amount of industrial sludge (dry weight basis) that can be applied to a unit area of land during a 365 day period.

(e) "Bulk industrial sludge" is industrial sludge that is not sold or given away in a bag or other container for application to the land.

(f) "Cumulative pollutant loading rate" is the maximum amount of an inorganic pollutant that can be applied to an area of land.

(g) "Forest" is a tract of land thick with trees and underbrush.

(h) "Land application" is the spraying or spreading of industrial sludge onto the land surface; the injection of industrial sludge below the land surface; or the incorporation of industrial sludge into the soil so that the industrial sludge can either condition the soil or fertilize crops or vegetation grown in the soil.

(i) "Monthly average" is the arithmetic mean of all measurements taken during the month.

(j) "Other container" is either an open or closed receptacle. This includes, but is not limited to, a bucket, a box, a carton, and a vehicle or trailer with a load capacity of one metric ton or less.

(k) "Pasture" is land on which animals feed directly on feed crops such as legumes, grasses, grain stubble, or stover.

(l) "Public contact site" is land with a high potential for contact by the public. This includes, but is not limited to, public parks, ball fields, cemeteries, plant nurseries, turf farms, and golf courses.

(m) "Range land" is open land with indigenous vegetation.

(n) "Reclamation site" is drastically disturbed land that is reclaimed using industrial sludge. This includes, but is not limited to, strip mines and construction sites.

504.12. General requirements.

(a) No person shall apply industrial sludge to the land except in accordance with the requirements in this part.

(b) No person shall apply bulk industrial sludge subject to the cumulative pollutant loading rates in section 504.13(b)(2) to agricultural land, forest, a public contact site, or a reclamation site if any of the cumulative pollutant loading rates in section 504.13(b)(2) has been reached.

(c) [Reserved]

(d) The person who prepares bulk industrial sludge that is applied to agricultural land, forest, a public contact site, or a reclamation site shall provide the person who applies the bulk industrial sludge written notification of the concentration of total nitrogen (as N on a dry weight basis) in the bulk industrial sludge.

(e)(1) The person or the permittee who applies industrial sludge to the land shall obtain information needed to comply with the requirements in this part.

(2)(i) Before bulk industrial sludge subject to the cumulative pollutant loading rates in section 504.13(b)(2) is applied to the land, the person who proposes to apply the bulk industrial sludge shall

contact the Department to determine whether bulk industrial sludge subject to the cumulative pollutant loading rates in section 504.13(b)(2) has been applied to the site.

(ii) If bulk industrial sludge subject to the cumulative pollutant loading rates in section 504.13(b)(2) has not been applied to the site, the cumulative amount for each pollutant listed in Table 2 of section 504.13 may be applied to the site in accordance with section 504.13(a)(2)(i).

(iii) If bulk industrial sludge subject to the cumulative pollutant loading rates in section 504.13(b)(2) has been applied to the site and the cumulative amount of each pollutant applied to the site in the bulk industrial sludge is known, the cumulative amount of each pollutant applied to the site shall be used to determine the additional amount of each pollutant that can be applied to the site in accordance with section 504.13(a)(2)(i).

(iv) If bulk industrial sludge subject to the cumulative pollutant loading rates in section 504.13(b)(2) has been applied to the site since July 20, 1993 and the cumulative amount of each pollutant applied to the site in the bulk industrial sludge since that date is not known, an additional amount of each pollutant shall not be applied to the site in accordance with section 504.13(a)(2)(i).

(f) When a person who prepares bulk industrial sludge provides the bulk industrial sludge to a person who applies the bulk industrial sludge to the land, the person who prepares the bulk industrial sludge shall provide the person who applies the industrial sludge notice and necessary information to comply with the requirements in this part.

(g) When a person who prepares industrial sludge provides the industrial sludge to another person who prepares the industrial sludge, the person who provides the industrial sludge shall provide the person who receives the industrial sludge notice and necessary information to comply with the requirements in this part.

(h) The person who applies bulk industrial sludge to the land shall provide the owner or lease holder of the land on which the bulk industrial sludge is applied notice and necessary information to comply with the requirements in this part.

(i) Any person who prepares outside the State bulk industrial sludge that is applied to land in South Carolina or who prepares in the State bulk industrial sludge that is applied to land in another state shall provide written notice, prior to the initial application of bulk industrial sludge to the land application site by the applicator, to the Department. For bulk industrial sludge prepared outside the State and applied to land in the state, the notice shall include:

(1) The location, by either street address or latitude and longitude, of each land application site.

(2) The approximate time period bulk industrial sludge will be applied to the site.

(3) The name, address, telephone number, and National Pollutant Discharge Elimination System permit number (if appropriate) for the person who prepares the bulk industrial sludge.

(4) The name, address, telephone number, and National Pollutant Discharge Elimination System permit number (if appropriate) for the person who will apply the bulk industrial sludge.

For use or land disposal outside the state, the notice shall include information showing the acceptance of the bulk industrial sludge for land application by the appropriate person(s). This information may be in the form of copies of permits or approvals, letters from the appropriate permitting authority, or an acceptance letter from the person agreeing to land apply the bulk industrial sludge.

(j) Any person who applies bulk industrial sludge subject to the cumulative pollutant loading rates in section 504.13(b)(2) to the land shall provide written notice, prior to the initial application of bulk industrial sludge to a land application site by the applicator, to the Department and the Department shall retain and provide access to the notice. The notice shall include:

(1) The location, by either street address or latitude and longitude, of the land application site.

(2) The name, address, telephone number, and National Pollutant Discharge Elimination System permit number (if appropriate) of the person who will apply the bulk industrial sludge.

(k) The Department may establish additional restrictions in permits based upon soil and groundwater conditions to insure protection of the groundwater and surface water of the State. Criteria may include but is not limited to soil permeability, clay content, and depth to groundwater.

(l) The Department may establish in permits the application buffer setbacks for property boundaries, roadways, residential developments, dwellings, water wells, drainageways, and surface water as deemed necessary to protect public health and the environment. Factors taken into consideration in the establishment of setbacks would indicate sludge application method, adjacent land usage, public access, aerosols, runoff prevention, and adjacent groundwater usage.

(m) The Department may establish permit conditions to require that the agronomic rate of sludge application remain consistent with the lime and fertilizer requirements for the cover, feed, food, and fiber crops based on published lime and fertilizer recommendations (such as "Nutrient Management for South Carolina", Cooperative Extension Service, Clemson University, EC 476).

(n) The Department may establish minimum requirements in permits for soil and/or groundwater monitoring, for bulk application sites, to verify compliance with this Regulation. Factors taken into consideration in the establishment of soil and groundwater monitoring will include groundwater depth, operation flexibility, application frequency, type of sludge, size of application area, and loading rate.

(1) The Department may establish pre-application and post-application site monitoring requirements in permits for limiting nutrients or limiting pollutants as determined by the Department.

(2) The Department may establish permit conditions which require the permittee to reduce, modify, or eliminate the sludge applications based on the results of this data.

(3) The Department may modify or revoke and reissue or revoke the permit based on this data.

(o) Any person who prepares bulk industrial sludge and applies it to the land, or provides the bulk industrial sludge to a person who applies the bulk industrial sludge, or provides the bulk industrial sludge to another person who treats or processes the bulk industrial sludge prior to land applying it, shall apply to the Department for a permit to land apply the bulk industrial sludge and shall receive a valid permit from the Department prior to the actual application. Any person who prepares industrial sludge and sells or gives it away in a bag or other container, or provides the industrial sludge to a person who sells or gives it away in a bag or other container, or provides the industrial sludge to another person who treats, mixes, alters or processes the industrial sludge for sale or gives it away in a bag or other container shall receive a valid permit from the Department prior to the sale or distribution of the material. The application for land applying sludges, or bagging, or selling, or giving away sludges will be in the form of a report prepared by a qualified Professional Engineer, qualified soil scientist, qualified agronomist, or other qualified individual. This report shall at a minimum contain:

(1) Sludge generator information shall be included as follows:

(i) Facility name, address, telephone number, county, and NPDES or other permit number (if applicable).

(ii) Plant discharge capacity in millions of gallons per day (MGD) (if applicable), amount of sludge generated per year (dry weight basis), description of sludge storage and amount of stockpiled sludge (if applicable), description of sludge treatment, and current method of disposal.

(2) Sludge analysis information shall be included as follows:

(i) Test results or rationale that demonstrates the non-hazardous nature of the sludge to the satisfaction of the Department.

(ii) Name, address, lab certification number, and telephone number of the laboratory conducting the analyses.

(iii) Sludge shall be analyzed for:

(A) Total solids (mg/l) and volatile solids (mg/kg).

(B) Nutrients (dry weight basis).

(1) Total Kjeldahl Nitrogen (mg/kg).

(2) Total inorganic nitrogen (mg/kg).

(3) Total ammonia nitrogen (mg/kg) and Total nitrate nitrogen (mg/kg).

(4) Total phosphorus (mg/kg).

(5) Total potassium (mg/kg).

(6) Calcium Carbonate Equivalency (if industrial sludge is alkaline stabilized).

(C) Pollutants (dry weight basis).

(1) Arsenic (mg/kg).

(2) Cadmium (mg/kg).

(3) Copper (mg/kg).

(4) lead (mg/kg).

(5) Mercury (mg/kg).

(6) Molybdenum (mg/kg).

(7) Nickel (mg/kg).

(8) Selenium (mg/kg).

(9) Zinc (mg/kg).

(10) Other compounds required by the permit or any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required to be monitored for in the industrial sludge (if applicable).

(D) If an analysis must be performed on the sludge to document compliance with pathogen reduction requirements and vector attraction reduction requirements, these analyses shall be submitted in the report along with an explanation.

(iv) Sludge handling and application information shall be included as follows:

(A) Description of method of transport (if applicable).

(B) The time of year of the sludge application and how it relates to crop planting and harvesting schedule (if applicable).

(C) Name, address, and telephone number of the contractor applying the sludge (if applicable).

(D) Type of equipment used to spread the sludge (if applicable).

(v) Application site information shall be included (as appropriate):

(A) Name and address of landowner and location of application site(s).

(B) Name and address of the party managing the site(s) (if different than the owner).

(C) Previous years when sludge was applied and application amounts (when sludge was applied under permits issued by the Department).

(D) Additional soil additives applied on the site(s).

(E) Description of method to control access to the site(s).

(F) Method of odor control (if applicable).

(G) Site location(s) on maps including:

(1) Topography and drainage characteristics.

(2) Adjacent land usage and location of inhabited dwellings.

(3) All water supply wells on adjacent property.

(4) Adjacent surface water bodies.

(5) Sludge use boundaries and buffer zones.

(6) Location of proposed groundwater monitoring wells (if applicable).

(7) Right-of-Ways

(8) Soil test, description of soil types, and boring locations (if applicable).

(vi) Site Monitoring Plan information shall be included as follows (when required):

(A) Groundwater monitoring information (if applicable).

(B) Soil monitoring methods and locations (if applicable).

(C) Surface water sampling methods and locations (if applicable).

(D) Metals testing, if required, due to previous application(s) (if applicable).

(E) Method to insure that the soil pH will remain within agronomic ranges during the life of the site (e.g. alkaline stabilized sludge projects).

(vii) The Department, at its discretion, may identify specific application information that may be excluded from a submission if the applicant has an alternate permitted method of disposal for the bulk industrial sludge (e.g. a municipal or industrial solid waste landfill disposal permit). The Department, may allow an applicant to exclude application information from a submission of a modified application or addition to a previously permitted activity.

(p) The Department, at its discretion, may request of an applicant any additional information deemed necessary to complete or correct deficiencies in the sludge disposal permit application before processing the application or issuing or denying the issuance of a permit.

(q) Applicants for land application of sludge must submit their applications on permit application forms if designated by the Department.

(r) If a deleterious impact to the groundwaters of the State from industrial sludge use or disposal practices is documented, through groundwater monitoring levels exceeding the standards set forth in R.61-68 or a significant adverse trend occurs, then it will be the obligation of the generator/preparer of the industrial sludge as directed by the Department to conduct an investigation to determine the vertical and horizontal extent of groundwater impact. The Department may require remediation of the groundwater to within acceptable levels for groundwater as set forth in R.61-68.

504.13. Pollutant limits.

(a) Industrial sludge

(1) Bulk industrial sludge or industrial sludge sold or given away in a bag or other container shall not be applied to the land if the concentration of any pollutant in the industrial sludge exceeds the ceiling concentration for the pollutant in Table 1 of section 504.13. However, the Department may allow, on a case-by-case basis, the application of bulk industrial sludge to the land when the concentration of any pollutant in the industrial sludge exceeds the ceiling concentration for the pollutant in Table 1 of section 504.13 provided the application rate is at or below the agronomic rates as defined by section 504.11(b). It must be clearly demonstrated to the Department's satisfaction that no adverse impact to public health or the environment will occur in these situations. Additional requirements in permits on management, operational standards, site restrictions, frequency of monitoring, recordkeeping, and reporting may be imposed in these situations.

(2) If bulk industrial sludge is applied to agricultural land, forest, a public contact site, or a reclamation site, either:

(i) the cumulative loading rate for each pollutant shall not exceed the cumulative pollutant loading rate for the pollutant in Table 2 of section 504.13; or

(ii) the concentration of each pollutant in the industrial sludge shall not exceed the concentration for the pollutant in Table 3 of section 504.13.

(3) If bulk industrial sludge is applied to a lawn or a home garden, the concentration of each pollutant in the industrial sludge shall not exceed the concentration for the pollutant in Table 3 of section 504.13.

(4) If industrial sludge is sold or given away in a bag or other container for application to the land, either:

(i) the concentration of each pollutant in the industrial sludge shall not exceed the concentration for the pollutant in Table 3 of section 504.13, or

(ii) the product of the concentration of each pollutant in the industrial sludge and the annual whole sludge application rate for the industrial sludge shall not cause the annual pollutant loading rate for the pollutant in Table 4 of section 504.13 to be exceeded. The procedure used to determine the annual whole sludge application rate is presented in appendix A of this part.

(5) The Department may determine on a case-by-case basis that an industrial sludge due to its pollutant content or pollutant concentration may not be land applied or sold or given away.

(b) Pollutant concentrations and loading rates -industrial sludge.

(1) Ceiling concentrations

TABLE 1 OF SECTION 504.13—CEILING
CONCENTRATIONS

Pollutant	Ceiling Concentration (milligrams per kilogram) Dry weight basis
Arsenic	75
Cadmium	85
Copper	4300
Lead	840
Mercury	57
Molybdenum	75
Nickel	420
Selenium	100
Zinc	7500

(2) Cumulative pollutant loading rates

TABLE 2 OF SECTION 504.13—CUMULATIVE
POLLUTANT LOADING RATES

Pollutant	Cumulative Pollutant Loading Rate (kilograms per hectare)
Arsenic	41
Cadmium	39
Copper	1500
Lead	300
Mercury	17
Nickel	420
Selenium	100
Zinc	2800

(3) Pollutant concentrations

TABLE 3 OF SECTION 504.13—POLLUTANT
CONCENTRATIONS

Pollutant	Monthly Average Concentrations (milligrams per kilogram) Dry weight basis
Arsenic	41
Cadmium	39
Copper	1500
Lead	300
Mercury	17
Nickel	420
Selenium	100
Zinc	2800

(4) Annual pollutant loading rates

TABLE 4 OF SECTION 504.13—ANNUAL POLLUTANT
LOADING RATES

Pollutant	Annual Pollutant Loading Rate (kilograms per hectare per 365 day period)
Arsenic	2.0
Cadmium	1.9
Copper	75
Lead	15
Mercury	0.85
Nickel	21
Selenium	5.0
Zinc	140

(c) [Reserved]

(d) Additional parameters may be required, from the application information or subsequent monitoring, in a permit thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR 136; Subchapter N (40 CFR Part 400 through 402 and 404 through 471)) may be required to be monitored (in permits) for in the industrial sludge.

504.14. Management practices.

(a) [Reserved]

(b) Bulk industrial sludge shall not be applied to agricultural land, forest, a public contact site, or a reclamation site that is flooded, frozen, or snow-covered so that the bulk industrial sludge enters a wetland or other waters of the State, as defined in R.61-9.122.2, except as provided in a permit issued pursuant to section 402 or 404 of the CWA.

(c) Bulk industrial sludge shall not be applied to agricultural land, forest, or a reclamation site that is 10 meters or less from waters of the State, as defined in R.61-9.122.2, unless otherwise specified by the Department.

(d) Bulk industrial sludge shall be applied to agricultural land, forest, a public contact site, or a reclamation site at a whole sludge application rate that is equal to or less than the agronomic rate for the bulk industrial sludge, unless, in the case of a reclamation site, otherwise specified by the Department.

(e) Either a label shall be affixed to the bag or other container in which industrial sludge that is sold or given away for application to the land, or an information sheet shall be provided to the person who receives industrial sludge sold or given away in an other container for application to the land. The label or information sheet shall contain the following information:

(1) The name and address of the person who prepared the industrial sludge that is sold or given away in a bag or other container for application to the land.

(2) A statement that application of the industrial sludge to the land is prohibited except in accordance with the instructions on the label or information sheet.

(3) The annual whole sludge application rate for the industrial sludge that does not cause any of the annual pollutant loading rates in Table 4 of section 504.13 to be exceeded.

(4) The annual whole sludge application rate for the industrial sludge that does not cause the agronomic rate for appropriate crops to be exceeded (to be presented in tons/acre or other units approved by the Department).

(f) Screening of industrial septage is required prior to land application. The screenings must be disposed of properly (e.g. municipal waste landfill).

504.15. Operational standards – pathogens and vector attraction reduction.

(a) Pathogens -industrial sludge

(1) If pathogens are expected to be present, the Class A pathogen requirements in section 504.32(a) or the Class B pathogen requirements and site restrictions in section 504.32(b) shall be met when bulk industrial sludge is applied to agricultural land, forest, a public contact site, or a reclamation site.

(2) If pathogens are expected to be present, the Class A pathogen requirements in section 504.32(a) shall be met when bulk industrial sludge is applied to a lawn or a home garden.

(3) If pathogens are expected to be present, the Class A pathogen requirements in section 504.32(a) shall be met when industrial sludge is sold or given away in a bag or other container for application to the land.

(b) [Reserved]

(c) Vector attraction reduction -industrial sludge

(1) When the industrial sludge is expected to attract vectors, one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8); a requirement that is equivalent to one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504(b)(8), as determined by the Department; or the vector attraction reduction requirements in section 504.33(b)(9) or (b)(10) shall be met when bulk industrial sludge is applied to agricultural land, forest, a public contact site, or a reclamation site.

(2) When the industrial sludge is expected to attract vectors, one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement, as determined by the Department, shall be met when bulk industrial sludge is applied to a lawn or a home garden.

(3) When the industrial sludge is expected to attract vectors, one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement, as determined by the Department, shall be met when industrial sludge is sold or given away in a bag or other container for application to the land.

(d) [Reserved]

504.16. Frequency of monitoring.

(a) Industrial sludge

(1) The frequency of monitoring for the pollutants listed in Table 1, Table 2, Table 3 and Table 4 of section 504.13 and other pollutants listed in a NPDES or land application permit; when pathogens are expected to be present, the pathogen density requirements in section 504.32(a) and in section 504.32(b)(2) through section 504.32(b)(4); and when the industrial sludge is expected to attract vectors, the vector attraction reduction requirements section 504.33(b)(1) through section 504.33(b)(4) and section 504.33(b)(6) through section 504.33(b)(8) shall be the frequency in Table 1 of section 504.16.

TABLE 1 OF SECTION 504.16—FREQUENCY OF MONITORING—LAND APPLICATION

Amount of industrial sludge* (metric tons per 365 day period)	Frequency
Greater than zero but less than 1,500.	Once per quarter** (four times per year)
Equal to or greater than 1,500 but less than 15,000.	Once per 60 days (six times per year)
Equal to or greater than 15,000.	Once per month (12 times per year)

* Either the amount of bulk industrial sludge applied to the land or the amount of industrial sludge received by a person who prepares industrial sludge that is sold or given away in a bag or other container for application to the land (dry weight basis).

** Facilities which generate less than 290 metric tons of sludge per year and land apply the sludge once per year or less only have to monitor once per year.

(2) After the industrial sludge has been monitored for two years at the frequency in Table 1 of section 504.16, the Department may reduce the frequency of monitoring for pollutant concentrations, for the pathogen density requirements in section 504.32(a)(5)(ii) and section 504.32(a)(5)(iii), if

applicable, and for the vector attraction reduction requirements section 504.33(b)(1) through section 504.33(b)(8), if applicable.

(b) [Reserved]

504.17. Recordkeeping.

(a) Industrial sludge

(1) The person who prepares the industrial sludge in section 504.10(b)(2) or in section 504.10(e) shall develop the following information and shall retain the information for five years:

(i) The concentration of each pollutant listed in Table 3 of section 504.13 and other pollutants listed in a NPDES or land application permit in the industrial sludge.

(ii) [Reserved]

(iii) If pathogens are expected to be present, a description of how the Class A pathogen requirements in section 504.32(a) are met.

(iv) When the industrial sludge is expected to attract vectors, a description of how one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement, as determined by the Department, is met.

(2) The person who derives the material in section 504.10(f) shall develop the following information and shall retain the information for five years:

(i) The concentration of each pollutant listed in Table 3 of section 504.13 and other pollutants listed in a NPDES or land application permit in the material.

(ii) [Reserved]

(iii) If pathogens are expected to be present, a description of how the Class A pathogen requirements in section 504.32(a) are met.

(iv) When the industrial sludge is expected to attract vectors, a description of how one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement, as determined by the Department, is met.

(3) If the pollutant concentrations in section 504.13(b)(3), the Class A pathogen requirements in section 504.32(a), and the vector attraction reduction requirements in either section 504.33(b)(9) or section 504.33(b)(10) are met when bulk industrial sludge is applied to agricultural land, forest, a public contact site, or a reclamation site:

(i) The person who prepares the bulk industrial sludge shall develop the following information and shall retain the information for five years.

(A) The concentration of each pollutant listed in Table 3 of section 504.13 and other pollutants listed in a NPDES or land application permit in the bulk industrial sludge.

(B) [Reserved]

(C) If pathogens are expected to be present, a description of how the pathogen requirements in section 504.32(a) are met.

(ii) The person who applies the bulk industrial sludge shall develop the following information and shall retain the information for five years.

(A) [Reserved]

(B) A description of how the management practices in section 504.14 are met for each site on which bulk industrial sludge is applied.

(C) If the industrial sludge is expected to attract vectors, a description of how the vector attraction reduction requirements in either section 504.33(b)(9) or section 504.33(b)(10) are met for each site on which bulk industrial sludge is applied.

(4) If the pollutant concentrations in section 504.13(b)(3) and the Class B pathogen requirements in section 504.32(b) are met when bulk industrial sludge is applied to agricultural land, forest, a public contact site, or a reclamation site:

(i) The person who prepares the bulk industrial sludge shall develop the following information and shall retain the information for five years:

- (A) The concentration of each pollutant listed in Table 3 of section 504.13 and other pollutants listed in a NPDES or land application permit in the bulk industrial sludge.
 - (B) [Reserved]
 - (C) If pathogens are expected to be present, a description of how the Class B pathogen requirements in section 504.32(b) are met.
 - (D) When one of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8) is met, a description of how the vector attraction reduction requirement is met.
- (ii) The person who applies the bulk industrial sludge shall develop the following information and shall retain the information for five years.
- (A) [Reserved]
 - (B) A description of how the management practices in section 504.14 are met for each site on which bulk industrial sludge is applied.
 - (C) A description of how the site restrictions in section 504.32(b)(5) are met for each site on which bulk industrial sludge is applied.
 - (D) When the vector attraction reduction requirement in either section 504.33(b)(9) or section 504.33(b)(10) is met, a description of how the vector attraction reduction requirement is met.
- (5) If the requirements in section 504.13(a)(2)(i) are met when bulk industrial sludge is applied to agricultural land, forest, a public contact site, or a reclamation site:
- (i) The person who prepares the bulk industrial sludge shall develop the following information and shall retain the information for five years.
 - (A) The concentration of each pollutant listed in Table 1 of section 504.13 and other pollutants listed in a NPDES or land application permit in the bulk industrial sludge.
 - (B) [Reserved]
 - (C) If pathogens are expected to be present, a description of how the pathogen requirements in either section 504.32(a) or section 504.32(b) are met.
 - (D) When one of the vector attraction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement, as determined by the Department, is met, a description of how the vector attraction requirement is met.
 - (ii) The person who applies the bulk industrial sludge shall develop the following information, retain the information in section 504.17(a)(5)(ii)(A) through section 504.17(a)(5)(ii)(G) indefinitely, and retain the information in section 504.17(a)(5)(ii)(H) through section 504.17(a)(5)(ii)(M) for five years.
 - (A) The location, by either street address or latitude and longitude, of each site on which bulk industrial sludge is applied.
 - (B) The number of hectares in each site on which bulk industrial sludge is applied.
 - (C) The date bulk industrial sludge is applied to each site.
 - (D) The cumulative amount of each pollutant (i.e., kilograms) listed in Table 2 of section 504.13 in the bulk industrial sludge applied to each site, including the amount in section 504.12(e)(2)(iii).
 - (E) The amount of industrial sludge (i.e., metric tons) applied to each site.
 - (F) [Reserved]
 - (G) A description of how the requirements to obtain information in section 504.12(e)(2) are met.
 - (H) [Reserved]
 - (I) A description of how the management practices in section 504.14 are met for each site on which bulk industrial sludge is applied.
 - (J) [Reserved]

(K) A description of how the site restrictions in section 504.32(b)(5) are met for each site on which Class B bulk industrial sludge is applied.

(L) [Reserved]

(M) If the vector attraction reduction requirements in either section 504.33(b)(9) or section 504.33(b)(10) are met, a description of how the requirements are met.

(6) If the requirements in section 504.13(a)(4)(ii) are met when industrial sludge is sold or given away in a bag or other container for application to the land, the person who prepares the industrial sludge that is sold or given away in a bag or other container shall develop the following information and shall retain the information for five years:

(i) The annual whole sludge application rate for the industrial sludge that does not cause the annual pollutant loading rates in Table 4 of section 504.13 to be exceeded.

(ii) The concentration of each pollutant listed in Table 4 of section 504.13 and other pollutants listed a NPDES or land application permit in the industrial sludge.

(iii) [Reserved]

(iv) If pathogens are expected to be present, a description of how the Class A pathogen requirements in section 504.32(a) are met.

(v) When the industrial sludge is expected to attract vectors, a description of how one of the vector attraction requirements in section 504.33(b)(1) through section 504.33(b)(8) or an equivalent vector attraction reduction requirement, as determined by the Department, is met.

(b) [Reserved]

504.18. Reporting.

(a) Any generator of industrial sludge that is applied to the land, any person who prepares industrial sludge that is applied to the land, or any person who applies industrial sludge to the land shall submit the following information to the Department:

(1) The information in section 504.17(a), except the information in section 504.17(a)(3)(ii), section 504.17(a)(4)(ii) and in section 504.17(a)(5)(ii), for the appropriate requirements on or before February 19 of each year, for the period of January 1 through December 31 of the previous calendar year.

(2) The information in section 504.17(a)(5)(ii)(A) through section 504.17(a)(5)(ii)(G) on or before February 19 of each year, for the period of January 1 through December 31 of the previous calendar year when 90 percent or more of any of the cumulative pollutant loading rates in Table 2 of section 504.13 is reached at a site.

(b) [Reserved]

PART C LAND DISPOSAL

504.20. Applicability.

(a) This part applies to any person who prepares industrial sludge that is placed on a land disposal site, to the owner/operator of a land disposal site, to industrial sludge placed on a land disposal site, and to a land disposal site.

(b) This part does not apply to industrial sludge stored on the land or to the land on which industrial sludge is stored. It also does not apply to industrial sludge that remains on the land for longer than two years when the person who prepares the industrial sludge demonstrates that the land on which the industrial sludge remains is not an active industrial sludge unit. The demonstration shall include the following information, which shall be retained by the person who prepares the industrial sludge for the period that the industrial sludge remains on the land:

(1) The name and address of the person who prepares the industrial sludge.

(2) The name and address of the person who either owns the land or leases the land.

(3) The location, by either street address or latitude and longitude, of the land.

(4) An explanation of why industrial sludge needs to remain on the land for longer than two years prior to final use or disposal.

(5) The approximate time period when the industrial sludge will be used or disposed.

(c) This part does not apply to industrial sludge treated on the land or to the land on which industrial sludge is treated.

(d) This part does not apply to industrial sludge that is allowed to remain in a closed wastewater treatment facility when the facility is closed in accordance with Regulation 61-82. For example, this part does not apply when the Department has approved a wastewater treatment lagoon closure which includes draining the lagoon and then leaving the sludge in place and disking it into the soil, and then filling the lagoon with suitable material or leveling the dikes.

504.21. Special definitions.

(a) "Active industrial sludge unit" is an industrial sludge unit that has not closed.

(b) "Industrial sludge unit" is land on which industrial sludge is placed for final disposal. This does not include land on which industrial sludge is either stored or treated. Land does not include waters of the State, as defined in R.61-9.122.2, and does not include beneficial use activities covered under Part B which comply with agronomic rate requirements and metals limitations or other bulk industrial sludge land application activities permitted on a case-by-case basis under Part B (504.13(a)(1)).

(c) "Land disposal site" is an area of land that contains one or more active industrial sludge units.

504.22. General requirements.

(a) No person shall place industrial sludge on an active industrial sludge unit unless the requirements in this part are met.

(1) The following activities or conditions constitute land disposal (unless the Department has issued a permit or granted approval for the specific activity):

(i) Storage of industrial sludge in sludge storage units, excluding sludge treatment, for more than two (2) years constitutes land disposal.

(ii) The design storage capacity of industrial sludge storage units will not be permitted to exceed two (2) years at the treatment plant design conditions, or

(iii) Accumulation of industrial sludge in a treatment works to greater than fifty (50) percent of the capacity of the unit or to an average depth of greater than design depth constitutes land disposal of sludge under this regulation, or

(iv) Accumulation of industrial sludge that adversely impacts the overall treatment works operation and maintenance or results in an excessive sludge inventory, may result in a facility being identified as a land disposal site.

(2) For any facility, except a landfill or a sludge only monofill, meeting the definition of a land disposal site on the date of this regulation, either sufficient amount of sludge must be removed from the facility in order to change the facility's classification, or a report detailing final closure must be submitted to the Bureau of Water, Department of Health and Environmental Control or an application for permitting under Solid Waste Regulations must be submitted to the Bureau of Land and Waste Management, Department of Health and Environmental Control. Either the sludge removal must be accomplished within one year after the date of this regulation or the closeout report or permit application must be submitted to the Department within one (1) year after the date of this regulation. If closure is the selected option, the plan must provide a schedule showing how the closure will be accomplished. The land disposal site must be either closed under Regulation 61-82 or permitted by Solid Waste Management Regulations by June 28, 2001. Facilities will be in compliance with this section if a timely and complete application for closure or permit is made and through no fault of the applicant a closure approval or permit has not been issued.

(3) [Reserved]

(b) [Reserved]

(c) [Reserved]

(d) The owner of a land disposal site in existence on or before the effective date of this regulation and then closed shall provide written notification to the subsequent owner of the site that industrial sludge was placed on the land.

(e) Land disposal of sludge in a landfill, including sludge only monofills, shall comply with State Solid Waste regulations and requirements in permits.

(f) [Reserved]

(g) [Reserved]

(h) New land disposal sites must be permitted under the provisions of Solid and Hazardous Waste Regulations prior to operation.

PART D PATHOGENS AND VECTOR ATTRACTION REDUCTION

504.30. Scope.

(a) This part contains the requirements for an industrial sludge to be classified either Class A or Class B with respect to pathogens when pathogens are expected to be present. Industrial sludge with no pathogens present or expected to be present will be classified as Class A with respect to pathogens.

(b) This part contains the site restrictions for land on which a Class B industrial sludge is applied.

(c) [Reserved]

(d) This part contains alternative vector attraction reduction requirements for industrial sludge that is applied to the land.

504.31. Special definitions.

(a) "Aerobic digestion" is the biochemical decomposition of organic matter in industrial sludge into carbon dioxide and water by microorganisms in the presence of air.

(b) "Anaerobic digestion" is the biochemical decomposition of organic matter in industrial sludge into methane gas and carbon dioxide by microorganisms in the absence of air.

(c) "Density of microorganisms" is the number of microorganisms per unit mass of total solids (dry weight) in the industrial sludge.

(d) "Land with a high potential for public exposure" is land that the public uses frequently. This includes, but is not limited to, a public contact site and a reclamation site located in a populated area (e.g., a construction site located in a city).

(e) "Land with a low potential for public exposure" is land that the public uses infrequently. This includes, but is not limited to, agricultural land, forest, and a reclamation site located in an unpopulated area (e.g., a strip mine located in a rural area).

(f) "Pathogenic organisms" are disease-causing organisms. These include, but are not limited to, certain bacteria, protozoa, viruses, and viable helminth ova.

(g) "pH" means the logarithm of the reciprocal of the hydrogen ion concentration measured at 25 degrees C., or measured at another temperature and then converted to an equivalent value at 25 degrees C.

(h) "Specific oxygen uptake rate (SOUR)" is the mass of oxygen consumed per unit time per unit mass of total solids (dry weight basis) in the industrial sludge.

(i) "Total solids" are the materials in industrial sludge that remain as residue when the industrial sludge is dried at 103 to 105 degrees Celsius.

(j) "Unstabilized solids" are organic materials in industrial sludge that have not been treated in either an aerobic or anaerobic treatment process to include extended aeration, activated sludge or other treatment processes approved by the Department.

(k) "Vector attraction" is the characteristic of industrial sludge that attracts rodents, flies, mosquitos, or other organisms capable of transporting infectious agents.

(l) "Volatile solids" is the amount of the total solids in industrial sludge lost when the industrial sludge is combusted at 550 degrees Celsius in the presence of excess air.

504.32. Pathogens.

(a) Industrial sludge -Class A

(1) The requirement in section 504.32(a)(2) and the requirements in either section 504.32(a)(3), section 504.32(a)(4), section 504.32(a)(5), section 504.32(a)(6), section 504.32(a)(7), or section 504.32(a)(8) shall be met for an industrial sludge to be classified Class A with respect to pathogens if pathogens are expected to be present.

(2) When pathogens are expected to be present and the industrial sludge is expected to attract vectors, the Class A pathogen requirements in section 504.32(a)(3) through section 504.32(a)(8) shall be met either prior to meeting or at the same time the vector attraction reduction requirements in section 504.33, except the vector attraction reduction requirements in section 504.33(b)(6) through section 504.33(b)(8), are met.

(3) Class A -Alternative 1 (Not available for composting).

(i) Either the density of fecal coliform in the industrial sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella sp. bacteria in the industrial sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the industrial sludge or material derived from industrial sludge is prepared to meet the requirements in section 504.10(b), section 504.10(e), or section 504.10(f).

(ii) The temperature of the industrial sludge that is used or disposed shall be maintained at a specific value for a period of time.

(A) When the percent solids of the industrial sludge is seven percent or higher, the temperature of the industrial sludge shall be 50 degrees Celsius or higher; the time period shall be 20 minutes or longer; and the temperature and time period shall be determined using equation (2), except when small particles of industrial sludge are heated by either warmed gases or an immiscible liquid.

$$D = \frac{131,700,000}{100.1400t} \text{ (Equation 2)}$$

Where,

D = time in days.

t = temperature in degrees Celsius.

TABLE 1 OF SECTION 504.32—If the industrial sludge is 7% solids or higher.

Temperature (Celsius)	Time
50.0 (minimum)	13.17 days
60.0	12 hours 43 minutes
65.0	2 hours 39 minutes
70.0	30 minutes
71.3	20 minutes (minimum)

(B) When the percent solids of the industrial sludge is seven percent or higher and small particles of industrial sludge are heated by either warmed gases or an immiscible liquid, the temperature of the industrial sludge shall be 50 degrees Celsius or higher; the time period shall be 15 seconds or longer; and the temperature and time period shall be determined using equation (2).

TABLE 2 OF SECTION 504.32—If the industrial sludge is 7% solids or higher and small particles of industrial sludge are heated by warm gases or an immiscible liquid.

Temperature (Celsius)	Time
50.0 (minimum)	13.17 days
65.0	2 hours 39 minutes
71.3	20 minutes
80.0	1 minute 12 seconds
84.9	15 seconds (minimum)

(C) When the percent solids of the industrial sludge is less than seven percent and the time period is at least 15 seconds, but less than 30 minutes, the temperature and time period shall be determined using equation (2).

TABLE 3 OF SECTION 504.32—If the industrial sludge is less than 7% solids and the time period is at least 15 seconds, but less than 30 minutes.

Temperature (Celsius)	Time
70.0	30 minutes (Maximum time. See (D) for greater than 30 minutes)
71.3	20 minutes
75.0	6 minutes
80.0	1 minute 12 seconds
84.9	15 seconds (minimum)

(D) When the percent solids of the industrial sludge is less than seven percent; the temperature of the industrial sludge is 50 degrees Celsius or higher; and the time period is 30 minutes or longer, the temperature and time period shall be determined using equation (3).

$$D = \frac{50,070,000}{100.1400t} \text{ (Equation 3)}$$

Where,

D = time in days.

t = temperature in degrees Celsius.

TABLE 4 OF SECTION 504.32—If the industrial sludge is less than 7% solids and the temperature of the industrial sludge is 50 degrees Celsius or higher; and the time period is 30 minutes or longer.

Temperature (Celsius)	Time
50.0 (minimum)	5.0 days
55.0	1.0 day
60.0	4 hours 48 minutes
65.0	58 minutes
67.0	30 minutes (minimum)

(iii) The temperature used in equation (2) and equation (3) will be the lowest, continuously measured temperature within the reaction vessel during a 24-hour period or the lowest measured temperature during any 24-hour period, if a continuous treatment process is used. If a batch treatment process is used, the temperature used in the equation (2) and equation (3) will be the lowest temperature measured during the batch treatment.

(iv) For design temperatures measuring greater than 70 degrees Celsius, continuous temperature monitoring shall be required.

(4) Class A -Alternative 2

(i) Either the density of fecal coliform in the industrial sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella sp. bacteria in the industrial sludge shall be less than three Most Probable Number per four grams of

total solids (dry weight basis) at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the industrial sludge or material derived from industrial sludge is prepared to meet the requirements in section 504.10(b), section 504.10(e), or section 504.10(f).

(ii)(A) The pH of the industrial sludge that is used or disposed shall be raised to above 12 and shall remain above 12 for 72 hours.

(B) The temperature of the industrial sludge shall be above 52 degrees Celsius for 12 hours or longer during the period that the pH of the industrial sludge is above 12.

(C) At the end of the 72 hour period during which the pH of the industrial sludge is above 12, the industrial sludge shall be air dried to achieve a percent solids in the industrial sludge greater than 50 percent.

(5) Class A -Alternative 3

(i) Either the density of fecal coliform in the industrial sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella sp. bacteria in industrial sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the industrial sludge or material derived from industrial sludge is prepared to meet the requirements in section 504.10(b), section 504.10(e), or section 504.10(f).

(ii)(A) The industrial sludge shall be analyzed prior to pathogen treatment to determine whether the industrial sludge contains enteric viruses.

(B) When the density of enteric viruses in the industrial sludge prior to pathogen treatment is less than one Plaque-forming Unit per four grams of total solids (dry weight basis), the industrial sludge is Class A with respect to enteric viruses until the next monitoring episode for the industrial sludge.

(C) When the density of enteric viruses in the industrial sludge prior to pathogen treatment is equal to or greater than one Plaque-forming Unit per four grams of total solids (dry weight basis), the industrial sludge is Class A with respect to enteric viruses when the density of enteric viruses in the industrial sludge after pathogen treatment is less than one Plaque-forming Unit per four grams of total solids (dry weight basis) and when the values or ranges of values for the operating parameters for the pathogen treatment process that produces the industrial sludge that meets the enteric virus density requirement are documented.

(D) After the enteric virus reduction in paragraph (a)(5)(ii)(C) of this subsection is demonstrated for the pathogen treatment process, the industrial sludge continues to be Class A with respect to enteric viruses when the values for the pathogen treatment process operating parameters are consistent with the values or ranges of values documented in paragraph (a)(5)(ii)(C) of this subsection.

(iii)(A) The industrial sludge shall be analyzed prior to pathogen treatment to determine whether the industrial sludge contains viable helminth ova.

(B) When the density of viable helminth ova in the industrial sludge prior to pathogen treatment is less than one per four grams of total solids (dry weight basis), the industrial sludge is Class A with respect to viable helminth ova until the next monitoring episode for the industrial sludge.

(C) When the density of viable helminth ova in the industrial sludge prior to pathogen treatment is equal to or greater than one per four grams of total solids (dry weight basis), the industrial sludge is Class A with respect to viable helminth ova when the density of viable helminth ova in the industrial sludge after pathogen treatment is less than one per four grams of total solids (dry weight basis) and when the values or ranges of values for the operating parameters for the pathogen treatment process that produces the industrial sludge that meets the viable helminth ova density requirement are documented.

(D) After the viable helminth ova reduction in paragraph (a)(5)(iii)(C) of this subsection is demonstrated for the pathogen treatment process, the industrial sludge continues to be Class A with respect to viable helminth ova when the values for the pathogen treatment process

operating parameters are consistent with the values or ranges of values documented in paragraph (a)(5)(iii)(C) of this subsection.

(6) Class A -Alternative 4

(i) Either the density of fecal coliform in the industrial sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella sp. bacteria in the industrial sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the industrial sludge or material derived from industrial sludge is prepared to meet the requirements in section 504.10(b), section 504.10(e), or section 504.10(f).

(ii) The density of enteric viruses in the industrial sludge shall be less than one Plaque-forming Unit per four grams of total solids (dry weight basis) at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the industrial sludge or material derived from industrial sludge is prepared to meet the requirements in section 504.10(b), section 504.10(e), or section 504.10(f), unless otherwise specified by the Department.

(iii) The density of viable helminth ova in the industrial sludge shall be less than one per four grams of total solids (dry weight basis) at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the industrial sludge or material derived from industrial sludge is prepared to meet the requirements in section 504.10(b), section 504.10(e), or section 504.10(f), unless otherwise specified by the Department.

(7) Class A -Alternative 5

(i) Either the density of fecal coliform in the industrial sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella, sp. bacteria in the industrial sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the industrial sludge or material derived from industrial sludge is prepared to meet the requirements in section 504.10(b), section 504.10(e), or section 504.10(f).

(ii) Industrial sludge that is used or disposed shall be treated in one of the Processes to Further Reduce Pathogens described in appendix B of this part if pathogens are expected to be present.

(8) Class A -Alternative 6

(i) Either the density of fecal coliform in the industrial sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of Salmonella, sp. bacteria in the industrial sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the industrial sludge or material derived from industrial sludge is prepared to meet the requirements in section 504.10(b), section 504.10(e), or section 504.10(f).

(ii) Industrial sludge that is used or disposed shall be treated in a process that is equivalent to a Process to Further Reduce Pathogens, as determined by the Department.

(b) Industrial sludge -Class B

(1)(i) The requirements in either section 504.32(b)(2), section 504.32(b)(3), or section 504.32(b)(4) shall be met for an industrial sludge to be classified Class B with respect to pathogens if pathogens are expected to be present.

(ii) The site restrictions in section 504.32(b)(5) shall be met when industrial sludge that meets the Class B pathogen requirements in section 504.32(b)(2), section 504.32(b)(3), or section 504.32(b)(4) is applied to the land.

(2) Class B -Alternative 1

(i) Seven representative samples of the industrial sludge shall be collected at the time the industrial sludge is used or disposed.

(ii) The geometric mean of the density of fecal coliform in the samples collected in (b)(2)(i) of this subsection shall be less than either 2,000,000 Most Probable Number per gram of total solids (dry weight basis) or 2,000,000 Colony Forming Units per gram of total solids (dry weight basis).

(3) Class B -Alternative 2. Industrial sludge that is used or disposed shall be treated in one of the Processes to Significantly Reduce Pathogens described in appendix B of this part.

(4) Class B -Alternative 3. Industrial sludge that is used or disposed shall be treated in a process that is equivalent to a Process to Significantly Reduce Pathogens, as determined by the Department.

(5) Site Restrictions

(i) Food crops with harvested parts that touch the industrial sludge/soil mixture and are totally above the land surface shall not be harvested for 14 months after application of industrial sludge.

(ii) Food crops with harvested parts below the surface of the land shall not be harvested for 20 months after application of industrial sludge when the industrial sludge remains on the land surface for four months or longer prior to incorporation into the soil.

(iii) Food crops with harvested parts below the surface of the land shall not be harvested for 38 months after application of industrial sludge when the industrial sludge remains on the land surface for less than four months prior to incorporation into the soil.

(iv) Food crops, feed crops, and fiber crops shall not be harvested for 30 days after application of industrial sludge.

(v) Animals shall not be grazed on the land for 30 days after application of industrial sludge.

(vi) Turf grown on land where industrial sludge is applied shall not be harvested for one year after application of the industrial sludge when the harvested turf is placed on either land with a high potential for public exposure or a lawn, unless otherwise specified by the Department.

(vii) Public access to land with a high potential for public exposure shall be restricted for one year after application of industrial sludge.

(viii) Public access to land with a low potential for public exposure shall be restricted for 30 days after application of industrial sludge.

(ix) The Department may establish in permits the required application buffer setbacks for property boundaries, roadways, residential developments, dwellings, water wells, drainageways, and surface water as deemed necessary to protect public health.

(x) The Department may establish minimum requirements in permits for soil and/or groundwater monitoring, for bulk application sites, to verify compliance with the Regulation.

(c) [Reserved]

(1) [Reserved]

(2) [Reserved]

(3) [Reserved]

504.33. Vector attraction reduction.

(a)(1) One of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8); a requirement that is equivalent to one of the vector attraction reduction requirements in section 504.33(b)(1) through (b)(8), as determined by the Department; or the vector attraction reduction requirements in section 504.33(b)(9) or (b)(10) shall be met when bulk industrial sludge is applied to agricultural land, forest, a public contact site, or a reclamation site when the industrial sludge is expected to attract vectors.

(2) One of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8); or an equivalent requirement, as determined by the Department, shall be met when bulk industrial sludge is applied to a lawn or a home garden when the industrial sludge is expected to attract vectors.

(3) One of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(8); or an equivalent requirement, as determined by the Department, shall be met when industrial sludge is sold or given away in a bag or other container for application to the land when the industrial sludge is expected to attract vectors.

(4) [Reserved]

(5) One of the vector attraction reduction requirements in section 504.33(b)(9), section 504.33(b)(10), or section 504.33(b)(12) shall be met when industrial septage is applied to agricultural land, forest, or a reclamation site when the industrial septage is expected to attract vectors.

(6) One of the vector attraction reduction requirements in section 504.33(b)(1) through section 504.33(b)(10) or section 504.33(b)(13) shall be met when industrial sludge is bulk applied to agricultural land, forest, a public contact site, or a reclamation site when the industrial sludge is expected to attract vectors.

(b)(1) The mass of volatile solids in the industrial sludge shall be reduced by a minimum of 38 percent (see calculation procedure in "Environmental Regulations and Technology-Control of Pathogens and Vector Attraction in Sewage Sludge", EPA-625/R-92/013, 1992, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268).

(2) When the 38 percent volatile solids reduction requirement in section 504.33(b)(1) cannot be met for an anaerobically digested industrial sludge, vector attraction reduction can be demonstrated by digesting a portion of the previously digested industrial sludge anaerobically in the laboratory in a bench-scale unit for 40 additional days at a temperature between 30 and 37 degrees Celsius. When at the end of the 40 days, the volatile solids in the industrial sludge at the beginning of that period is reduced by less than 17 percent, vector attraction reduction is achieved.

(3) When the 38 percent volatile solids reduction requirement in section 504.33(b)(1) cannot be met for an aerobically digested industrial sludge, vector attraction reduction can be demonstrated by digesting a portion of the previously digested industrial sludge that has a percent solids of two percent or less aerobically in the laboratory in a bench-scale unit for 30 additional days at 20 degrees Celsius. When at the end of the 30 days, the volatile solids in the industrial sludge at the beginning of that period is reduced by less than 15 percent, vector attraction reduction is achieved.

(4) The specific oxygen uptake rate (SOUR) for industrial sludge treated in an aerobic process shall be equal to or less than 1.5 milligrams of oxygen per hour per gram of total solids (dry weight basis) at a temperature of 20 degrees Celsius. Other values may be allowed by the Department on a case-by-case basis.

(5) Industrial sludge shall be treated in an aerobic process for 14 days or longer. During that time, the temperature of the industrial sludge shall be higher than 40 degrees Celsius and the average temperature of the industrial sludge shall be higher than 45 degrees Celsius. Other processes may be allowed by the Department on a case-by-case basis.

(6) The pH of industrial sludge shall be raised to 12 or higher by alkali addition and, without the addition of more alkali, shall remain at 12 or higher for two hours and then at 11.5 or higher for an additional 22 hours at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or given away in a bag or other container for application to the land; or at the time the industrial sludge is prepared to meet the requirements in section 504.10(b), (c), (e), or (f).

(7) The percent solids of industrial sludge that does not contain unstabilized solids generated in a primary wastewater treatment process shall be equal to or greater than 75 percent based on the moisture content and total solids prior to mixing with other materials, at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or given away in a bag or other container for application to the land; or at the time the industrial sludge is prepared to meet the requirements in section 504.10(b), (c), (e), or (f).

(8) The percent solids of industrial sludge that contains unstabilized solids generated in a primary wastewater treatment process shall be equal to or greater than 90 percent based on the moisture content and total solids prior to mixing with other materials, at the time the industrial sludge is used or disposed; at the time the industrial sludge is prepared for sale or given away in a bag or other container for application to the land; or at the time the industrial sludge is prepared to meet the requirements in section 504.10(b), (c), (e), or (f).

(9)(i) Industrial sludge shall be injected below the surface of the land.

(ii) No significant amount of the industrial sludge shall be present on the land surface within one hour after the industrial sludge is injected.

(iii) When the industrial sludge that is injected below the surface of the land is Class A with respect to pathogens, the industrial sludge shall be injected below the land surface within eight hours after being discharged from the pathogen treatment process.

(10)(i) Industrial sludge applied to the land surface shall be incorporated into the soil within six hours after application to or placement on the land, unless otherwise specified by the Department.

(ii) When industrial sludge that is incorporated into the soil is Class A with respect to pathogens, the industrial sludge shall be applied to or placed on the land within eight hours after being discharged from the pathogen treatment process.

(11) [Reserved]

(12) The pH of industrial septage shall be raised to 12 or higher by alkali addition and, without the addition of more alkali, shall remain at 12 or higher for 30 minutes.

(13) The vector attraction reduction requirement may be met through an alternative method to be determined by the Department on a case-by-case basis.

504.50. Odor Control Requirements.

The permit holder shall use best management practices normally associated with the proper operation and maintenance of a sludge wastewater treatment site, any sludge storage or lagoon areas, transportation of sludges, and all individual activities permitted under R.61-9.504 to ensure that an undesirable level of odor does not exist.

(a) The permittee shall prepare an odor abatement plan for the industrial sludge treatment sites, any sludge storage or lagoon areas, and land application or surface disposal sites. Permittees that land-apply sludge must prepare the plan within 180 days of the effective date of this regulation (effective date of June 26, 2003). Permittees that have facilities described above that require plans have one (1) year from the June 26, 2003 effective date to prepare the plan. Odor abatement plans must be submitted for new projects with the submission of permit applications. The plan must include the following topics:

(1) Operation and maintenance practices which are used to eliminate or minimize undesirable odor levels in the form of best management practices for Odor Control;

(2) Use of treatment processes for the reduction of undesirable odors;

(3) Use of setbacks; and

(4) Contingency plans and methods to address odor problems for the different type of disposal/application methods used.

(b) Unless otherwise requested, prior to issuance of a new or expanded land application disposal permit (either NPDES or Land Application), the Department may review the odor abatement plan for compliance with this Part (504.50). The Department may require changes to the plan as appropriate.

(c) No permittee may cause, allow, or permit emission into the ambient air of any substance or combinations of substances in quantities that an undesirable level of odor is determined to result unless preventative measures of the type set out below are taken to abate or control the emission to the satisfaction of the Department. When an odor problem comes to the attention of the Department through field surveillance or specific complaints, the Department may determine, in accordance with section 48-1-120 of the Pollution Control Act, if the odor is at an undesirable level by considering the character and degree of injury or interference to:

(1) The health or welfare of the people;

(2) Plant, animal, freshwater aquatic, or marine life;

(3) Property; or

(4) Enjoyment of life or use of affected property.

(d) After determining that an undesirable level of odor exists, the Department may require:

(1) the permittee to submit a corrective action plan to address the odor problem,

(2) remediation of the undesirable level of odor within a reasonable timeframe, and

(3) in an order, specific methods to address the problem.

(e) If the permittee fails to control or abate the odor problems addressed in this section within the specified timeframe, the Department may revoke disposal/application activities associated with the site or the specific aspect of the sludge management program.

APPENDIX A. PROCEDURE TO DETERMINE THE ANNUAL WHOLE SLUDGE APPLICATION RATE FOR AN INDUSTRIAL SLUDGE

Section 504.13(a)(4)(ii) requires that the product of the concentration for each pollutant listed in Table 4 of section 504.13 in industrial sludge sold or given away in a bag or other container for application to the land and the annual whole sludge application rate (AWSAR) for the industrial sludge not cause the annual pollutant loading rate for the pollutant in Table 4 of section 504.13 to be exceeded. This appendix contains the procedure used to determine the AWSAR for an industrial sludge that does not cause the annual pollutant loading rates in Table 4 of section 504.13 to be exceeded.

The relationship between the annual pollutant loading rate (APLR) for a pollutant and the annual whole sludge application rate (AWSAR) for an industrial sludge is shown in equation (1).

$$\text{APLR} = C \times \text{AWSAR} \times 0.001 \quad (1)$$

Where:

APLR = Annual pollutant loading rate in kilograms per hectare per 365 day period.

C = Pollutant concentration in milligrams per kilogram of total solids (dry weight basis).

AWSAR = Annual whole sludge application rate in metric tons per hectare per 365 day period (dry weight basis).

0.001 = A conversion factor.

To determine the AWSAR, equation (1) is rearranged into equation (2):

$$\text{AWSAR} = \frac{\text{APLR}}{C \times 0.001} \quad (2)$$

The procedure used to determine the AWSAR for an industrial sludge is presented below.

PROCEDURE:

1. Analyze a sample of the industrial sludge to determine the concentration for each of the pollutants listed in Table 4 of section 504.13 in the industrial sludge.
2. Using the pollutant concentrations from Step 1 and the APLRs from Table 4 of section 504.13, calculate an AWSAR for each pollutant using equation (2) above.
3. The AWSAR for the industrial sludge is the lowest AWSAR calculated in Step 2.

APPENDIX B. PATHOGEN TREATMENT PROCESSES

A. PROCESSES TO SIGNIFICANTLY REDUCE PATHOGENS (PSRP)

1. Aerobic digestion. Industrial sludge is agitated with air or oxygen to maintain aerobic conditions for a specific mean cell residence time at a specific temperature. Values for the mean cell residence time and temperature shall be between 40 days at 20 degrees Celsius and 60 days at 15 degrees Celsius.

2. Air drying. Industrial sludge is dried on sand beds or on paved or unpaved basins. The industrial sludge dries for a minimum of three months. During two of the three months, the ambient average daily temperature is above zero degrees Celsius.

3. Anaerobic digestion. Industrial sludge is treated in the absence of air for a specific mean cell residence time at a specific temperature. Values for the mean cell residence time and temperature shall be between 15 days at 35 to 55 degrees Celsius and 60 days at 20 degrees Celsius.

4. Composting. Using either the within-vessel, static aerated pile, or windrow composting methods, the temperature of the industrial sludge is raised to 40 degrees Celsius or higher and remains at 40 degrees Celsius or higher for five days. For four hours during the five days, the temperature in the compost pile exceeds 55 degrees Celsius.

5. Lime stabilization. Sufficient lime is added to the industrial sludge to raise the pH of the industrial sludge to 12 after two hours of contact.

6. Industrial sludge. Industrial sludge may meet the PSRP requirement through an alternate procedure to be determined by the Department on a case-by-case basis.

B. PROCESSES TO FURTHER REDUCE PATHOGENS (PFRP)

1. Composting. Using either the within-vessel composting method or the static aerated pile composting method, the temperature of the industrial sludge is maintained at 55 degrees Celsius or higher for three days.

Using the windrow composting method, the temperature of the industrial sludge is maintained at 55 degrees or higher for 15 days or longer. During the period when the compost is maintained at 55 degrees or higher, there shall be a minimum of five turnings of the windrow.

2. Heat drying. Industrial sludge is dried by direct or indirect contact with hot gases to reduce the moisture content of the industrial sludge to 10 percent or lower. Either the temperature of the industrial sludge particles exceeds 80 degrees Celsius or the wet bulb temperature of the gas in contact with the industrial sludge as the industrial sludge leaves the dryer exceeds 80 degrees Celsius.

3. Heat treatment. Liquid industrial sludge is heated to a temperature of 180 degrees Celsius or higher for 30 minutes.

4. Thermophilic aerobic digestion. Liquid industrial sludge is agitated with air or oxygen to maintain aerobic conditions and the mean cell residence time of the industrial sludge is 10 days at 55 to 60 degrees Celsius.

5. Beta ray irradiation. Industrial sludge is irradiated with beta rays from an accelerator at dosages of at least 1.0 megarad at room temperature (ca. 20 degrees Celsius).

6. Gamma ray irradiation. Industrial sludge is irradiated with gamma rays from certain isotopes, such as Cobalt 60 and Cesium 137, at room temperature (ca. 20 degrees Celsius).

7. Pasteurization. The temperature of the industrial sludge is maintained at 70 degrees Celsius or higher for 30 minutes or longer.

8. Industrial sludge. Industrial sludges may meet the PFRP requirement through an alternate procedure to be determined by the Department on a case-by-case basis.

HISTORY: Added by State Register Volume 20, Issue No. 6, eff June 28, 1996.

APPENDIX C. PCB. POLYCHLORINATED BIPHENYLS

(1) Beginning with the effective date of this appendix, sludges for land application (including sewage sludge, sludges and septage that may be mixed with grease trap waste) must be sampled at least quarterly (based on calendar year quarters) for PCBs using EPA SW-846 Method 8082A with an appropriate sample preparation method approved for use by the Department based on the matrix of

the sample. This includes but is not limited to: bulk sewage sludge applied to agricultural land, forests or public contact sites; sewage sludge sold or given away in a bag or other container for application to the land; domestic septage; reclamation sites; or other materials mixed with sludge before application. Reporting the above information, in addition to requirements specified later in this appendix, should be included in annual reports required by permits.

(2) If levels of PCBs are greater than or equal to one (1) milligram per kilogram (mg/kg dry weight basis), but less than ten (10) milligrams per kilogram (mg/kg dry weight basis), confirmation sludge sampling must be done as soon as practicable and the results provided to the Department within five (5) calendar days of receipt by the permittee.

(3) If levels of PCBs are greater than or equal to ten (10) milligrams per kilogram (mg/kg dry weight basis), confirmation sludge sampling must be done as soon as practicable and the results provided to the Department within five (5) calendar days of receipt of the results by the permittee. In addition, representative soil sampling of land application sites that may have received sludge during the monitoring period must be conducted within 30 days of knowledge of the confirmation sampling that confirms sludge PCB levels equal to or greater than ten (10) milligrams per kilogram (mg/kg dry weight basis). The results of the soil sampling must be provided to the Department within five (5) calendar days of receipt by the permittee. The Department may require any further action as deemed necessary and consistent with applicable laws.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4444, eff June 27, 2014.

61-9.505. LAND APPLICATION PERMITS AND STATE PERMITS.

Editor's Note

The following constitutes the history for 61-9.505, 505.1 through 505.64.

HISTORY: Added by State Register Volume 20, Issue No. 6, Part II, eff June 28, 1996. Amended by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003; State Register Volume 32, Issue No. 5, eff May 23, 2008.

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- 505.44 Establishing limitations, standards and other Land Application permit and State permit conditions.
- 505.45 Calculating Land Application permit and State permit conditions.
- 505.46 Duration of Land Application permits and State permits.
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Part D—Transfer, Modification, Revocation and Reissuance, and Termination of Land Application permits and State permits

- 505.61 Transfer of Land Application permits and State permits.
- 505.62 Modification or revocation and reissuance of Land Application permits and State permits.
- 505.63 Minor modifications of Land Application permits and State permits.
- 505.64 Termination of Land Application permits and State permits.

PART A
DEFINITIONS AND GENERAL PROGRAM REQUIREMENTS

505.1. Purpose and scope.

(a) Coverage.

(1) These regulations contain provisions for the Land Application permit and State permit Program under the South Carolina Pollution Control Act (PCA), S.C. Code Ann. section 48-1-10 et seq.

(2) These regulations contain provisions for other permits issued for subsurface distribution systems (such as tile fields or drip irrigation systems).

(b) Scope of the Land Application permit and State permit requirement.

(1) The Land Application permit and State permit program requires permits for the discharge of pollutants from any source directly or indirectly into groundwaters of the State and to the land of the State. The terms “Land Application permit”, “ State permit”, “pollutant”, “source”, “groundwaters of the State”, and the “land of the State” are defined in section 505.2.

(2) The following are additional sources that may require Land Application permits or State permits for discharges:

(i) Recirculated Process Wastewater. The submission and information requirements shall be determined by the Department.

(ii) Wastewater Evaporation Systems for Process Wastewater. The submission and information requirements shall be determined by the Department.

(iii) Agricultural Waste Facilities, except those regulated under South Carolina R.61-43. The submission and information requirements shall be determined by the Department.

(iv) [Reserved]

(3) The permit program established under this regulation also applies to owners or operators of any treatment works treating domestic sewage, whether or not the treatment works is otherwise required to obtain a Land Application permit or State permit in accordance with this section, unless all requirements implementing section 405(d) of the CWA applicable to the treatment works treating domestic sewage are included in a permit issued under the appropriate provisions of subtitle C of the Solid Waste Disposal Act; Part C of the Safe Drinking Water Act; the Marine Protection, Research, and Sanctuaries Act of 1972; the Clean Air Act; or under an NPDES permit (R.61-9.122) approved by the Department as adequate to assure compliance with section 405 of the Clean Water Act (CWA).

(4) The Department may designate any person subject to the standards for sewage sludge use and disposal as a “treatment works treating domestic sewage” as defined in R.61-9.122.2, where it finds that an NPDES permit is necessary to protect public health and the environment from the adverse effects of sewage sludge or to ensure compliance with the technical standards for sludge use and disposal developed under the CWA section 405(d). Any person owning or operating a facility designated as “treatment works treating domestic sewage” shall submit an application for a permit under R.61-9.122.21 within 120 days of being notified by the Department that a permit is required.

(5) See South Carolina R.61-67, Standards for Wastewater Facility Construction, section 300.G, Pump and Haul Operations, related to requirements for transporting wastewater for disposal.

(c) Compliance Period.

(1) [Reserved]

(2) All provisions of this Regulation for facilities that are in operation shall be achieved in accordance with a schedule of compliance or other conditions that may be in a reissued permit. For modifications of existing facilities that require construction, the Department may modify or revoke and reissue existing Land Application and State permits to include specific provisions of this Regulation.

(3) All Land Application permits, State permits or other permits for new facilities or expansions of existing facilities issued on or after the effective date of this regulation shall be required to comply with this regulation. Land Application or State permits issued on or after the effective date of this regulation for new land application sites, land application sites approved for an increase (either quantity or loading) in pollutant disposal, or expansions of existing land application sites shall be required to comply with the regulation.

(d) Relation to other requirements.

(1) Permit application forms. Applicants for permits shall submit their applications on permit application forms designated by the Department. The basic information required in the general form (Form 1) and all or part of the additional information required by NPDES applications (Forms 2 A through E) listed in R.61-9.122.21 may be required by the Department for Land Application permits and State permits. In addition, the Department may identify specific information necessary for the Land Application permit and State permit activities.

(2) Technical Regulations. The Permit program has separate additional regulations. These separate regulations are used by the Department to determine what requirements must be placed in permits if they are issued. These separate regulations are located in R.61-9.122, 125, 129, 133, 403, 503 and 504. Additional items under 40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471) may be placed in permits if they are issued.

(e) Public participation. R.61-9.124 (Procedures for Decision Making) establishes the requirements for public participation in Land Application Permit issuance and enforcement and related variance proceedings.

(f) Environmental Protection Fees. R.61-30 establishes the requirements for the submission of specific fees for the activities regulated by the Department.

(g) Authority.

(1) Section 48-1-90(a), S.C. Code of Laws (1976), provides that "it shall be unlawful for any person, directly or indirectly, to throw, drain, run, allow to seep, or otherwise discharge into the environment of the State organic or inorganic matter, including sewage, industrial wastes and other wastes, except as in compliance with a permit issued by the Department."

(2) Section 48-1-100(a), S.C. Code of Laws (1976), provides that "if, after appropriate public comment procedures, as defined by Department regulations, the Department finds that the discharge from the proposed outlet ... will not be in contravention of provisions of Chapter 1, Title 48, S.C. Code of Laws, a permit to construct and a permit to discharge must be issued to the applicant."

(3) [Reserved]

(4) Section 405 of the CWA provides, in part, that "Where the disposal of sewage sludge resulting from the operation of a treatment works as defined in section 212 of this Act (including the removal of in-place sewage sludge from one location and its deposit at another location) would result in any pollutant from such sewage sludge entering the [waters of the State], such disposal is prohibited except in accordance with a[n NPDES] permit issued by the [Department] under section 402 of this Act."

(5) Section 405(d)(4) of the CWA requires the Department, prior to promulgation of standards for sewage sludge use and disposal, to "impose conditions in [NPDES] permits issued to publicly owned treatment works under section 402 of this Act, or take such other measures as the [Department] deems appropriate to protect public health and the environment from any adverse effects which may occur from toxic pollutants in sewage sludge."

(6) Section 405(f) of the CWA provides that permits must include requirements implementing the standards for sludge use and disposal (40 CFR Part 503) "unless such requirements have been included in a permit issued under the appropriate provisions of subtitle C of the Solid Waste

Disposal Act; part C of the Safe Drinking Water Act, the Marine Protection, Research, and Sanctuaries Act of 1972; the Clean Air Act; or under State [of South Carolina] permit programs approved by the Administrator...” Section 405(f) also authorizes the Department to issue permits with requirements for sludge use or disposal that assure compliance with 40 CFR Part 503 to any treatment works treating domestic sewage that is not subject to NPDES (i.e., has no point source discharge) and has not been issued a permit that includes applicable 40 CFR Part 503 standards under the other permit programs listed in section 405(f)(1) of the CWA.

(7) Sections 405(c) and (f) of the CWA authorize EPA approval of State [of South Carolina] permit programs for use and disposal of sewage sludge.

(8) Section 48-1-50(22), S.C. Code of Laws (1976), requires the owner or operator of any source or disposal system to establish and maintain such operational records; make reports; install, use, and maintain monitoring equipment or methods; sample and analyze emissions or discharges in accordance with prescribed methods, at locations, intervals, and procedures as the Department shall prescribe; and provide such other information as the Department reasonably may require.

(9) Section 48-1-40, S.C. Code of Laws (1976), authorizes the Department “after public hearing as herein provided, [to] adopt standards and determine what qualities of water ... shall indicate a polluted condition and these standards shall be promulgated and made a part of the rules and regulations of the Department.” Section 48-1-50(23) authorizes the Department to “[a]dopt ... effluent control regulations, standards and limitations that are applicable to the entire State, that are applicable only within specified areas or zones of the State, or that are applicable only when a specified class of pollutant is present.” Section 501(a) of CWA provides that “The [Department] is authorized to prescribe such regulations as are necessary to carry out [its] functions under this Act.”

(10) Section 48-1-100(a), S.C. Code of Laws (1976), requires an opportunity for public comment before issuance of permits to discharge.

(h) Preliminary Engineering Reports and Construction Permit Applications shall be consistent with R.61-67 (Standards for Wastewater Facility Construction).

505.2. Definitions.

(a) The definitions contained in R.61-9.122, R.61-9.124, R.61-9.125, R.61-9.129, R.61-9.133, R.61-9.403, R.61-9.503 and R.61-9.504 apply to this regulation. Terms not defined in this section or sections referenced previously have the meaning given by the PCA.

(b) Definitions:

(1) “Agricultural waste facility” means any collection, treatment, disposal or recycling activity involving livestock (such as cattle, poultry, swine and turkeys), dogs, horses, pigeons, quail, or other birds and animals including any activity with the production of manures, dead birds or litter.

(2) “Aquifer” means a geologic formation, group of formations, or part of a formation that contains sufficient saturated permeable material to yield usable quantities of groundwater to springs or wells.

(3) “Background groundwater analysis” means the chemical or biological quality of groundwater before application of wastewater or sludge; or the groundwater chemistry or biological quality up-gradient to the site of concern.

(4) “Basin or lagoon” means any in-ground or earthen structure designed to receive, treat, store, temporarily retain and/or allow for the infiltration/evaporation of wastewater.

(5) “Down-gradient” means the portion of the water table that is down the hydraulic slope of the water table with respect to a specific area or point of reference.

(6) “Evaporation basin” means a basin designed specifically for the atmospheric or enhanced evaporation of liquid.

(7) “Groundwater” means water below the land surface found in fractured rock or various soil strata.

(8) “Groundwaters of the State” means all sources of groundwater wholly, partially, or bordering the State of South Carolina or within its jurisdiction.

(9) "Hydraulic loading" means the rate at which liquid is applied to the land per unit area. The term "application rate" may be used for "hydraulic loading".

(10) "Hydrogeologic characteristics" means the physical properties of the subsurface and its interaction with the hydraulic properties of groundwater (e.g., migration or infiltration).

(11) "Infiltration" means the flow of water downward from the land surface into and through the soil.

(12) "Land" for the purpose of this regulation means the soil and rock above the water table aquifer and the ground surface.

(13) "Land Application" means use and/or disposal of treated wastewater, sewage sludge, industrial sludge, septage, or additional sources (see R.61-9.505.1(b)(2)) to the land.

(14) "Land Application Permit" refers to a permit issued by the Department applicable to a treatment system, source or site with no resulting discharge to surface waters of the State.

(15) "Land of the State" means all land surface which is wholly or partially within the State of South Carolina or within its jurisdiction.

(16) "Land slope" means the rate of increase or decrease of elevation over a given linear distance.

(17) "Land surface" means the area of land open to the atmosphere.

(18) [Reserved]

(19) "New or expansions" means a facility or land application site that is: new and has not been permitted (including existing sites such as golf courses that have not been used for effluent disposal); an increase (either in quantity or loading) in pollutant disposal to the facility or land application site; a change in the pollutant disposal to the facility or land application site (such as the introduction of a new pollutant in the effluent); or expansions (in physical size, or hydraulic loading) of existing permitted facilities or land application sites. The term "new or expanding" may also be used.

(20) "Monitoring well" means any well used to sample groundwater for water quality analysis or to measure groundwater levels.

(21) "Percolation pond" means any lagoon, basin or constructed impoundment having a leakage rate in excess of 500 gallons/day/acre.

(22) "Permeability" means the capacity of soil, rock, or other material to transmit fluids.

(23) "Pollutant":

(i) Means filter backwash, sewage, sewage sludge, industrial sludge, septage, or industrial, municipal, agricultural and domestic waste.

(ii) Does not mean water, gas, or other material which is injected into a well to facilitate production of oil or gas, or water derived in association with oil and gas production and disposed of in a well, if the well used either to facilitate production or for disposal purposes is approved by authority of the State in which the well is located, and if the State determines that the injection or disposal will not result in the degradation of groundwater or surface water resources.

(24) "Potable water well" means a well that supplies drinking water for human consumption.

(25) [Reserved]

(26) "Restrictive soil horizon" means the top of the most impermeable soil layer encountered.

(27) "Seasonal high water table" means the highest water table as determined in the soil profile by the encountered indications of soil mottling or iron concretions or by measuring seasonal fluctuations of the water table in a water table well over a period acceptable to the Department.

(28) "Spray field" means a specified area where properly treated wastes, treated effluent from process, agricultural or domestic wastewater, sewage sludge, industrial sludge or other sources is applied to the land. The terms "application area", "application site", or "spray disposal area" may also be used.

(29) "Soil boring" means any hand-or mechanically-powered method by which samples of the subsurface can be retrieved for characterization or description.

(30) "Source" means any discernible conveyance, including but not limited to, any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, or mobile equipment (such as

sludge application truck or device), from which pollutants are or may be discharged. This term does not include return flows from irrigated agriculture.

(31) "State permit" refers to a permit issued by the Department for other sources covered by this regulation (other than Land Application Permits) such as activities covered under R.61-9.505.1(b)(2). The term "State Permit Program" may also be used to describe the entire permit program under R.61-9.505.

(32) "Storage or holding basin" means any basin designed to retain wastewater before, during or after treatment and would not include waters of the State.

(33) "Tile field" means a specific area where a network of soil adsorption trenches is installed below the land surface for the purpose of providing final treatment and disposal of wastewater.

(34) [Reserved]

(35) "Treated wastewater" means properly treated effluent from process or domestic wastewater, treated wastes from other sources (see R.61-9.505.1(b)(2)) or treated effluent from a treatment facility.

(36) "Up-gradient" means the portion of the water table that is up the hydraulic slope of the water table with respect to a specific area or point of reference.

(37) "Vadose zone" means the zone between the land surface and the water table.

(38) "WWTP" means wastewater treatment plant.

(39) "Water table" means the level below the land surface at which all the voids are filled with water at a pressure equal to atmospheric. The depth to the water level in the ground is to be measured at least 24 hours after encountering it in a well.

(40) "Water table mound" means a high point in the seasonal or normal water table which is artificially created by the infiltration of liquid.

(41) "Well" means any excavation which is cored, bored, drilled, jetted, dug, or otherwise constructed and has a depth greater than its largest surface diameter.

(42) "ND" or "No Discharge" means land application. The terms "ND permit" or "No Discharge permit" may be used for "Land Application permit".

505.3. Exclusions.

The following discharges do not require Land Application permits or State permits:

(a) The introduction of sewage, industrial wastes or other pollutants into publicly owned treatment works by indirect dischargers. Plans or agreements to switch to this method of disposal in the future do not relieve dischargers of the obligation to have and comply with permits until all discharges of pollutants directly or indirectly to groundwaters of the State and any land surface of the State are eliminated. (See also R.61-9.122.47(b)). This exclusion does not apply to the introduction of pollutants to privately owned treatment works or to other discharges through pipes, sewers, or other conveyances (owned by a State, municipality, or other party) not leading to treatment works.

(b) Any introduction of pollutants from non-point source agricultural and silvicultural activities, including storm water runoff from orchards, cultivated crops, pastures, range lands, and forest lands, but not discharges directly or indirectly to groundwaters of the State and any land surface of the State from both concentrated animal feeding operations as defined in R.61-9.122.23, and from silvicultural point sources as defined in R.61-9.122.27.

(c) Return flows from irrigated agriculture.

(d) Discharges permitted under Underground Injection Control (61-87). a South Carolina County Health Department or other Department program area.

(e) Individual Sewage Treatment and Disposal Systems serving one piece of deeded property that are permitted under Regulation 61-56. This includes but is not limited to any individual residence or single piece of deeded property using a septic tank system if a permit for the discharge is obtained under the provisions of R.61-56.

(f) Provided the requirements in section 505.8 are met and a permit is issued to Construct an Individual Sewage Treatment and Disposal System under R.61-56, serving more than one piece of

deeded property, a Land Application or State Permit will not be required. This exclusion may not apply if industrial wastes or other pollutants are discharged.

505.4. Prohibitions.

No State or Land Application permit may be issued:

(a) When the conditions of the permit do not provide for compliance with the applicable requirements of the CWA, State regulations, or regulations promulgated under the PCA;

(b) When the applicant is required to obtain a State or other appropriate certification under section 401 of the CWA and that certification has not been obtained or waived;

(c) When the imposition of conditions cannot ensure compliance with the applicable surface or groundwater quality requirements of all affected States;

(d) For the discharge of any radiological, chemical, or biological warfare agent or high-level radioactive waste;

(e)(1) For any Land Application Permit or State permit which is inconsistent with a plan or plan amendment approved under section 208(b) of the CWA, unless the Department finds such variance necessary to protect the public health, safety, and welfare;

(2) In reissuance of a Land Application Permit or State permit which requires connection to a regional sewer system or other treatment facilities under the water quality management plan under section 208 of the CWA, once the permittee is notified by the Department that the regional sewer system is operational.

(f) To a new source or a new discharger, if the discharge from its construction or operation will cause or contribute to the violation of groundwater or surface water quality standards. The Department may issue a permit if the owner or operator of a new source or new discharger proposing to discharge, which does not currently meet applicable groundwater or surface water quality standards or is not expected to meet those standards even after the application of the effluent limitations, demonstrates that the existing dischargers are subject to compliance schedules designed to bring the area into compliance with applicable ground or surface water quality standards.

505.5. Effect of a Land Application permit or State permit.

(a)(1) Except for "standards for sewage sludge use or disposal" under 405(d) of the CWA, compliance with a permit during its term constitutes compliance, for purposes of enforcement, with the Pollution Control Act. However, a permit may be modified, revoked and reissued, or terminated during its term for cause as set forth in section 505.62 and section 505.64.

(2) Compliance with a permit condition which implements a particular "standard for sewage sludge use or disposal" shall be an affirmative defense in any enforcement action brought for a violation of that "standard for sewage sludge use or disposal".

(b) The issuance of a Land Application permit or State permit does not convey any property rights of any sort, nor any exclusive privilege.

(c) The issuance of a Land Application permit or State permit does not authorize any injury to persons or property or invasion of other private rights, or any infringement of State or local law or regulations.

(d) If a deleterious impact to the groundwaters of the State from the permitted use or disposal practices is documented through groundwater monitoring levels exceeding the standards set forth in R.61-68 or a significant adverse trend occurs, then it will be the obligation of the permittee as directed by the Department to conduct an investigation to determine the vertical and horizontal extent of groundwater impact. The Department may require remediation of the groundwater to within acceptable levels for groundwater as set forth in R.61-68.

505.6. Continuation of expiring Land Application permits or State permits.

(a) The conditions of an expired permit continue in force under S.C. Code section 1-23-370(b) until the effective date of a new permit (see R.61-9.124.15), except when the permit requires connection to a regional sewer system or other treatment facilities under the water quality management plan under section 208 of the CWA and the permittee has been notified by the Department that the regional sewer system is operational, if:

(1) The permittee has submitted a timely application under section 505.21 which is a complete (under section 505.21(e)) application for a new permit; and

(2) The Department, through no fault of the permittee, does not issue a new permit with an effective date under R.61-9.124.15 on or before the expiration date of the previous permit (for example, when issuance is impracticable due to time or resource constraints); or

(3) The permittee has submitted a timely application under section 505.21 which is a complete application for a new permit and makes a timely appeal of the new permit.

(b) Effect. Permits continued under this section remain fully effective and enforceable.

(c) Enforcement. When the permittee is not in compliance with the conditions of the expiring or expired permit, the Department may choose to do any or all of the following:

(1) Initiate enforcement action based upon the permit which has been continued;

(2) Issue a notice of intent to deny the new permit under R.61-9.124.6. If the permit is denied, the owner or operator would then be required to cease the activities authorized by the continued permit or be subject to enforcement action for operating without a permit;

(3) Issue a new permit under R.61-9.124 with appropriate conditions; or

(4) Take other actions authorized by these regulations.

505.7. Confidentiality of information.

(a) [Reserved]

(b) Claims of confidentiality for the following information shall be denied:

(1) The name and address of any permit applicant or permittee;

(2) Permit applications, permits, and effluent data.

(c) Information required by permit application forms provided by the Department under section 505.21 may not be claimed confidential. This includes information submitted on the forms themselves and any attachments used to supply information required by the forms.

505.8. Permit requirements by others.

For permits issued under R.61-56 to construct an Individual Sewage Treatment and Disposal System serving more than one piece of deeded property the following requirements apply:

(a) A permit activity will not occur which is inconsistent with a plan or plan amendment approved under section 208(b) of the CWA, unless the Department finds such variance necessary to protect the public health, safety, and welfare.

(b) A public entity shall own the system and shall be responsible for the operation, maintenance and replacement of all components unless otherwise approved by the Department. The Department may consider a request for a private entity or person, however the proposal must be evaluated on a case by case basis. The Department can evaluate the capability of reliable system operation in its evaluation.

(c) If the project is owned by a private entity or person, the Department shall require financial assurances for the operation, maintenance, and replacement of the tank and tile field system and relevant pumping components. If residential wastewater is not being managed, the Department may consider waiving this requirement, if justified.

(d) The permit holder shall be required to properly operate and maintain in good working order and operate as efficiently as possible all facilities and systems which are installed or used to achieve compliance with the terms and conditions of the permit.

PART B

LAND APPLICATION PERMIT AND STATE PERMIT APPLICATION AND SPECIAL PROGRAM REQUIREMENTS

505.21. Application for a Land Application Permit and State Permit.

(a) Duty to apply.

(1) Any person who discharges or proposes to discharge pollutants directly or indirectly to groundwaters of the State or to any land of the State, or who owns or operates a "sludge only

facility” and who does not have an effective permit, except persons covered by general permits under R.61–9.122.28 excluded under section 505.3, or a user of a privately owned treatment works, unless the Department requires otherwise under section 505.44(m), shall submit a complete application to the Department in accordance with this section and R.61–9.124.

(2) A person discharging or proposing to discharge wastes directly or indirectly to the groundwaters of the State or any land of the State shall promptly make application for and obtain a valid Land Application permit or State Permit and, if required, a valid State Construction Permit;

(3) A person operating or proposing to operate a treatment works from which a discharge does not occur, shall promptly make application for and obtain a valid State Permit (or approval by the Department). The Department may also require the submittal of any additional information or data identified under R.61-9.

(b) [Reserved]

(c) Time to apply.

(1) Any person proposing a new discharge shall submit an application at least 180 days before the date on which the discharge is desired to commence, unless permission for a later date has been granted by the Department. Different submittal dates may be required under the terms of applicable general permits. Persons proposing a new discharge are encouraged to submit their applications well in advance of the requirements to avoid delay.

(2) Permits required under section 405(f) of the CWA.

(i) POTW’s with currently effective Land Application permits shall submit the application information required by paragraph (d)(2)(ii) of this section with the next application submitted in accordance with paragraph (d) of this section or within 120 days after promulgation of a “standard for sewage sludge use or disposal” applicable to the POTW’s sludge use or disposal practice(s), whichever occurs first.

(ii) Any other existing “treatment works treating domestic sewage” not covered under paragraph (c)(2)(i) of this section shall submit an application to the Department within 120 days after promulgation of a “standard for sewage sludge use or disposal” applicable to its sludge use or disposal practice(s) or upon request of the Department prior to promulgation of an applicable “standard for sewage sludge use or disposal”, if the Department determines that a permit is necessary to protect public health and the environment from any potential adverse effects that may occur from toxic pollutants in sewage sludge.

(iii) Any “treatment works treating domestic sewage” that commences operations after promulgation of an applicable “standard for sewage sludge use or disposal” shall submit an application to the Department at least 180 days prior to the date proposed for commencing operations.

(3) A person proposing to operate a treatment works from which no discharge occurs shall apply at least 180 days prior to the anticipated commencement of the activity or in accordance with a schedule determined by the Department in individual cases, for a State construction permit on an appropriate form supplied by the Department.

(d) Duty to reapply.

(1) Any permittee with an effective permit shall submit a new application at least 180 days before the expiration date of the existing permit, unless permission for a later date has been granted by the Department. The Department shall not grant permission for applications to be submitted later than the expiration date of the existing permit.

(2)(i) All applicants for permits shall complete application forms to apply under section 505.

(ii) In addition to any other applicable requirements in this regulation, all POTW and other “treatment works treating domestic sewage”, including “sludge-only facilities”, shall submit with their applications the information listed at section 122.21(q) within the time frames established in paragraph (c)(2) of this section.

(e) Completeness.

(1) The Department shall not issue a permit before receiving a complete application for a permit except for general permits. An application for a permit is complete when the Department receives an application form and any supplemental information which are completed to its satisfaction.

(2) The Department, at its discretion, may request of an applicant any additional information deemed necessary to complete or correct deficiencies in a Land Application permit or State permit application, before processing the application or issuing or denying the issuance of a permit.

(3) The Department may take enforcement action as prescribed by the State law or this regulation against any person who fails to file a complete application, if deficiencies are not corrected or complete information is not supplied within sixty (60) days to the Department following its request.

(4) The Department may consider an application incomplete if the applicant has not complied with the Environmental Protection Fees Regulation R.61-30.

(f) Information requirements.

(1) [Reserved]

(2) All applicants for Land Application permits and State permits (including permits being reissued or expanded) shall provide the following information to the Department, using the application form provided by the Department (additional information required of applicants is set forth in paragraph (g)):

(i) The activities conducted by the applicant which require it to obtain a Land Application permit or State permit.

(ii) Name, mailing address, and location of the facility for which the application is submitted.

(iii) Up to four Standard Industrial Codes (SIC) which best reflect the principal products or services provided by the facility.

(iv) The operator's name, address, telephone number, ownership status, and status as Federal, State, private, public, or other entity.

(v) [Reserved]

(vi) A listing of all wastewater permits or construction approvals received or applied for related to this facility and/or application.

(vii) A topographic map (or other map if a topographic map is unavailable) extending one mile beyond the property boundaries of the source, depicting the facility and any intake and discharge structures; any hazardous waste treatment, storage, or disposal facilities; any well where fluids from the facility are injected underground; and those wells, springs, other surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant in the map area.

(viii) A brief description of the nature of the business, activity, or project type.

(3) For new facilities, expanding or permit modifications a previously approved or proposed engineering report for the project in accordance with R.61-67.

(4) Project name: Provide the official (legal) name of the WWTP or sludge disposal site.

(5) County: Give county (or counties) where the proposed or existing wastewater treatment facility and/or site is located.

(6) Owner's name, address and telephone number: Provide the name, mailing address and the area code and telephone number of the owner. If the mailing address of the WWTP or site is different from the owner's mailing address, supply this information on an attached sheet of paper.

(7) Project status: Identify if the project is for a new or existing WWTP, or new or existing site. Provide the Land Application or State permit number and identify whether it is for a proposed expansion of either an existing WWTP or a renewal of an issued (if applicable) land disposal permit.

(8) Project description: Specify the type of project and give a brief description of the WWTP or site operation.

(9) Location of the WWTP and land disposal sites: Provide a map or maps showing the location of the WWTP and land disposal site(s). The map(s) shall be an 8 1/2" x 11" photocopy of the applicable portion of a U.S. Geological Survey 7 1/2 minute quad sheet (or a 15 minute quad if a 7 1/2 minute quad is not available). The quad sheet name shall be provided on the copy submitted to the Department. Give the latitude and longitude of the center of the WWTP site and a brief location description of the WWTP site. If the application is for a sludge or septage land application site owned by an entity that does not or will not have a WWTP, indicate "not applicable". For each

disposal site, give the size in acres, the latitude and longitude of the center of the site, and a brief location description of the site.

(10) Description of waste to be land applied: Provide a description of the wastewater or sludge to be land applied. State whether the waste is domestic and/or industrial wastewater. If the wastewater is not strictly domestic, give a detailed characterization of the wastewater. If the detailed characterization is contained in a Preliminary Engineering Report (PER) accompanying this application, then state that the information is in the PER.

(11) Volume and quantity of waste to be land applied: Provide the volume in gallons per day and the quantity in pounds per day of the waste to be land applied to each disposal site.

(12) Frequency of application: Provide the proposed frequency application in times per day, week or other period for each disposal site.

(13) Site application rate(s): Provide the proposed application rate in inches per week, pounds per acre per day (use annual rates for crop uptake) for sludge disposal, or other units as appropriate for each disposal site, whichever is the limiting factor.

(14) Groundwater Quality Monitoring: Identify whether the monitoring is proposed (if required) or existing. Also, provide the number of monitoring wells proposed or existing at each land disposal site.

(15) Residual solids: Identify the proposed or existing sludge disposal method (for wastewater treatment facilities).

(16) Hazardous substances: Identify whether or not the discharge contains a substance that could be considered hazardous as defined under section 101(14) of CERCLA. Provide the substance name, concentration and source.

(17) For wastewater treatment facilities: Proof of ownership (fee simple title) of any land application site(s) for treated effluent disposal. A contract, lease or other legally binding agreement may be substituted provided that:

(i) The contract, lease or agreement shall be for a period of at least 30 years with an automatic right of renewal for an additional 30 years. Cancellation wording may be included if all parties agree and obtain prior Departmental approval of any cancellation of the agreement. For activities involving limited applications (such as one time sludge or septage land application), the contract, lease or agreement time shall be determined on a project specific basis.

(ii) The contract, lease or agreement shall clearly identify that the use of the land application site is for effluent application and may take precedence over other uses unless there is a permitted secondary year round disposal option (e.g. an NPDES permit).

(iii) The specific quantity of effluent to be applied on a daily or weekly basis shall be provided.

(iv) The contract, lease or agreement shall be binding on all heirs, assignees, and successors.

(v) The applicant shall provide an alternate disposal option for any land application site that does not accept effluent year round. The applicant shall provide for year round disposal for the proposed flow on the land application site unless there is a permitted secondary year round disposal option (e.g. an NPDES permit).

(g) Requirements for manufacturing, commercial and mining activities. Manufacturing, commercial and mining dischargers applying for Land Application permits or State permits shall provide the following information to the Department, using application forms provided by the Department.

(1) Discharge location. The latitude and longitude to the nearest 15 seconds for each discharge location.

(2) NPDES permit application Form 2(C). See R.61-9.122.

505.22. Signatories to Land Application permit and State permit applications and reports.

Signatories to permit applications and reports shall be in accordance with R.61-9.122.22.

505.23. General Land Application permits and State permits.

(a) Coverage. The Department may issue a general permit in accordance with the following:

(1) Area. The general permit shall be written to cover a category of discharges, sludge use or disposal practices, or facilities described in the permit under paragraph (a)(2)(ii) of this section, except those covered by individual permits, within a geographic area. The area shall correspond to existing geographic or political boundaries.

(2) Sources. The general permit may be written to regulate, within the area described in paragraph (a)(1) of this section.

(i) [Reserved]

(ii) A category of sources (including industrial sludge) or “treatment works treating domestic sewage”, if the sources or “treatment works treating domestic sewage”:

(A) Involve the same or substantially similar types of operations;

(B) Discharge the same types of wastes or engage in the same types of sludge use or disposal practices;

(C) Require the same effluent limitations, operating conditions, or standards for sewage sludge use or disposal, or industrial sludge use or disposal;

(D) Require the same or similar monitoring; and

(E) In the opinion of the Department are more appropriately controlled under a general permit than under individual permits.

(b) Administration.

(1) General permits may be issued, modified, revoked and reissued, or terminated in accordance with applicable requirements of R.61-9.124.

(2) Authorization to discharge or authorization to engage in sludge use and disposal practices.

(i) Except as provided in paragraphs (b)(2)(v) and (b)(2)(vi) of this section, dischargers (or treatment works treating domestic sewage) seeking coverage under a general permit shall submit to the Department a written notice of intent to be covered by the general permit. A discharger (or treatment works treating domestic sewage) who fails to submit a notice of intent in accordance with the terms of the permit is not authorized to discharge (or, in the case of sludge disposal permit, to engage in a sludge use or disposal practice), under the terms of the general permit unless the general permit, in accordance with paragraph (b)(2)(v) of this section, contains a provision that a notice of intent is not required or the Department notifies a discharger (or treatment works treating domestic sewage) that it is covered by a general permit in accordance with paragraph (b)(2)(vi) of this section. A complete and timely notice of intent (NOI) to be covered, in accordance with general permit requirements, fulfills the requirements for permit applications.

(ii) The contents of the notice of intent shall be specified in the general permit and shall require the submission of information necessary for adequate program implementation, including at a minimum, the legal name and address of the owner or operator, the facility name and address, type of facility or discharges, and the disposal sites. All notices of intent shall be signed in accordance with R.61-9.122.22.

(iii) General permits shall specify the deadlines for submitting notices of intent to be covered and the date(s) when a discharger is authorized to discharge under the permit.

(iv) General permits shall specify whether a discharger (or treatment works treating domestic sewage) that has submitted a complete and timely notice of intent to be covered in accordance with the general permit and that is eligible for coverage under the permit, is authorized to discharge (or, in the case of a sludge disposal permit, to engage in a sludge use or disposal practice) in accordance with the permit either upon receipt of the notice of intent by the Department, after a waiting period specified in the general permit, on a date specified in the general permit, or upon receipt of notification of inclusion by the Department. Coverage may be terminated or revoked in accordance with paragraph (b)(3) of this section.

(v) Dischargers may, at the discretion of the Department, be authorized to discharge under a general permit without submitting a notice of intent where the Department finds that a notice of intent requirement would be inappropriate. The Department shall provide in the public notice of the general permit the reasons for not requiring a notice of intent.

(vi) The Department may notify a discharger (or treatment works treating domestic sewage) that it is covered by a general permit, even if the discharger (or treatment works treating domestic sewage) has not submitted a notice of intent to be covered. A discharger (or treatment works treating domestic sewage) so notified may request an individual permit under paragraph (b)(3)(iii) of this section.

(3) Requiring an individual permit.

(i) The Department may require any person authorized by a general permit to apply for and obtain an individual Land Application permit or State permit. An applicant, any affected State, or interstate agency, or any other interested person may petition the Department to take action under this paragraph. The petition shall indicate specific reasons why an individual permit is requested and the interest in or relationship of the petitioner to the applicant. Cases where an individual Land Application permit or State permit may be required include the following:

(A) The discharger or "treatment works treating domestic sewage" is not in compliance with the conditions of the general Land Application permit or State permit;

(B) A change has occurred in the availability of demonstrated technology or practices for the control or abatement of pollutants applicable to the point source or treatment works treating domestic sewage;

(C) Effluent limitation guidelines are promulgated for point sources covered by the general Land Application permit or State permit;

(D) A Water Quality Management plan containing requirements applicable to the discharge is approved;

(E) Circumstances have changed since the time of the request to be covered so that the discharger is no longer appropriately controlled under the general permit, or either a temporary or permanent reduction or elimination of the authorized discharge is necessary;

(F) Standards for sewage sludge use or disposal, or industrial sludge use or disposal have been promulgated for the sludge use and disposal practice covered by the general Land Application permit or State permit.

(ii) [Reserved]

(iii) Any owner or operator authorized by a general permit may request to be excluded from the coverage of the general permit by applying for an individual permit. The owner or operator shall submit an application under R.61-9.505.21, with reasons supporting the request, to the Department no later than 90 days after the publication of the general permit in the State Register. The request shall be processed in accordance with R.61-9.124. The request shall be granted by issuing of an individual permit if the reasons cited by the owner or operator are adequate to support the request.

(iv) When an individual Land Application permit or State permit is issued to an owner or operator otherwise subject to a general Land Application permit or State permit, the applicability of the general permit to the individual Land Application permittee or State permittee is automatically terminated on the effective date of the individual permit.

(v) A source excluded from a general permit solely because it already has an individual permit may request that the individual permit be revoked, and that it be covered by the general permit. If the individual permit is revoked by the Department, the general permit shall apply to the source.

(c) Degree of Waste Treatment Required. All pollutants shall receive such treatment or corrective action so as to insure compliance with the terms and conditions of the issued permit.

(d) Submittal and Signatory Requirements.

(1) A Notice of Intent (NOI) shall be on forms as may be prescribed and furnished from time to time by the Department. An NOI shall be accompanied by all pertinent information as the Department may require in order to establish effluent limitations in accordance with this regulation, including, but not limited to, complete engineering reports, schedule of progress, plans, specifications, maps, measurements, quantitative and qualitative determinations, records, and all related materials.

(2) Engineering reports, plans and specifications submitted to the Department's Land Application permit or State permitting divisions shall be signed by a Professional Engineer registered in the State of South Carolina and competent in the field of sewage and industrial waste treatment.

(3) Material submitted shall be complete and accurate.

(4) Any NOI form submitted to the Department shall be signed in accordance with this Regulation.

(5) All other reports or requests for information required by the Department shall be signed by a person designated in R.61-9.122.22 or a duly authorized representative of such person, if:

(i) The representative so authorized is responsible for the overall operation of the facility from which the discharge originates, e.g., a plant manager, superintendent or person of equivalent responsibility;

(ii) The authorization is made in writing by the person designated under R.61-9.122.22; and

(iii) The written authorization is submitted to the Department.

(6) Any changes in the written authorization submitted to the Department which occur after the issuance of a permit shall be reported to the Department by submitting a copy of a new written authorization that meets the requirements of paragraph (d)(5) above.

(7) Any person signing any document under (d) above shall make the following certification: "I certify under penalty of law that I have personally examined and am familiar with the information submitted in the attached document; and based on my inquiry of those individuals immediately responsible for obtaining the information, I believe the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

(e) Other Requirements.

(1) Notice and Public Participation. Public notice and participation requirements for Land Application Permits shall be in accordance with this Regulation (R.61-9).

(2) Terms and Conditions of Permits. General permits issued shall be subject to the terms and conditions contained in this Regulation (R.61-9).

(3) Monitoring, Recording and Reporting Requirements. Monitoring, recording, and reporting requirements shall be in accordance with the permit and this Regulation (R.61-9).

(4) Duration, Continuation, and Transferability of Permits. General permits shall be issued for a fixed term in accordance with this Regulation (R.61-9).

PART C

LAND APPLICATION PERMIT AND STATE PERMIT CONDITIONS

505.41. Conditions applicable to all Land Application permits and State permits.

The following conditions apply to all Land Application permits and State permits. Additional conditions applicable to Land Application permits and State permits are in section 505.42. All conditions applicable to Land Application permit and State permit shall be incorporated into the permits either expressly or by reference. If incorporated by reference, a specific citation must be given in the permit.

(a) Duty to comply. The permittee shall comply with all conditions of the permit. Any permit noncompliance constitutes a violation of the Pollution Control Act and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or denial of a permit renewal application. The Department's approval of wastewater facility Plans and Specifications does not relieve the permittee of responsibility to meet permit limits.

(1) [Reserved]

(2) Failure to comply with permit conditions or the provisions of this regulation may subject the permittee to civil penalties under S.C. Code Section 48-1-330 or criminal sanctions under S.C. Code Section 48-1-320. Sanctions for violations of the Federal Clean Water Act may be imposed in accordance with the provisions of R.61-9.122.41(a)(2) and (3).

(3) A person who violates any provision of this regulation, a term, condition or schedule of compliance contained within a valid Land Application permit or State permit is subject to the actions defined in State law and this regulation.

(b) Duty to reapply. If the permittee wishes to continue an activity regulated by its permit after the expiration date of the permit, the permittee must apply for and obtain a new permit.

(c) Need to halt or reduce activity not a defense. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of its permit.

(d) Duty to mitigate. The permittee shall take all reasonable steps to minimize or prevent any discharge or sludge use or disposal in violation of its permit which has a reasonable likelihood of adversely affecting human health or the environment.

(e)(1) Proper operation and maintenance. The permittee shall at all times properly operate and maintain in good working order and operate as efficiently as possible all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the terms and conditions of this permit. Proper operation and maintenance includes effective performance based on design facility removals, adequate funding, adequate operator staffing and training and also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems which are installed by a permittee only when the operation is necessary to achieve compliance with the conditions of the permit.

(2) The permittee shall develop and maintain at the facility a complete Operations and Maintenance Manual for the waste treatment facilities and/or land application system. The manual shall be made available for on-site review during normal working hours. The manual shall contain operation and maintenance instructions for all equipment and appurtenances associated with the waste treatment facilities and land application system. The manual shall contain a general description of the treatment process(es), the operational procedures to meet the requirements of (e)(1) above, and the corrective action to be taken should operating difficulties be encountered.

(3)(i) Except as stated in (ii) below, the permittee shall provide for the daily performance of treatment facility inspections by a certified operator of the appropriate grade ("the operator") as defined in the permit for the facility. The inspections shall include, but should not necessarily be limited to, areas which require visual observation to determine efficient operations and for which immediate corrective measures can be taken using the O & M manual as a guide. All inspections shall be recorded and shall include the date, time, and name of the person making the inspection, corrective measures taken, and routine equipment maintenance, repair, or replacement performed. The permittee shall maintain all records of inspections at the permitted facility as required by the permit, and the records shall be made available for on-site review during normal working hours.

(ii) The Department may make exceptions to operating requirements, if stated in the permit, as follows:

(A) Attendance by the operator is normally required only on days when treatment, land application, or discharge occurs.

(B) For performance of daily inspections, permits may allow a reduced grade of operator for limited time periods under specific circumstances when justified by the permittee in a staffing plan and approved by the Department.

(C) Reduced inspection frequency, but in no case less than weekly, may be suitable when specified in the permit, if there is complete telemetry of operating data and there is either a simple treatment system with a low potential for toxicity but requiring pumps or other electrical functions or the ability to stop the discharge for an appropriate period when necessary.

(D) In other circumstances where the permittee demonstrates the capability to evaluate the facility in an alternative manner equivalent to the inspection requirements in subparagraph 3(i).

(E) Any exceptions allowed in (A), (B), (C), and (D) above are subject to compliance with permit conditions.

(4)(i) Purpose. This regulation establishes rules for governing the operation and maintenance of wastewater sewer systems, including gravity or pressure interceptor sewers. It is the purpose of this rule to establish standards for the management of sewer systems to prevent and/or minimize system failures that would lead to public health or environmental impacts.

(ii) Authority and applicability. Under Section 48–1–30 of the Code of Laws of South Carolina (1976 as amended), the Department is authorized to adopt such rules and regulations as may be necessary to implement the Pollution Control Act. This regulation applies to all sewer systems that have been or would be subject to a DHEC construction permit under Regulation 61–67 and whose owner owns or operates the wastewater treatment system to which the sewer discharges and which discharges under a State permit. Nothing in this regulation supersedes a more stringent requirement that may be imposed by sewer system owners that manage wastewater from satellite systems. This regulation (505.41(e)(4)) is effective when published in the State Register.

(iii) General requirements. The requirements to properly operate and maintain sewer systems are the responsibility of the system owner. General Standards. The sewer system owner must:

(A) Properly manage, operate, and maintain at all times all parts of its sewer system(s), to include maintaining contractual operation agreements to provide services, if appropriate;

(B) Provide adequate capacity to convey base flows and peak flows for all parts of the sewer system or, if capital improvements are necessary to meet this standard, develop a schedule of short and long term improvements;

(C) Take all reasonable steps to stop and mitigate the impact of releases of wastewater to the environment; and

(D) Notify the Department within 30 days of a proposed change in ownership of a sewer system.

(iv) [Reserved]

(f) Permit actions. A Land Application or State permit may be modified, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance does not stay any permit condition.

(g) Property rights. A Land Application or State permit does not convey any property rights of any sort,

(h) Duty to provide information. The permittee shall furnish to the Department, within a reasonable time, any information which the Department may request to determine whether cause exists for modifying, revoking and reissuing, or terminating its permit or to determine compliance with its permit. The permittee shall also furnish to the Department upon request, copies of records required to be kept by its permit.

(i) Inspection and entry. The permittee shall allow the Department, or an authorized representative (including an authorized contractor acting as a representative of the Department), upon presentation of credentials and other documents as may be required by law, to:

(1) Enter upon the permittee's premises where a regulated facility or activity including all land disposal sites is located or conducted, or where records must be kept under the conditions of its permit;

(2) Have access to and copy, at reasonable times, any records that must be kept under the conditions of its permit;

(3) Inspect at reasonable times any facilities, equipment (including monitoring and control equipment) including all land disposal sites, practices, or operations regulated or required under its permit;

(4) Sample or monitor at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by the Pollution Control Act, any substances or parameters at any location including all land disposal sites.

(j) Monitoring and records.

(1)(i)(A) Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity.

(B) Samples shall be reasonably distributed in time, while maintaining representative sampling.

(C) No sampling or analysis, which is otherwise valid, shall be terminated for the purpose of preventing the analysis from showing a permit or water quality violation.

(ii) Flow Measurements.

(A) Where primary flow meters are required, appropriate flow measurement devices and methods consistent with accepted scientific practices shall be present and used to ensure the accuracy and reliability of measurements of the volume of monitored discharges. The devices shall be installed, calibrated, and maintained to ensure that the accuracy of the measurements is consistent with the accepted capability of that type of device. Devices selected shall be capable of measuring flows with a maximum deviation of not greater than 10 percent from the true discharge rates throughout the range of expected discharge volumes. The primary flow device, where required, must be accessible to the use of a continuous flow recorder.

(B) Where permits require an estimate of flow, the permittee shall maintain at the permitted facility a record of the method(s) used in "estimating" the discharge flow (e.g., pump curves, production charts, water use records) for the outfall(s) designated on limits pages to monitor flow by an estimate.

(C) Records of any necessary calibrations must also be kept.

(iii) The Department may designate a single, particular day of the month on which any group of parameters listed in the permit must be sampled. When this requirement is imposed in a permit, the Department may waive or alter compliance with the permit requirement for a specific sampling event for extenuating circumstances.

(2) Except for records of monitoring information required by a permit related to the permittee's sewage sludge use and disposal activities, which shall be retained for a period of at least five years (or longer as required by 40 CFR Part 503, R.61-9.503, or R.61-9.504), the permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by its permit, and records of all data used to complete the application for its permit, for a period of at least 3 years from the date of the sample, measurement, report or application. This period may be extended by request of the Department at any time.

(3) Records of monitoring information shall include:

- (i) The date, exact place, and time of sampling or measurements;
- (ii) The individual(s) who performed the sampling or measurements;
- (iii) The date(s) analyses were performed;
- (iv) The individual(s) who performed the analyses;
- (v) The analytical techniques or methods used; and
- (vi) The results of such analyses.

(4) Analyses for required monitoring must be conducted according to test procedures approved under 40 CFR Part 136 unless other test procedures have been specified in the permit or, in the case of sludge use or disposal, unless otherwise specified in R.61-9.503 or R.61-9.504.

(5) The PCA provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under its permit shall be subject to civil and criminal penalties as provided for in the act, law or other appropriate regulations.

(k) Signatory requirement.

(1) All applications, reports, or information submitted to the Department shall be signed and certified (See R.61-9.122.22).

(2) The PCA provides that any person who knowingly makes any false statement, representation, or certification in any application, record, report, plan or other document submitted or required to be maintained under a permit, including monitoring reports or reports of compliance or non-compliance shall be subject to civil or criminal provisions as provided for in the act, law or other appropriate regulations.

(l) Reporting requirements.

(1) Planned changes. The permittee shall give prior notice to the Department as soon as possible of any planned physical alterations or additions to the permitted facility (and obtain a Construction Permit if required under R.61-67). Prior notice is required only when:

(i) [Reserved]

(ii) The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants which are subject neither to effluent limitations in the permit, nor to notification requirements under R.61-9.122.42(a)(1).

(iii) The alteration or addition results in a significant change in the permittee's sludge use or disposal practices, and such alteration, addition, or change may justify the application of permit conditions that are different from or absent in the existing permit, including notification of additional use or disposal sites not reported during the permit application process or not reported pursuant to an approved land application plan;

(2) Anticipated noncompliance. The permittee shall give advance notice as soon as possible to the Department of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements.

(3) Transfers. A Land Application or State permit is not transferable to any person except after notice to the Department. The Department may require modification or revocation and reissuance of the permit to change the name of permittee and incorporate such other requirements as may be necessary under the Pollution Control Act. (See R.61-9.505.61. In some cases, modification or revocation and reissuance is mandatory.)

(4) Monitoring reports. Monitoring results shall be reported at the intervals specified in the permit.

(i) Monitoring results (with the exception of any Annual Reporting requirements under section 503.18, section 503.28, section 503.48 or section 504.18) must be reported on a Discharge Monitoring Report (DMR) or forms provided or specified by the Department for reporting results of monitoring of sludge use or disposal practices.

(ii) If the permittee monitors any pollutant more frequently than required by the permit using test procedures approved under 40 CFR Part 136 or, in the case of sludge use or disposal, approved under 40 CFR Part 136 unless otherwise specified in R.61-9.503, R.61-9.504, or as specified in the permit, the results of this monitoring shall be included in the calculation and reporting of the data submitted in the DMR or sludge reporting form specified by the Department.

(iii) Calculations for all limitations which require averaging of measurements shall utilize an arithmetic mean unless otherwise specified by the Department in the permit.

(5) Compliance schedules. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of its permit shall be submitted no later than 14 days following each schedule date.

(6) Twenty-four hour reporting.

(i) The permittee shall report any noncompliance which may endanger health or the environment. Any information shall be provided orally within 24 hours from the time the permittee becomes aware of the circumstances. A written submission shall also be provided within 5 days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times; and, if the noncompliance has not been

corrected, the anticipated time it is expected to continue and steps taken or planned to reduce, eliminate, and prevent recurrence of the noncompliance.

(ii) The following shall be included as information which must be reported within 24 hours under this paragraph.

(A) Any unanticipated bypass which exceeds any effluent limitation in the permit. (See R.61-9.505.44.)

(B) Any upset which exceeds any effluent limitation in the permit.

(C) Violation of a maximum daily discharge limitation for any of the pollutants listed by the Department in the permit to be reported within 24 hours. (See R.61-9.505.44).

(iii) The Department may waive the written report on a case-by-case basis for reports required under paragraph (l)(6)(ii) of this section, if the oral report has been received within 24 hours.

(7) Other noncompliance. The permittee shall report all instances of noncompliance not reported under paragraphs (l)(4), (5), and (6) of this section, at the time monitoring reports are submitted. The reports shall contain the information listed in paragraph (l)(6) of this section.

(8) Other information. Where the permittee becomes aware that it failed to submit any relevant facts in a permit application, or submitted incorrect information in a permit application or in any report to the Department, it shall promptly submit such facts or information.

(m) Bypass.

(1) Definitions.

(i) "Bypass" means the intentional diversion of waste streams from any portion of a treatment facility including holding basins.

(ii) "Severe property damage" means substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.

(2) Bypass not exceeding limitations. The permittee may allow any bypass to occur which does not cause effluent limitations to be exceeded, but only if it also is for essential maintenance to assure efficient operation. These bypasses are not subject to the provisions of paragraph (m)(3) and (m)(4) of this section.

(3) Notice.

(i) Anticipated bypass. If the permittee knows in advance of the need for a bypass, it shall submit prior notice, if possible, at least ten days before the date of the bypass.

(ii) Unanticipated bypass. The permittee shall submit notice of an unanticipated bypass as required in paragraph (l)(6) of this section (24-hour reporting).

(4) Prohibition of bypass

(i) Bypass is prohibited, and the Department may take enforcement action against a permittee for bypass, unless:

(A) Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;

(B) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass which occurred during normal periods of equipment downtime or preventive maintenance; and

(C) The permittee submitted notices as required under paragraph (m)(3) of this section.

(ii) The Department may approve an anticipated bypass, after considering its adverse effects, if the Department determines that it will meet the three conditions listed above in paragraph (m)(4)(i) of this section.

(n) Upset.

(1) Definition. "Upset" means an exceptional incident in which there is unintentional and temporary noncompliance with technology based permit effluent limitations because of factors beyond the reasonable control of the permittee. An upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventive maintenance, or careless or improper operation including the land disposal sites.

(2) Effect of an upset. An upset constitutes an affirmative defense to an action brought for noncompliance with such technology based permit effluent limitations if the requirements of paragraph (n)(3) of this section are met. No determination made during administrative review of claims that noncompliance was caused by upset, and before an action for noncompliance, is final administrative action subject to judicial review.

(3) Conditions necessary for a demonstration of upset. A permittee who wishes to establish the affirmative defense of upset shall demonstrate, through properly signed, daily operating logs, or other relevant evidence that:

(i) An upset occurred and that the permittee can identify the cause(s) of the upset;

(ii) The permitted facility including the land disposal sites were at the time being properly operated; and

(iii) The permittee submitted notice of the upset as required in paragraph (l)(6)(ii)(B) of this section (24 hour reporting).

(iv) The permittee complied with any remedial measures required under paragraph (d) of this section.

(4) Burden of proof. In any enforcement proceeding, the permittee seeking to establish the occurrence of an upset has the burden of proof.

(o) Misrepresentation of Information.

(1) Any person making application for a Land Application permit or State permit or filing any record, report, or other document pursuant to a regulation of the Department, shall certify that all information contained in such document is true. All application facts certified to by the applicant shall be considered valid conditions of the permit issued pursuant to the application.

(2) Any person who knowingly makes any false statement, representation, or certification in any application, record, report, or other documents filed with the Department pursuant to the State law, and the rules and regulations pursuant to that law, shall be deemed to have violated a permit condition and shall be subject to the penalties provided for pursuant to 48-1-320 or 48-1-330.

(p) Other requirements.

(1) No portion of a new or expanding application site for effluent application shall be located in the 100 year flood plain unless there is a permitted secondary year round disposal option (e.g. an NPDES permit).

(2) Effluent application shall not occur during periods when the ground is frozen, ponded, there is standing water on the application site, or the ground is flooded.

(3) New or expanding facilities with basins, storage ponds or other constructed impoundments (except for systems designed to operate in this manner, e.g. infiltration basins) must be appropriately lined as determined by the Department. The Department may consider the level of treatment and, if the basin or structure is existing, the scope of the modifications that may be required in the determination of whether a basin, storage pond or other constructed impoundments must be lined. Storage facilities for Reclaimed water (as described in section 505.45) will not require a liner unless specifically required by the Department.

(4) New or expanding facilities with basins, storage ponds or constructed impoundments shall be constructed in accordance with R.61-67 (if construction is required).

(5) Basins, storage ponds, or constructed impoundments (except for systems designed to operate in this manner, e.g., infiltration basins) which are in use may be required to be monitored with groundwater monitoring wells as approved by the Department. The basin, storage pond or constructed impoundment may be considered unlined if the leakage rate is greater than 500 gallons per day per acre, or information available would indicate to the Department that specific

hydrological conditions would require groundwater monitoring. The Department may consider the level of treatment, or the type of wastewater (e.g., influent characteristics) in the determination of whether an unlined basin, storage pond or other constructed impoundments must have groundwater monitoring. Storage facilities for reclaimed water (as described in section 505.45) will not require groundwater monitoring unless specifically required by the Department.

(6) There shall be no runoff of any effluent, sludge, treated waste or mixture of pollutants outside the permitted area.

(7) Lined basins, storage ponds, or constructed impoundments may be required by the Department to have groundwater monitoring wells to assure compliance with State Water Quality Standards R.61-68.

(8) [Reserved]

(9) [Reserved]

505.42. Additional conditions applicable to specified categories of Land Application permits and State permits.

The following conditions, in addition to those set forth in section 505.41, apply to all Land Application permit or State permits within the categories specified below:

(a) R.61-9.122.42(a) and (b) shall apply.

(b) Irrigation of treated wastewater. This includes all methods of surface application, including but not limited to, fixed gun application, travelling or mobile gun application, or center pivot application.

(1) Spray field slopes shall not exceed 10 percent unless approved by the Department. The Department may require that slopes be less than 10% based on site conditions.

(2) Effluent distribution systems shall be designed so that the distribution pattern maximizes uniform application. The Department may require the permittee to modify existing land application site(s) distribution systems based on site conditions (e.g., potential for ponding, runoff, or discharges to open ditches).

(3) Soil borings may be required by the Department to depict the lithologic and hydrogeologic characteristics of the subsurface. The requirements of R.61-67 would apply.

(4)(i) At proposed spray sites with satisfactory soil conditions, design application rates for hydraulic loading shall not exceed (with the exception of seasonal application) the rates shown in Table I (unless one of the conditions in (4)(ii)-(vi) apply) :

Table I

Depth to Seasonal High Water (or measured high water depth, e.g. piezometer readings)	Design Application Rate (gallons per day per acre) (gpd/acre)
5 feet or more	2 inches/week (in/wk), 7,758 gpd/acre
4 feet	1 in/wk, 3,879 gpd/acre
3 feet	0.5 in/wk, 1,940 gpd/acre
less than 3 feet	no application (unless otherwise approved by the Department)

(ii) The applicant may request intermediate loading rates, if the seasonal high water table is between the depths shown in the table.

(iii) If the seasonal high water table (or measured high water depth e.g. piezometer readings), is less than three (3) feet, the Department may consider permitting the land application site if the domestic wastewater facilities are designed to meet monthly average effluent limits for 5-day Biochemical Oxygen Demand (BOD₅) of 10 mg/l, Ammonia nitrogen (NH₃-N) of 2 mg/l and Nitrate (N) of 10 mg/l, or industrial facilities with non-process wastewater or other suitable wastes. The Department may eliminate some or all of the groundwater monitoring requirements for these facilities.

(iv) The application rate may be limited based on pollutant loading including any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR

Parts 400 through 402 and 404 through 471). The applicant for domestic wastewater or other systems with a nitrate/nitrogen loading may be required to provide the Department, a nitrate to nitrogen loading balance to determine if the application rates shown in Table I shall be adjusted.

(v) The Department may consider application rates in excess of two (2) inches per week for sites that meet the depth to groundwater shown in Table I, provided the application period is only for a portion of the year, or the application is for reclaimed water. The applicant must provide sufficient information to the Department to justify a higher application rate (information required may include, but is not limited to a water balance for the summer season).

(vi) For Domestic wastewater facilities designed to meet monthly average effluent limits of a 5-day Biochemical Oxygen Demand (BOD₅) of 10 mg/l, NH₃-N of 2 mg/l and Nitrate of 10 mg/l, or industrial facilities with non-process wastewater, or other suitable wastes. If the seasonal high water table (or measured high water depth e.g. piezometer readings), for the land application site is three (3) feet or more, the Department may eliminate some or all of the groundwater monitoring requirements for these facilities.

(5) The design application frequency for effluent irrigation shall not exceed a spray to rest ratio suitable for the soil conditions. A spray to rest ratio of 1:20 shall be used unless an alternative rate is approved by the Department. The application frequency for other activities (such as sludge or septage application) would be determined on a site specific basis.

(6) The application site shall be divided into designed spray areas to meet this spray to rest ratio and a continuous application period per defined spray area shall be designed not to exceed 1.2 hours per day, or up to 8 consecutive hours per week (only under those limited conditions when excessive rainfall on the application sites requires application in one day). If the design application rate on a daily basis is exceeded, the Department may require the permittee to provide additional spray application area or alternative disposal methods may be required (e.g. expanding storage capacity for effluent at the facility). Alternative application periods (such as golf course irrigation) may be approved by the Department.

(7) For permitted spray disposal areas which already receive irrigation (e.g. stormwater, potable water or well water), the effluent application rates may be modified by the Department to correspond to the depth to the measured high water table or to the seasonal high water table, whichever is more shallow.

(8) The new or expanding spray field shall be at least 200 feet from surface waters of the State, occupied buildings and potable water wells unless otherwise approved by the Department. The new or expanding spray field shall be at least 100 feet from the property boundary except for golf courses where it shall be at least 75 feet. The Department may require modification to existing permitted spray fields to control the application areas by the addition or expansion of a buffer zone. The applicant may request the buffer zone for specific spray areas be eliminated for sites where the adjacent property owner agree to the elimination of the buffer in writing. The Department may approve an elimination of the buffer zone based on the information provided by the applicant.

(9) A dike or berm around the perimeter of the spray field may be required in specific areas determined by the Department as necessary to prevent potential surface runoff from entering or leaving the spray site. The Department may consider alternate methods of runoff controls that may be proposed by the applicant.

(10) A system for monitoring the quality of groundwater shall also be established for the proposed spray site (for those systems requiring groundwater monitoring). The location of all the monitor wells shall be approved by the Department. The applicant shall provide at least one monitoring well up-gradient of the spray area and at least two groundwater monitoring wells down-gradient. For larger spray fields, more than three groundwater monitoring wells may be required. For land application on golf courses with secondary effluent limits, nine monitor wells shall be provided for 18 fairways (or one groundwater well per two fairways for differing course sizes). The Department may reduce the number of groundwater monitoring wells required based on site conditions (e.g. a significant number of existing groundwater monitoring wells in a small area with multiple golf courses, or existing groundwater monitoring data).

(11) Groundwater samples for new application sites (for those systems requiring groundwater monitoring) shall be analyzed for the following parameters. Background groundwater sampling data may be required for new sites prior to the use of the site using similar parameters. For existing or expanding sites the Department may eliminate any parameter based on actual site information, wastewater characteristics or the groundwater data from consistent wastewater plant operations. Groundwater sampling may be required for existing sites (with no current groundwater monitoring wells), or expanding sites prior to the permitting of the expansion, to determine actual groundwater conditions.

(i) Water table elevation and water table depth

(ii) [Reserved]

(iii) Chloride

(iv) Ammonia (NH₃)

(v) Nitrate (N)

(vi) [Reserved]

(vii) pH (field)

(viii) Sodium

(ix) Total dissolved solids (TDS) This parameter may be added to the continuing groundwater monitoring based on the result of field specific conductance.

(x) Field specific conductance

(12) Additional parameters may be required in the initial background groundwater analysis and subsequent monitoring thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required (in a permit) to be monitored in groundwater.

(13) The Department may require the applicant provide a nutrient balance which may include, but not be limited to, nutrient uptake of the proposed groundcover, crop or silviculture, design application rates, size and soil conditions present, and the total nutrient loading to the application site. The Department may adjust the application rates to each site based on the nutrient balance.

(c) Rapid Infiltration.

(1) New or expansions.

(i) New or expanding rapid infiltration basins must be limited to sites where the minimum separation of seasonal high groundwater table will remain 15 feet or more below the basin bottom throughout the year. Consideration may be given to separation of the seasonal high water table by less than 15 feet based on an evaluation of the quality of the effluent being applied. Consideration may also be given to a site when the seasonal high water table is less than 15 feet at some times but the actual separation of the water table is at least 15 feet at any time application occurs.

(ii) The annual hydraulic loading rates shall be no greater than fifteen percent (15%) of the lowest measured basin infiltration rate, unless approved by the Department. Loading rates may also be adjusted by the Department based on the pollutant loading parameters, including any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)). The applicant for domestic wastewater or other systems with a nitrate or nitrogen loading may be required to provide the Department, a nitrate to nitrogen loading balance to determine if the application rates shall be adjusted.

(iii)(A) cation to rest cycle shall consist of no less than a 1:4 ratio in the summer period (March-October) and a 1:6 ratio in the winter period (November-February). The Department may consider other information (e.g., temperature data) to modify the design summer and winter periods for specific sites.

(B) The Department may require the permittee whenever the scheduled resting cycle fails to restore infiltration rates to acceptable levels, to recondition the basin surface (e.g. by scraping and/or loosening of the soil surface by discing or harrowing).

(iv) The design hydraulic loading rate to the rapid infiltration basin shall be calculated to include monthly average precipitation rates for the site area. The most restrictive soil horizon shall have a 2 inches/hour infiltration rate or greater.

(v) The water table mound shall be maintained 6 feet or more below the bottom of the infiltration basin during effluent application. The Department may require the permittee to modify the application rate to achieve this separation.

(vi) Drinking water supply wells shall be protected from potential groundwater contamination by a minimum buffer zone of at least 1,000 feet beyond the rapid infiltration basin. A greater distance may be required by the Department in some cases depending on local hydrogeologic conditions.

(vii) The minimum number of groundwater monitoring wells shall be one up-gradient and one down-gradient for each infiltration basin. Additional wells may be required depending on the hydrogeologic conditions and/or basin size and number of basins. There shall be a minimum of two down-gradient wells or one per infiltration basin, whichever is greater.

(viii) Groundwater samples for new rapid infiltration basins shall be analyzed for the following parameters. For expanding rapid infiltration basins, the Department may eliminate any parameter based on actual site information, wastewater characteristics or the groundwater data from consistent wastewater plant operations:

- (A) Water table elevation and water table depth
- (B) [Reserved]
- (C) Chloride
- (D) Ammonia (NH₃)
- (E) Nitrate (N)
- (F) [Reserved]
- (G) pH (field)
- (H) Sodium
- (I) Total dissolved solids (TDS)
- (J) [Reserved]

(ix) Additional parameters may be required in the initial background groundwater analysis and subsequent monitoring thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required (in a permit) to be monitored in groundwater.

(2) All other rapid infiltration facilities.

(i) The minimum number of groundwater monitoring wells shall be one up-gradient and one down-gradient per each infiltration basin. Additional wells may be required depending on the hydrogeologic conditions and/or basin size and number of basins. There shall be a minimum of two down-gradient wells or one per infiltration basin, whichever is greater.

(ii) Groundwater samples for other rapid infiltration basins shall be analyzed for the following parameters. The Department may eliminate any parameter based on actual site information or the groundwater data from consistent wastewater plant operations:

- (A) Water table elevation and water table depth
- (B) [Reserved]
- (C) Chloride
- (D) Ammonia (NH₃)
- (E) Nitrate (N)
- (F) [Reserved]
- (G) pH (field)
- (H) Sodium

(I) Total dissolved solids (TDS)

(J) [Reserved]

(iii) Additional parameters may be required in the initial background groundwater analysis and subsequent monitoring thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required (in a permit) to be monitored in groundwater.

(d) Overland Flow.

(1) New or expansions.

(i) Any discharge to Surface Waters of the State shall require an NPDES permit issued in accordance with R.61-9.122.

(ii) Overland flow systems shall be designed so that the surface water and groundwater standards (R.61-68) shall be maintained.

(iii)(A) The applicant must include as part of the design for a new or expanding overland flow project, at least three ring and infiltrometer tests which shall be performed on the most permeable soil type(s) encountered during the soil borings.

(B) If, during the infiltration tests, the soils at the site are found to be more permeable than 0.2 in/hr, groundwater monitoring wells around the system as specified in paragraph (vi)(A) below shall be provided.

(iv) The permittee shall be required to maintain a water-tolerant turf grass that will facilitate the treatment of wastewater. Alternative proposed groundcover, crops or silviculture may be requested by the applicant. The Department may approve alternative covers.

(v) The overland flow design application period shall not exceed 12 hours per day for each terrace or slope or portion thereof. The NPDES or land application permit issued for the overland flow facility shall provide specific discharge flow limits or application rates.

(vi)(A) For those overland flow systems requiring groundwater monitoring, the minimum number of groundwater monitoring wells is one up-gradient of the entire overland flow system and two down-gradient of each area to be monitored.

(B) Groundwater monitoring wells may not be required at overland flow systems containing surficial permeable soils if they are engineered such that partially treated wastewater will not contact groundwater.

(vii) Groundwater monitoring (if required by the Department) for overland flow systems shall be analyzed for the following parameters. The Department may eliminate any parameter based on actual site information, wastewater characteristics or the groundwater data from consistent wastewater plant operations:

(A) Water table elevation and water table depth

(B) [Reserved]

(C) Chloride

(D) Ammonia (NH₃)

(E) Nitrate (N)

(F) [Reserved]

(G) pH (field)

(H) Sodium

(I) Total dissolved solids (TDS)

(J) [Reserved]

(viii) Additional parameters may be required in the initial background groundwater analysis and subsequent monitoring thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required (in a permit) to be monitored in groundwater.

(2) All other facilities.

(i)(A) The minimum number of monitoring wells is one up-gradient of the entire overland flow system and two down-gradient of each area to be monitored.

(B) Groundwater monitoring wells may not be required at overland flow systems containing surficial permeable soils if they are engineered such that partially treated wastewater will not contact groundwater.

(ii) Groundwater monitoring (if required by the Department) for overland flow systems shall be analyzed for the following parameters. The Department may eliminate any parameter based on actual site information or the groundwater data from consistent wastewater plant operations:

(A) Water table elevation and water table depth

(B) [Reserved]

(C) Chloride

(D) Ammonia (NH₃)

(E) Nitrate (N)

(F) [Reserved]

(G) pH (field)

(H) Sodium

(I) Total dissolved solids (TDS)

(J) [Reserved]

(iii) Additional parameters may be required in the initial background groundwater analysis and subsequent monitoring thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required to be monitored (in a permit) in groundwater.

(e) Tile Field.

(1) New or expanding.

(i) The submission and information requirements will be determined by the Department.

(ii) A public entity shall own the system and shall be responsible for the operation, maintenance and replacement of all components unless otherwise approved by the Department. The Department may consider a request for a private entity or person, however the proposal must be evaluated on a case by case basis. The Department can evaluate the capability of reliable system operation in its evaluation.

(iii) If the project is owned by a private entity or person, the Department shall require financial assurances for the operation and maintenance of the system. This financial assurance would typically be required for residential or domestic wastewater sources.

(iv) [Reserved]

(v) A program for monitoring the quality of groundwater may be established for domestic systems (having contributions from industrial facilities), for applicable industrial wastewater systems and other systems, if required by the Department.

(vi) Groundwater monitoring (if required by the Department) for tile field systems shall be analyzed for the following parameters. The Department may eliminate any parameter based on actual site information, wastewater characteristics or the groundwater data from consistent wastewater plant operations:

(A) Water table elevation and water table depth

(B) [Reserved]

(C) Chloride

(D) Ammonia (NH₃)

(E) Nitrate (N)

(F) [Reserved]

(G) pH (field)

(H) Sodium

(I) Total dissolved solids (TDS) This parameter may be added to the continuing groundwater monitoring based on the result of field specific conductance.

(J) Field Specific Conductance

(vii) Additional parameters may be required in the initial background groundwater analysis and subsequent monitoring thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required to be monitored (in a permit) in groundwater.

(2) All other tile field facilities.

(i) A program for monitoring the quality of groundwater may be established for domestic systems (having contributions from industrial facilities), for applicable industrial wastewater systems and other systems, if required by the Department.

(ii) Groundwater monitoring (if required by the Department) for other tile field systems shall be analyzed for the following parameters. The Department may eliminate any parameter based on actual site information or the groundwater data from consistent wastewater plant operations:

(A) Water table elevation and water table depth

(B) [Reserved]

(C) Chloride

(D) Ammonia (NH₃)

(E) Nitrate (N)

(F) [Reserved]

(G) pH (field)

(H) Sodium

(I) Total dissolved solids (TDS) or Field specific conductance

(J) [Reserved]

(iii) Additional parameters may be required in the initial background groundwater analysis and subsequent monitoring thereafter, but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required (in a permit) to be monitored in groundwater.

(f) Percolation or Evaporation Basins.

(1) A groundwater monitoring program may be required by the Department for existing systems to determine if there is a need to evaluate the groundwater conditions at the site to assure compliance with State Water Quality Standards R.61-68. If a deleterious impact to the groundwaters of the State from the permitted use or disposal practices is documented, through groundwater monitoring levels exceeding the standards set forth in R.61-68 or a significant adverse trend occurs, then it will be the obligation of the permittee as directed by the Department to conduct an investigation to determine the vertical and horizontal extent of groundwater impact. The Department may require remediation of the groundwater to within acceptable levels for groundwater as set forth in R.61-68.

(2) A program for monitoring the quality of groundwater may be established for domestic systems (having contributions from industrial facilities), for applicable industrial wastewater systems and other systems, if required by the Department. The Department may consider influent characteristics in this determination.

(i) Groundwater monitoring (if required by the Department). for percolation or evaporation basins shall be analyzed for the following parameters. The Department may eliminate any parameter based on actual site information or the groundwater data from consistent wastewater plant operations:

- (A) Water table elevation and water table depth
- (B) [Reserved]
- (C) Chloride
- (D) Ammonia (NH₃)
- (E) Nitrate (N)
- (F) [Reserved]
- (G) pH (field)
- (H) Sodium
- (I) Total dissolved solids (TDS)
- (J) [Reserved]

(ii) Additional parameters may be required in the initial background groundwater analysis and subsequent monitoring thereafter but such needs will be assessed on an individual project basis. Any pollutant required for monitoring under effluent guidelines (40 CFR Part 136; Subchapter N (40 CFR Parts 400 through 402 and 404 through 471)) may be required (in a permit) to be monitored in groundwater.

(g)(1) Spray irrigation or land application of sewage sludge shall be in accordance with R.61-9.503. Spray irrigation or land application of Industrial sludge shall be in accordance with R.61-9.504.

(2) If total suspended solids concentration of the treated wastewater solids or sludge is less than 2000 mg/l the Department may require the facility to comply with the additional requirements for land application of wastewater (R.61-9.505.42(b)).

(h) Reclaimed wastewater systems.

(1) Provided the level of treatment meets the requirement outlined in section 505.45(i), there would not be specific buffer area requirements.

(2) A groundwater monitoring program may be required by the Department for existing or new systems to determine if there is a need to evaluate the background groundwater conditions at the site to assure compliance with State Water Quality Standards R.61-68.

(3) Piping shall be clearly marked to identify reclaimed water lines and the Department may establish specific guidelines for use of reclaimed water systems.

(4) Reclaimed wastewater systems may be required to provide covered storage systems (or other alternative methods) to maintain effluent quality prior to distribution.

505.43. Establishing Land Application permit and State permit conditions.

(a) In addition to conditions required in all permits (section 505.41 and section 505.42), the Department shall establish conditions, as required on a case-by-case basis, to provide for and assure compliance with all applicable requirements of the CWA and PCA and regulations. These shall include conditions under section 505.46 (duration of permits), section 505.47(a) (schedules of compliance), and section 505.48 (monitoring).

(b)(1) An “applicable requirement” is a State statutory or regulatory requirement which takes effect prior to final administrative disposition of a permit. At the discretion of the Department, the comment period may be reopened where new requirements become effective during the permitting process and are of sufficient magnitude to make additional proceedings desirable. An applicable requirement is also any requirement which takes effect prior to the modification or revocation and reissuance of a permit, to the extent allowed in section 505.62.

(2) New or reissued permits and, to the extent allowed under section 505.62 modified or revoked and reissued permits shall incorporate each of the applicable requirements referenced in section 505.44 and section 505.45.

(c) Incorporation. All permit conditions shall be incorporated either expressly or by reference.

505.44. Establishing limitations, standards, and other Land Application permit and State permit conditions.

In addition to the conditions established under section 505.43(a), each Land Application permit and State permit may include conditions meeting the following requirements when applicable.

(a) [Reserved]

(b)(1) [Reserved]

(2) Standards for sewage sludge use or disposal under section 405(d) of the CWA, unless those standards have been included in a permit issued under the appropriate provisions of Subtitle C of the Solid Waste Disposal Act; Part C of Safe Drinking Water Act; the Marine Protection, Research, and Sanctuaries Act of 1972; the Clean Air Act; or under regulation R.61-9.503. When there are no applicable standards for sewage sludge use or disposal, the permit may include requirements developed on a case-by-case basis to protect public health and the environment from any adverse effects which may occur from toxic pollutants in sewage sludge. If any applicable standard for sewage sludge use or disposal is promulgated under section 405(d) of the CWA and that standard is more stringent than any limitation on the pollutant or practice in the permit, the Department may initiate proceedings under these regulations to modify or revoke and reissue the permit to conform to the standard for sewage sludge use or disposal.

(c) Reopener clause: For any permit issued to a treatment works treating domestic sewage (including "sludge-only facilities"), the Department shall include a reopener clause to incorporate any applicable standard for sewage sludge use or disposal promulgated under section 405(d) of the CWA and R.61-9.503. The Department may promptly modify or revoke and reissue any permit containing the reopener clause required by this paragraph, if the standard for sewage sludge use or disposal is more stringent than any requirements for sludge use or disposal in the permit or controls a pollutant or practice not limited in the permit.

(d) Water quality standards (Regulation 61-68) and State requirements:

(1) Achieve surface and groundwater quality standards, including State narrative criteria for water quality.

(i) Limitations must control all pollutants or pollutant parameters (either conventional, nonconventional, or toxic pollutants) which the Department determines are or may be discharged at a level which will cause or contribute to an excursion above any State water quality or groundwater standard, including State narrative criteria for water quality.

(ii) Where the Department has not established a surface or groundwater quality criterion for a specific chemical pollutant that is present in an effluent at a concentration that causes or contributes to an excursion above a narrative criterion within an applicable State water quality standard, the permitting authority may establish effluent limits or other requirements, including indicator parameters for pollutants of concern.

(iii) Conform to the conditions for State certification under R.61-101 and section 401 of the CWA.

(iv) Conform to applicable water quality requirements under section 401(a)(2) of the CWA when the discharge affects a State other than the certifying State;

(v) Conform to any more stringent limitations, treatment standards, or schedule of compliance requirements established under Federal or State law or regulations;

(vi) Ensure consistency with the requirements of a Water Quality Management plan approved under section 208(b) of the CWA;

(e) [Reserved]

(f) [Reserved]

(g) Twenty-four hour reporting. The permittee shall report any non-compliance which may endanger public health or the environment. The permittee shall notify the Department orally within 24 hours of becoming aware of such conditions.

(h) Durations for permits, as set forth in section 505.46.

(i) Monitoring requirements. In addition to section 505.48, the following monitoring requirements apply:

(1) To assure compliance with permit limitations and protection of the environment, requirements to monitor:

(i) Each pollutant limited in the permit and as necessary to characterize any other pollutant, which may be in the wastewater, which has a significant potential to have an effect on the environment or operation of treatment or disposal facilities,

(ii) The volume of effluent applied as specified in the permit.

(iii) Other measurements as appropriate including pollutants in internal waste streams under section 505.45(h), frequency, rate of discharge, etc., for noncontinuous discharges under section 505.45(e); pollutants subject to notification requirements under section 505.42(a); and pollutants in sewage sludge or other monitoring as specified in 40 CFR Part 503 or R.61-9.503 or R.61-9.504; or as determined to be necessary on a case-by-case basis pursuant to section 405(d)(4) of the CWA.

(iv) According to test procedures approved under 40 CFR Part 136 or identified in R.61-9.503 or R.61-9.504 for the analyses of pollutants having approved methods under that part, and according to a test procedure specified in the permit for pollutants having no approved methods.

(2) Requirements to report monitoring results shall be established on a case-by-case basis with a frequency dependent on the nature and effect of the discharge.

(3) Permits which do not require the submittal of monitoring result reports at least annually shall require that the permittee report all instances of noncompliance not reported under R.61-9.505.41(l)(1), (4), (5) and (6) at least annually.

(j) Pretreatment program for POTWs. Requirements for POTWs to:

(1) Identify, in terms of character and volume of pollutants, any significant indirect dischargers into the POTW subject to pretreatment standards under section 307(b) of the CWA and R.61-9.403.

(2) Submit a local program when required by and in accordance with R.61-9.403 to assure compliance with pretreatment standards to the extent applicable under section 307(b). The local program shall be incorporated into the permit as described in R.61-9.403. The program shall require all indirect dischargers to the POTW to comply with the reporting requirements of R.61-9.403.

(3) For POTWs which are "sludge-only facilities," a requirement to develop a pretreatment program under R.61-9.403 when the Department determines that a pretreatment program is necessary to assure compliance with section 405(d) of the CWA.

(k) Best management practices to control or abate the discharge of pollutants.

(l) [Reserved]

(m) Privately owned treatment works. For a privately owned treatment works, any conditions expressly applicable to any user, as a limited co-permittee, that may be necessary in the permit issued to the treatment works to ensure compliance with applicable requirements under this part. Alternatively, the Department may issue separate permits to the treatment works and to its users, or may require a separate permit application from any user. The Department's decision to issue a permit with no conditions applicable to any user, to impose conditions on one or more users, to issue separate permits, or to require separate applications, and the basis for that decision, shall be stated in the fact sheet for the draft permit for the treatment works.

(n) [Reserved]

(o) Sewage sludge. Requirements under section 405 of the CWA governing the disposal of sewage sludge from publicly owned treatment works or any other treatment works treating domestic sewage for any use for which regulations have been established, in accordance with any applicable regulations.

505.45. Calculating Land Application permit and State permit conditions.

(a) Outfalls and discharge points. Permit effluent limitations, standards and prohibitions shall be established for each outfall or discharge point of the permitted facility, except as otherwise provided under section 505.44(k) (BMPs, where limitations are infeasible) and paragraph (i) of this section (limitations on internal waste streams).

(b) Production-based limitations. Permit effluent limitations, standards, or prohibitions shall be calculated based on design flow, number of units or other methods established by the Department.

(c) Metals. All permit effluent limitations, standards, or prohibitions for a metal shall be expressed in terms of "total recoverable metal" or "total metals" as defined in 40 CFR Part 136, 40 CFR Part 503, or R.61-9.503 unless:

(1) An applicable effluent standard or limitation has been promulgated under the CWA or under R.61-68 which specifies the limitation for the metal in the dissolved or valent or total form; or

(2) In establishing permit limitations on a case-by-case basis under R.61-9.125.3, it is necessary to express the limitation on the metal in the dissolved or valent or total form to carry out the provisions of the CWA; or

(3) All approved analytical methods for the metal inherently measure only its dissolved form (e.g., hexavalent chromium).

(d) Continuous discharges. For continuous discharges, all permit effluent limitations, standards, and prohibitions, including those necessary to achieve water quality standards, may be stated as:

(1) Maximum daily and average monthly discharge limitations for all dischargers other than publicly owned treatment works and private facilities; and

(2) Average weekly and average monthly discharge limitations for POTWs and private facilities.

(e) Non-continuous discharges. Discharges which are not continuous, as defined in section 122.2, may be particularly described and limited, considering the following factors, as appropriate:

(1) Frequency (for example, a batch discharge shall not occur more than once every 3 weeks);

(2) Total mass (for example, not to exceed 100 kilograms of zinc and 200 kilograms of chromium per batch discharge);

(3) Maximum rate of discharge of pollutants during the discharge (for example, not to exceed 2 kilograms of zinc per minute); and

(4) Prohibition or limitation of specified pollutants by mass, concentration, or other appropriate measure (for example, shall not contain at any time more than 0.1 mg/l zinc nor more than 250 grams (¼ kilogram) of zinc in any discharge).

(f) Mass limitations.

(1) All pollutants limited in permits may have limitations, standards, or prohibitions expressed in terms of mass except:

(i) For pH, temperature, radiation, or other pollutants which cannot appropriately be expressed in mass;

(ii) When applicable standards and limitations are expressed in terms of other units of measurement; or

(iii) If in establishing permit limitations on a case-by-case basis under R.61-9.125.3, limitations expressed in terms of mass are infeasible because the mass of the pollutant discharged cannot be related to a measure of operation (for example, discharges of TSS from certain mining operations), and permit conditions ensure that dilution will not be used as a substitute for treatment.

(2) Pollutants limited in terms of mass additionally may be limited in terms of other units of measurement, and the permit shall require the permittee to comply with both limitations.

(g) Limits for nutrients (e.g., nitrate) may be required based on the information provided by the applicant including but not be limited to, an analysis of the nutrient uptake of the proposed groundcover, crop or silviculture, design application rates, size and soil conditions present, and the total nutrient loading to the site.

(h) Internal waste streams. When permit effluent limitations or standards imposed at the point of discharge are impractical or infeasible, effluent limitations or standards for discharges of pollutants may be imposed on internal waste streams before mixing with other waste streams or cooling water streams. In those instances, the monitoring required by section 505.44(i) shall also be applied to the internal waste streams.

(i) Minimum treatment requirement.

(1) Purpose. This section provides information on the minimum level of effluent quality for specific categories of Land Application permits or State permits.

(2) Definitions. Terms used are defined as follows:

(i) "7-day average." The arithmetic mean of pollutant parameter values of samples collected in a period of 7 consecutive days.

(ii) "30-day average." The arithmetic mean of pollutant parameter values of samples collected in a period of 30 consecutive days.

(iii) "BOD₅" The five day measure of the pollutant parameter biochemical oxygen demand (BOD).

(iv) "CBOD₅". The five day measure of the pollutant parameter carbonaceous biochemical oxygen demand (CBOD₅).

(v) "Effluent concentrations consistently achievable through proper operation and maintenance." For a given pollutant parameter, the 95th percentile value for the 30-day average effluent quality achieved by a treatment works in a period of at least two years, excluding values attributable to upsets, bypasses, operational errors, or other unusual conditions.

(vi) "Facilities eligible for treatment equivalent to secondary treatment." Treatment works shall be eligible for consideration for effluent limitations described for treatment equivalent to secondary treatment, if:

(A) The effluent BOD₅ and TSS concentrations consistently achievable through proper operation and maintenance exceed the minimum level of the effluent quality set forth in section 505.45(i)(3)(i) and section 505.45(i)(3)(ii).

(B) A trickling filter or waste stabilization pond including aerated lagoon is used as the principal process, and

(C) The treatment works provide significant biological treatment of municipal and/or domestic wastewater.

(vii) "mg/l." Milligrams per liter.

(viii) "Percent removal." A percentage expression of the removal efficiency across a treatment plant for a given pollutant parameter, as determined from the 30-day average values of the raw wastewater influent pollutant concentrations to the facility and the 30-day average values of the effluent pollutant concentrations for a given time period.

(ix) "Significant biological treatment." The use of an aerobic or anaerobic biological treatment process in a treatment works to consistently achieve a 30-day average of at least 65 percent removal of BOD₅.

(x) "Reclaimed wastewater systems." A method of advanced wastewater treatment designed to produce an effluent of such a high quality to be suitable for irrigation in areas with public contact such as yard irrigation and public open spaces.

(xi) "TSS." The pollutant parameter total suspended solids.

(3) The following paragraphs describe the minimum level of effluent quality attainable by secondary treatment for municipal and/or domestic wastewater in terms of the parameters BOD₅ and TSS.

(i) BOD₅. For all facilities except reclaimed wastewater systems, septic tanks, trickling filters and waste stabilization ponds.

(A) The 30-day average shall not exceed 30 mg/l.

(B) The 7-day average shall not exceed 45 mg/l.

(C) At the option of the Department, in lieu of the parameter BOD₅ and the levels of the effluent quality specified in paragraphs (3)(i)(A) and (3)(i)(B), the parameter CBOD₅ may be substituted with the following levels of the CBOD₅ effluent quality provided:

(I) The 30-day average shall not exceed 25 mg/l.

(II) The 7-day average shall not exceed 40 mg/l.

(ii) TSS. For all facilities except reclaimed wastewater systems, septic tanks, trickling filters and waste stabilization ponds.

(A) The 30-day average shall not exceed 30 mg/l.

(B) The 7-day average shall not exceed 45 mg/l.

(iii) Waste stabilization ponds.

(A) The Department may adjust the minimum level of effluent quality set forth for municipal and/or domestic wastewater treatment works subject to this part to conform to the suspended solids concentrations achievable with waste stabilization ponds, provided that:

(I) Waste stabilization ponds, including aerated lagoon systems, are the principal process used for secondary treatment;

(II)

(1) The term "TSS concentrations achievable with waste stabilization ponds" means a TSS value, determined by the Department, which is equal to the effluent concentration achieved 90 percent of the time within the State.

(2) Allowable limits:

(i) The 30-day average shall not exceed 90 mg/l.

(ii) The 7-day average shall not exceed 135 mg/l.

(4) Treatment equivalent to secondary treatment. This section describes the minimum level of effluent quality required for facilities eligible for treatment equivalent to secondary treatment.

(i) BOD₅. For trickling filters and waste stabilization ponds.

(A) The 30-day average shall not exceed 45 mg/l.

(B) The 7-day average shall not exceed 65 mg/l.

(ii) TSS For trickling filters.

(A) The 30-day average shall not exceed 45 mg/l.

(B) The 7-day average shall not exceed 65 mg/l.

(iii) CBOD₅ limitations: For trickling filters and waste stabilization ponds.

(A) Where data are available to establish CBOD₅ limitations for a treatment works subject to this section, the Department may substitute the parameter CBOD₅ for the parameter BOD₅ on a case-by-case basis provided that the levels of CBOD₅ effluent quality are not less stringent than the following:

(1) The 30-day average shall not exceed 40 mg/l.

(2) The 7-day average shall not exceed 60 mg/l.

(B) Where data are available, the parameter CBOD₅ may be used for effluent quality limitations established under this section. Where concurrent BOD effluent data are available, they must be submitted with the CBOD data as a part of the approval process.

(5) Chemical oxygen demand (COD) or total organic carbon (TOC) may be substituted with Departmental approval for BOD₅ under section 505.45(i)(3) and section 505.45(i)(4), when a long-term BOD:COD or BOD:TOC correlation has been demonstrated.

(6) For reclaimed water systems, with application in areas with a high potential for contact (e.g. residential irrigation systems, multifamily irrigation systems, commercial irrigation systems in common residential areas, public parks, and open spaces).

(i) BOD₅ shall not exceed 5 mg/l monthly average and 7.50 mg/l weekly average.

(ii) Total Suspended Solids (TSS) shall not exceed 5 mg/l monthly average and 7.50 mg/l weekly average.

(iii) Turbidity limits may be established in terms of Turbidity Units, or other means similar to the protection of Drinking Water.

(iv) Total Residual Chlorine (TRC) in the effluent shall be maintained in a manner that a detectable residual chlorine level is maintained in the distribution system and the fecal coliform

limits are met. The Department may establish specific total residual chlorine limits for reclaimed water systems based on the site conditions and the distribution system design.

(v) Additional parameters may be required based on the permit application but such needs will be assessed on an individual basis. Any pollutant present in the wastewater may be required to be monitored (in a permit) in the effluent or groundwater.

(7) For tile field systems with Land Application or State Permits.

(i) The technical design standards for Individual Waste Disposal Systems R.61-56, may be utilized by the Department for these facilities.

(ii) The Department may require monitoring and reporting and/or specific limitations for any pollutant present in the wastewater. These requirements may be assessed on an individual project basis.

(8) For dischargers other than POTWs and domestic wastewater. Adequate treatment shall be determined by the Department on an individual project basis.

(9) Fecal coliform limitations.

(i) Land application systems. For all POTW and for those other systems including in the influent a significant amount of, or having a significant effect from, domestic sewage, at least as stringent as 200/100 ml monthly average and 400/100 ml daily maximum, or the bacteriological standard from the nearest surface water body as defined in R.61-68 (if this surface water is classified with a more restrictive standard), except where it can be shown that neither storm water nor wastewater will run off the disposal site to a waterway and that the isolation of the disposal site will eliminate exposure of persons to pathogens. A significant amount or effect is related to the effluent having a reasonable potential to violate the above-stated bacteriological requirement. For all other discharges, the Department may use the previously identified limits, or establish other fecal coliform limitations to reflect the specific discharge and site conditions. Domestic sewage is defined at R.61-9.503.9.

(ii) Tile field and rapid infiltration. No limits, unless specifically required by the Department.

(iii) Reclaimed wastewater. Coliform limitations (for those activities covered under the reclaimed water description) similar to the standards in State Primary Regulations (R.61-58) shall be met in the effluent and the distribution system. Other uses of reclaimed water (e.g., golf course irrigation) would be covered under land application systems or for surface water discharges covered under R.61-9.122.

(iv) Overland Flow. Effluent limits for discharge to surface waters of 2⁰⁰/₁₀₀ ml monthly average and 4⁰⁰/₁₀₀ ml daily maximum, or fecal coliform standard for the surface water body as defined in R.61-68.

(10) Nitrate monitoring or limitations (as N).

(i) Land application systems. Monitor and Report effluent Nitrate (as N) concentrations. Monitor and Report Nitrate (as N) concentrations for sludge and septage application. No limits, unless specifically required by the Department. The Department may eliminate this requirement for wastes with minimal, or no nitrate loading (such as water plant sludges).

(ii) Tile field and rapid infiltration. No limits, unless specifically required by the Department.

(iii) Reclaimed wastewater. Monitor and Report effluent Nitrate (as N) concentrations. No limits, unless specifically required by the Department.

(iv) Overland Flow. Monitor and Report effluent Nitrate (as N) concentrations. No limits, unless specifically required by the Department. The Department may eliminate this requirement for wastes with minimal, or no nitrate loading.

505.46. Duration of Land Application permits and State permits.

(a) A Land Application permit issued (except for permits issued for activities covered under 40 CFR Part 503) pursuant to State law and this regulation shall be effective for a fixed term not to exceed ten (10) years. A Land Application permit issued for activities covered under 40 CFR Part 503 pursuant to State law and this regulation shall be effective for a fixed term not to exceed five (5) years. An issued State permit shall remain effective until cancelled or revoked by the Department.

(b) Except as provided in R.61-9.505.6, the term of a Land Application permit shall not be extended by modification beyond the maximum duration specified in this section.

(c) The Department may issue any permit for a duration that is less than the full allowable term under this section.

505.47. Schedules of compliance.

(a) General. The State or Land Application permit may, when appropriate, specify a schedule of compliance leading to compliance with CWA, PCA, and regulations.

(1) Time for compliance. Any schedules of compliance under this section shall require compliance as soon as possible, or as provided for under section 505.47(c).

(2) The first Land Application permit or State permit issued to a new source or a new discharger shall contain a schedule of compliance only when necessary to allow a reasonable opportunity to attain compliance with requirements issued or revised after commencement of construction but less than three years before commencement of the relevant discharge. For recommencing dischargers, a schedule of compliance shall be available only when necessary to allow a reasonable opportunity to attain compliance with requirements issued or revised less than three years before recommencement of discharge.

(3) Interim dates. Except as provided in paragraph (b)(1)(ii) of this section, if a permit establishes a schedule of compliance which exceeds nine (9) months from the date of permit issuance, the schedule shall set forth interim requirements and the date for their achievement.

(i) The time between interim dates shall not exceed nine (9) months, except that in the case of a schedule for compliance with standards for sewage sludge use and disposal, the time between interim dates shall not exceed six months.

(ii) If the time necessary for completion of any interim requirement (such as the construction of a control facility) is more than nine (9) months and is not readily divisible into stages for completion, the permit shall specify interim dates for the submission of reports of progress toward completion of the interim requirements and indicate a projected completion date.

(4) Reporting. The permit shall be written to require that no later than 14 calendar days following each interim date and the final date of compliance, the permittee shall notify the Department in writing of its compliance or noncompliance with the interim or final requirements, or submit progress reports if paragraph (a)(3)(ii) is applicable.

(b) Alternative schedules of compliance. A State or Land Application permit applicant or permittee may cease conducting regulated activities (by terminating of discharge for State or Land Application permit sources) rather than continuing to operate and meet permit requirements as follows:

(1) If the permittee decides to cease conducting regulated activities at a given time within the term of a permit which has already been issued:

(i) The permit may be modified to contain a new or additional schedule leading to timely cessation of activities; or

(ii) The permittee shall cease conducting permitted activities before non-compliance with any interim or final compliance schedule requirement already specified in the permit.

(2) If the decision to cease conducting regulated activities is made before issuance of a permit whose term will include the termination date, the permit shall contain a schedule leading to termination which will ensure timely compliance with applicable requirements no later than the statutory deadline.

(3) If the permittee is undecided whether to cease conducting regulated activities, the Department may issue or modify a permit to contain two schedules as follows:

(i) Both schedules shall contain an identical interim deadline requiring a final decision on whether to cease conducting regulated activities no later than a date which ensures sufficient time to comply with applicable requirements in a timely manner, if the decision is to continue conducting regulated activities;

(ii) One schedule shall lead to timely compliance with applicable requirements, no later than the statutory deadline;

(iii) The second schedule shall lead to cessation of regulated activities by a date which will ensure timely compliance with applicable requirements no later than the statutory deadline.

(iv) Each permit containing two schedules shall include a requirement that after the permittee has made a final decision under paragraph (b)(3)(i) of this section, it shall follow the schedule leading to compliance if the decision is to continue conducting regulated activities, and follow the schedule leading to termination, if the decision is to cease conducting regulated activities.

(4) The applicant's or permittee's decision to cease conducting regulated activities shall be evidenced by a firm public commitment satisfactory to the Department, such as a resolution of the board of directors of a corporation.

(c) Terms and Conditions of Permits: Schedules of Compliance.

(1) A person issued a Land Application permit or State permit by the Department who is not in compliance with applicable effluent standards and limitations or other requirements contained therein at the time the permit is issued, shall be required to achieve compliance within a period of time as set forth by the Department, with effluent standards and limitations, with water quality standards, or with specific requirements or conditions set by the Department. The Department shall require compliance with terms and conditions of the permit in the shortest reasonable period of time as determined thereby or within a time schedule for compliance which shall be specified in the issued permit.

(2) If a time schedule for compliance specified in a Land Application permit or State permit which is established by the Department pursuant to paragraph (c)(1) above, exceeds nine (9) months, the time schedule shall provide for interim dates of achievement for compliance with certain applicable terms and conditions of the permit.

(d) Terms and Conditions of Permits: Compliance Reports by Dischargers.

(1) Within fourteen (14) calendar days after an interim date of compliance or the final date of compliance specified in a Land Application permit or State permit, a permittee shall provide the Department with written notice of his compliance or noncompliance with the requirements or conditions specified to be completed by that date.

(2) Failure to submit the written notice to the Department is just cause for the Department to pursue enforcement action against the discharger pursuant to the State law or this regulation.

(e) Noncompliance. A discharger who fails or refuses to comply with an interim or final date of compliance specified in a State or a Land Application permit, may be deemed by the Department to be in violation of the permit and may be subject to enforcement action prescribed in the State law or this regulation.

505.48. Requirements for recording and reporting of monitoring results.

(a) All permits shall specify:

(1) Requirements concerning the proper use, maintenance, and installation, when appropriate, of monitoring equipment or methods (including biological monitoring methods when appropriate).

(2) Monitoring shall include type, intervals, and frequency sufficient to yield data which are representative of the monitored activity including, when appropriate, continuous monitoring.

(3) Applicable reporting requirements based upon the impact of the regulated activity and as specified in section 505.44. Reporting shall be no less frequent than specified in the above regulation.

(4) That a permittee required to monitor a waste discharge shall maintain records of all information resulting from such monitoring, including the date, place and time of sampling; the dates analyses were performed; the person performing the analyses; the analytical techniques, procedures or methods used; and the results of such analyses. All records and results of monitoring activities and calibration and maintenance records shall be retained by the permittee a minimum of three (3) years, unless otherwise required or extended by the Department.

(b) Any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required by the Department to be maintained as a condition in a permit, or who alters or falsifies the results obtained by such devices or methods, shall be deemed to have violated a permit

condition and shall be subject to the penalties provided pursuant to 48-1-320 and 48-1-330 of the Code.

PART D
TRANSFER, MODIFICATION, REVOCATION AND REISSUANCE, AND TERMINATION
OF LAND APPLICATION PERMITS AND STATE PERMITS

505.61. Transfer of Land Application permits and State permits.

(a) Transfers by modification. Except as provided in paragraph (b) of this section, a permit may be transferred by the permittee to a new owner or operator only if the permit has been modified or revoked and reissued (under section 505.62(e)(2)), or a minor modification made (under section 505.63(d)), to identify the new permittee and incorporate such other requirements as may be necessary under PCA.

(b) Other transfers. As an alternative to transfers under paragraph (a) of this section, any Land Application permit or State permit may be transferred to a new permittee if:

- (1) The current permittee notifies the Department at least 30 days in advance of the proposed transfer date, and complies with the requirements in paragraph (b)(2) of this section;
- (2) The notice includes a written agreement between the existing and new permittee containing a specific date for transfer of permit responsibility, coverage, and liability between them; and
- (3) Permits are non-transferable except with prior consent of the Department. A modification under this subparagraph may also be a minor modification under section 505.63.

505.62. Modification or revocation and reissuance of Land Application permits and State Permits.

(a) When the Department receives any information (for example, inspects the facility, receives information submitted by the permittee as required in the permit (see section 505.41), receives a request for modification or revocation and reissuance under R.61-9.124.5, or conducts a review of the permit file), it may determine whether or not one or more of the causes listed in paragraphs (d) and (e) of this section for modification or revocation and reissuance or both exist.

(b) If cause exists, the Department may modify or revoke and reissue the permit accordingly, subject to the limitations of R.61-9.124.5(c), and may request an updated application, if necessary. When a permit is modified, only the conditions subject to modification are reopened. If a permit is revoked and reissued, the entire permit is reopened and subject to revision and the permit is reissued for a new term. See R.61-9.124.5(c)(2).

(c) If a permit modification satisfies the criteria in section 505.63 for "minor modifications" the permit may be modified without a draft permit or public review. Otherwise, a draft permit must be prepared and other procedures in R.61-9.124 followed.

(d) Causes for modification. The following are causes for modification or revocation and reissuance of permits.

- (1) Alterations. There are material and substantial alterations or additions to the permitted facility or activity (including a change or changes in the permittee's sludge use or disposal practice) which occurred after permit issuance which justify the application of permit conditions that are different or absent in the existing permit.
- (2) Information. The Department has received new information.
- (3) New regulations. The standards or regulations on which the permit was based have been changed by promulgation of amended standards or regulations or by judicial decision after the permit was issued.
- (4) Compliance schedules. The Department determines good cause exists for modification of a compliance schedule or terms and conditions of a permit, such as an act of God, strike, flood, or materials shortage or other events over which the permittee has little or no control and for which there is no reasonably available remedy. See also section 505.63(c) (minor modifications).
- (5) [Reserved]

(6) 307(a) toxics. When required to incorporate an applicable 307(a) of the CWA toxic effluent standard or prohibition (see R.61-9.122(b)(1)).

(7) Reopener. When required by the "reopener" conditions in a permit, or when established in the permit under R.61-403.10(e)(pretreatment program).

(8) [Reserved]

(9) Pretreatment. As necessary under R.61-9.403.8(e) (compliance schedule for development of pretreatment program).

(10) [Reserved]

(11) Non-limited pollutants. When the level of discharge of any pollutant which is not limited in the permit exceeds the level which may cause an adverse impact to surface or groundwaters.

(12) [Reserved]

(13) [Reserved]

(14) [Reserved]

(15) To correct technical mistakes, such as errors in calculation, or mistaken interpretations of law made in determining permit conditions.

(16) When the discharger has installed the treatment technology considered by the permit writer when developing effluent limits and has properly operated and maintained the facilities, but nevertheless has been unable to achieve those effluent limitations.

(17) [Reserved]

(18) Land application plans. When required by a permit condition to incorporate a land application plan for beneficial reuse of sewage sludge, to revise an existing land application plan, or to add a land application plan.

(e) Causes for modification or revocation and reissuance. The following are causes to modify or, alternatively, revoke and reissue a permit:

(1) Cause exists for termination under section 505.64, and the Department determines that modification or revocation and reissuance is appropriate.

(2) The Department has received notification (as required in the permit, see section 505.41(l)(3)) of a proposed transfer of the permit. A permit also may be modified to reflect a transfer after the effective date of an automatic transfer (section 505.61(b)); but it will not be revoked and reissued after the effective date of the transfer, except upon the request of the new permittee.

(3) There is a violation of any terms or conditions of the permit, or of a State surface or groundwater standard.

(4) The permittee has obtained a permit by misrepresentation or has failed to disclose all relevant facts to the Department. This includes providing inaccurate or misleading information to the Department on a permit application, or conditions have changed and the permit application does not reflect the actual conditions.

505.63. Minor modifications of Land Application permits and State permits.

The Department may modify a permit to make the corrections or allowances for changes in the permitted activity listed in this section, without following the procedures of R.61-9.124. Any Land Application permit modification not processed as a minor modification under this section must be made for cause and with R.61-9.124 draft permit and public notice as required for Land Application Permits in section 505.62. Minor modifications may only:

(a) Correct typographical errors;

(b)(1) Require more frequent monitoring or reporting by the permittee, change the monitoring day, or make other changes which do not result in the discharge of other or more pollutants;

(2) Change or add a requirement to use an analytical method.

(c)(1) Change an interim compliance date in a schedule of compliance, provided the new date is not more than 120 days after the date specified in the existing permit and does not interfere with attainment of the final compliance date requirement or

(2) Delete schedules of compliance or specific interim limits, if final limits are placed in effect.

(d) Approve permit transfer for a Change in Ownership, as follows:

(1) Allow for a change in ownership or operational control of a facility where the Department determines that no other change in the permit is necessary, provided that a written agreement containing a specific date for transfer of permit responsibility, coverage, and liability between the current and new permittee has been submitted to the Department.

(2) Whenever there occurs a change in the ownership of treatment works which are the subject of a Land Application permit or State permit, the new owner shall notify the Department of this change in ownership within thirty (30) days thereof and shall be bound by all the terms and conditions of said permit or permits.

(3) Change facility name.

(4) Permits are non-transferable except with the prior consent of the Department.

(e) Delete a discharge when the discharge from that outfall is terminated and does not result in discharge of pollutants from other outfalls except in accordance with permit limits.

(f)(1) Add intermediate, lower-flow-capacity pages of effluent limits that have no loadings higher than the current permit (e.g., adding a 0.5 MGD page [requiring secondary treatment] if the permit already has a 1 MGD page [requiring secondary treatment]).

(2) Add or revise CWA section 208 certification requirements.

(3) [Reserved]

(4) Change sludge disposal sites from one approved landfill to another.

(g) Incorporate conditions of a POTW pretreatment program that has been approved in accordance with the procedures in R.61-9.403.11 (or a modification thereto that has been approved in accordance with the procedures in R.61-9.403.18) as enforceable conditions of the POTW's permits.

(h)(1) Change the operator grade or other operator requirements, including revision to frequency of operator visits.

(2)(i) Change a sampling date stated in the permit or add a sampling date,

(ii) Add specific sample locations if unclear in the issued permit,

(iii) Reduce sampling frequency after some period of time, if specifically allowed in an issued permit.

(3) Add the treatment system reliability classification.

(4) Require submittal of closure plans.

(5) Change page numbers of the issued permit.

(6)(a) Comply with 403.8(c) concerning pretreatment programs.

(b) Add a compliance schedule to require development of a new pretreatment program, requiring, where appropriate, that the permittee comply with 403.8(b) Deadline for Program Approval.

505.64. Termination of Land Application permits and State permits.

(a) The following are causes for terminating a permit during its term, or for denying a permit renewal application:

(1) Noncompliance by the permittee with any condition of the permit or of a State surface or groundwater standard:

(2) The permittee's failure in the application or during the permit issuance process to disclose fully all relevant facts, or the permittee's misrepresentation of any relevant facts at any time;

(3) A determination that the permitted activity endangers human health or the environment and can only be regulated to acceptable levels by permit modification or termination; or

(4)(i) A change in any condition that requires either a temporary or permanent reduction or elimination of any discharge or sludge use or disposal practice controlled by the permit (for example, plant closure or termination of discharge by connection to a POTW).

(ii) Cessation of substantially all manufacturing operations, which are a basis for effluent limits or which contribute to a discharge, for a period of 180 days or longer.

(5) A permittee with a permit which requires connection to a regional sewer system or other treatment facilities under the water quality management plan under section 208 of the CWA is ineligible for reissuance of a permit once notified by the Department that the regional sewer system is operational.

(6) The permittee's failure to comply with the Environmental Protection Fees Regulation R.61-30.

(b) The Department shall follow the applicable procedures in R.61-9.124 in terminating any Land Application permit under this section.

61-9.600. VIABILITY REQUIREMENTS.

Editor's Note

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

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600.1. Purpose and Applicability.

(a) Purpose. This regulation establishes rules to ensure that entities owning wastewater systems demonstrate the technical, managerial, and financial means to comply with the regulations as a prerequisite for receiving a wastewater discharge permit (e.g., NPDES), including permit transfers.

(b) Authority and Applicability. This Part (R.61-9.600) applies to owners of wastewater systems, including facilities to collect, transport, treat and discharge wastewater and wastewater residuals, excluding permits under R.61-56 and service connections as defined by R.61-67. This Part (R.61-9.600) does not apply to a single business or industrial site that owns a wastewater system serving only its own operations or property, excluding residences. Provisions under this Part (R.61-9.600) may be waived by the Department to remedy existing public health or environmental problems. This rule applies on the date published in the State Register.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

600.2. Definitions.

The definitions contained in R.61-9.122, apply to this regulation. Terms not defined in this section or sections referenced previously have the meaning given by the PCA.

"Business plan" means, in the context of R.61-9.600, a document consisting of three sub-plans, a Facilities Plan, a Management Plan, and a Financing Plan, as applicable, which shows how a wastewater system (or group of systems under a common owner) will be self-sustaining and that the owner has the commitment and capability (financial, managerial, and technical capability) to consistently comply with applicable laws and regulations governing wastewater collection, treatment, and disposal.

"Department" means the South Carolina Department of Health and Environmental Control.

"Viable wastewater system owner" means an owner who has demonstrated the financial, technical, and managerial capability to handle all aspects of operation, maintenance, and replacement of wastewater systems to reasonably assure compliance with Department laws and regulations.

"Wastewater system" means facilities for the collection, transportation, treatment, and disposal of wastewater.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

600.3. General Requirements.

(a) The system owner or proposed owner is responsible for demonstrating viability in accordance with this Part.

(b) Without a demonstration that the proposed owner is or will be a viable wastewater system owner, or unless otherwise exempted, the Department may deny permit requests under R.61-67 or R.61-9. The Department may take necessary actions to bring an existing owner to the point of being a viable wastewater system owner, including requiring changes that will provide for proper operation, maintenance, and replacement of facilities, and to be in compliance with applicable statutes and regulations concerning sewerage systems.

(c) In determining whether a wastewater system owner is viable, the Department may consider information regarding how the owner has demonstrated viability of any existing operations in the state, information provided in a business plan, plans for setting sewer service rates in accordance with rules of the S.C. Public Service Commission (where applicable), and other relevant information. If an owner owns other wastewater systems, the Department may consider the overall resources of the owner such that an individual wastewater system does not have to be financially self-sustaining.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

600.4. New Wastewater Systems and Transfers of Systems.

(a) Prior to issuance of a wastewater permit under R.61-9 or R.61-67, including a transfer of an NPDES or Land Application permit, the proposed owner must demonstrate viability per the definition of "Viable wastewater system owner."

(b) If the proposed wastewater system owner does not own other wastewater systems in South Carolina, the demonstration must include the submission of a business plan which demonstrates how the system will be self-sustaining and that the owner has the commitment and capability (financial, managerial, and technical capability) to consistently comply with applicable laws and regulations governing wastewater collection, treatment, and disposal.

(c) If the proposed wastewater system is connecting to an existing system where the ownership will be the same (proposed and existing system having the same owner), this demonstration is not required.

(d) If the proposed wastewater system owner already owns other wastewater systems in South Carolina, the Department may consider financial and managerial information related to the owner's other wastewater system operations in the state.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

600.5. Existing Systems.

If an existing wastewater system has operation, maintenance or compliance problems warranting a formal enforcement action, the Department may require, in an order, the owner to submit a business plan to facilitate viability by identifying the elements necessary to perform proper operation, maintenance, and improvements and to stay in compliance (or come into compliance) with applicable regulatory requirements.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

61-9.610. OPERATION AND MAINTENANCE OF SATELLITE SEWER SYSTEMS.

Editor's Note

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

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610.1. Purpose.

This regulation establishes rules for governing the operation and maintenance of wastewater sewer systems, including gravity or pressure interceptor sewers. It is the purpose of this rule to establish standards for the management of sewer systems to prevent and/or minimize system failures that would lead to public health or environmental impacts.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

610.2. Authority and applicability.

Under Section 48–1–30 of the Code of Laws of South Carolina (1976 as amended), the Department is authorized to adopt such rules and regulations as may be necessary to implement the Pollution Control Act. This regulation applies to all sewer systems that have been or would be subject to a DHEC construction permit under Regulation 61–67, except for those whose owner owns or operates the wastewater treatment system to which the sewer discharges and which discharges under NPDES or a State permit (see 122.41(e)(4) and 505.41(e)(4)), and to systems approved pursuant to 61–9.505.8. Nothing in this regulation supersedes a more stringent requirement that may be imposed by sewer system owners that manage wastewater from satellite systems. This regulation is effective when published in the State Register.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

610.3. General requirements.

The requirements to properly operate and maintain sewer systems are the responsibility of the system owner. General Standards. The sewer system owner must:

- (a) Properly manage, operate, and maintain at all times all parts of its sewer system(s), to include maintaining contractual operation agreements to provide services, if appropriate;
- (b) Provide adequate capacity to convey base flows and peak flows for all parts of the sewer system or, if capital improvements are necessary to meet this standard, develop a schedule of short and long term improvements;
- (c) Take all reasonable steps to stop and mitigate the impact of releases of wastewater to the environment; and
- (d) Notify the Department within 30 days of a proposed change in ownership of a sewer system.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

610.6. Permitting of satellite sewer systems.

The Department may issue permits for the operation of a satellite sewer system in cases where the sewer system owner does not have an NPDES or Land Application discharge permit for the wastewater for that sewer system. Such permits do not supersede or replace the requirement under R.61–67.100.E.7 to obtain an approval to place a system into operation.

- (a) Authority for general permits for sewer system operation. The requirements for operation and maintenance of a sewer system may be set forth in a general permit issued by the Department. If a general permit is issued, the Department has the authority to apply general permit coverage to system owners and subsequently enforce the provisions of the general permit. For existing systems, the provisions of the permit will be effective upon notice to individual system owners. For proposed systems, they will obtain coverage upon issuance of a construction permit issued pursuant to R.61–67 if the owner has demonstrated it will be a viable operator in accordance with R.61–9.600.
- (b) Authority for individual permit for sewer system operation. If a general permit does not address the circumstances appropriate to a sewerage system proposed for permitting under R.61–67, the Department may require an individual operating permit.
- (c) Sewer system permit coverage transfers. If a sewer system is sold, coverage under the permit must be transferred by the Department to a new owner before the previous owner is free of the responsibilities outlined in the permit. A request to transfer the permit may be denied if the new owner or proposed new owner cannot demonstrate that it will be a viable operator in accordance with R.61–9.600.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

610.7. Sewer system permit (general and individual) administration.

- (a) The Department may issue a permit to implement the requirements of R.61–9.610. Once a permit is issued and effective, the Department has the authority to grant or deny coverage or deny transfer of coverage.
- (b) Where applicable, applicants for permits must submit their applications on permit application forms designated by the Department.

(c) Permit issuance or modification of a permit shall be preceded by a 30-day public comment period.

(d) Term of permits. Permits issued under R.61-9.610 may be issued without a finite term.

HISTORY: Added by State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

61-11. Repealed by State Register Volume 39, Issue No. 6, Doc. No. 4468, eff June 26, 2015.

Editor's Note

Former R. 61-11 was titled **Hypodermic Devices**.

61-12. STANDARDS FOR LICENSING ABORTION CLINICS.

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PART I DEFINITIONS AND REQUIREMENTS FOR LICENSURE

SECTION 101. Definitions.

For the purposes of these regulations, the following definitions apply:

- A. Abortion. The use of an instrument, medicine, drug, or other substance or device with intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus.
- B. Abortion Clinic. Any facility, other than a hospital as defined in Section 101.J, in which any second trimester or five or more first trimester abortions per month are performed.
- C. Allied Health Professional. A person other than a physician who possesses specialized training and skill acquired by completing certain courses of study or intensive job-related training and, where applicable, has been duly licensed or registered by appropriate licensing or certification agencies. All allied health professionals must be supervised by a physician.
- D. Conception. The fecundation of the ovum by the spermatozoa.
- E. Consent. A signed and witnessed voluntary agreement to the performance of an abortion.
- F. Department. The South Carolina Department of Health and Environmental Control.
- G. Emancipated Minor. A minor who is or has been married or has by court order been freed from the care, custody, and control of her parents.
- H. Fetal Death. Death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.
- I. Fire Safety Authority. The State Fire Marshal, or his designee, who performs facility fire and safety inspections.
- J. Hospital. An institution licensed for hospital operation by the Department in accordance with the provisions of Article 3, Chapter 7, Title 44, of the S.C. Code of Laws, 1976, as amended, and that has also been certified by the Department to be a suitable facility for the performance of abortion.
- K. In Loco Parentis. Any person over the age of 18 who has placed him/herself in the position of a lawful parent by assuming obligations that are incidental to the parental relationship and has so served for a period of 60 days.

L. Licensee. The person, partnership, corporation, association, organization, or professional entity on whom rests the ultimate responsibility and authority for the conduct of the abortion clinic.

M. Medical Emergency. That condition which, on the basis of the physician's good faith judgment, so complicates a pregnancy as to necessitate an immediate abortion to avert the risk of her death or for which a delay will create serious risk of substantial and irreversible impairment of major bodily functions.

N. Minor. A female under the age of 17.

O. Physician. A person licensed to practice medicine in this State.

P. Pregnancy. The condition of a woman carrying a fetus or embryo within her body.

Q. Probable Gestational Age of the Embryo or Fetus.

What, in the judgment of the attending physician, based upon the attending physician's examination and the woman's medical history, is with reasonable probability, the gestational age of the embryo or fetus at the time the abortion is planned to be performed. This estimate must be guided by recommendations found in The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services, i.e., calculated from the first day of the last menstrual period.

R. Products of Conception. Fetal and embryonic tissues resulting from implantation in the uterus.

S. Trimester. A 12-week period of pregnancy.

1. First. The first 12 weeks of pregnancy commencing with conception rather than computed on the basis of the menstrual cycle.

2. Second. That portion of a pregnancy following the 12th week and extending through the 24th week of gestation.

3. Third. That portion of pregnancy beginning with the 25th week of gestation.

4. All other references in this regulation to gestational age will refer to that calculated from the first day of the last menstrual period as used in The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services. The following is furnished to provide clarification of gestational age:

Calculation	Weeks of Gestational Age									
Conception	8	10	12	14	16	18	20	22	24	
LMP	10	12	14	16	18	20	22	24	26	

T. Viability. That stage of human development when the fetus is potentially able to live outside of the mother's womb with or without the aid of artificial life support systems. (Section 44-41-10(l) of the S.C. Code of Laws further states that "for the purposes of this chapter, a legal presumption is hereby created that viability occurs no sooner than the twenty-fourth week of pregnancy." The "twenty-fourth week," as stated in the S.C. Code, is based on computation from date of conception, i.e., the twenty-sixth week from the first day of the last menstrual period.)

SECTION 102. License Requirements.

A. License. It shall be unlawful to operate an abortion clinic within South Carolina without possessing a valid license issued annually by the Department. (I)

B. Issuance of License. A license is issued pursuant to the provisions of Section 44-41-10 et seq., of the S.C. Code of Laws of 1976, as amended, and these standards, and shall be posted in a conspicuous place in a public area within the facility. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of a facility. A license is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws and regulations of the State of South Carolina.

C. Effective Date and Term of License. A license shall be effective for a 12-month period following the date of issue and shall expire one year following such date; however, a facility that has not been inspected during that year may continue to operate under its existing license until an inspection has occurred.

D. Separate Licenses. Separate licenses are required for facilities not maintained on the same premises.

E. Licensing Fees. The initial and annual license fee shall be \$500.00 for each licensed facility. Such fee shall be made payable to the Department. Fees are non-refundable.

F. Inspections. Each facility shall be inspected prior to initial licensure and at least annually thereafter by authorized representatives of the Department.

1. All licensed facilities are subject to inspection at any time.

2. Department inspectors shall have access to all properties and areas, objects, records and reports, and shall have the authority to make photocopies of those documents required in the course of inspections or investigations. (II)

G. Initial License. A new facility, or one that has not been continuously licensed under these or prior standards, shall not provide care to patients until it has been issued an initial license. When it is determined that the facility is in compliance with the requirements of these standards, and a properly completed application and licensing fee have been received by the Department, a license shall be issued. Chapter 9 of this regulation sets forth the prerequisites for initial licensure. (I)

H. License Renewal. Applicants for an annual license renewal shall file an application with the Department, pay a license fee, and undergo a licensing inspection.

I. Noncompliance. When noncompliance(s) with the licensing standards exists, the applicant or licensee shall be notified by the Department of the violation(s) and required to provide information as to how and when each violation will be corrected and how future occurrences may be prevented.

J. Facility Name. No proposed abortion clinic shall be named, nor may any existing abortion clinic have its name changed to, the same or similar name as any other abortion clinic licensed in the State. If it is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

K. Change of License. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

1. Change of ownership by purchase or lease;
2. Change of facility's name or address.

L. Exceptions to Licensing Standards. The Department may make exception(s) to these standards where it is determined that the health and welfare of the community require the services of the facility and that the exception(s), as granted, will have no significant adverse impact on the health, safety, or welfare of the facility's patients.

SECTION 103. Penalties.

When it determines that a facility is in violation of any statutory provision, rule or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice, may deny, suspend, or revoke licenses, or assess a monetary penalty. Under such conditions, the following shall apply:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or welfare of the patients of the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a direct or immediate relationship to the health, safety or well-being of the facility's patients. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III

violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section, i.e., (I) or (II). Violations of sections that are not annotated in that manner denote Class III violations.

E. In arriving at a decision to penalize a facility, the Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or well-being; efforts by the facility to correct; overall conditions; history of compliance; any other pertinent conditions that may be applicable to current statutes and regulations.

F. When a decision is made to assess monetary penalties, the following schedule will be used as a guide to determine the dollar amount:

MONETARY PENALTY RANGES			
FREQUENCY	CLASS I	CLASS II	CLASS III
1st	\$ 200 – 1000	\$ 100 – 500	\$ 0
2nd	500 – 2000	200 – 1000	100 – 500
3rd	1000 – 5000	500 – 2000	200 – 1000
4th	5000	1000 – 5000	500 – 2000
5th	5000	5000	1000 – 5000
6th	5000	5000	5000

G. Any facility that is dissatisfied with Department decisions may request a hearing pursuant to the Administrative Procedures Act.

PART II ADMINISTRATION AND MANAGEMENT

SECTION 201. Licensee. (II)

A. The licensee of each facility has the ultimate responsibility for the overall operation of the facility. Every facility shall be organized, equipped, staffed and administered to provide adequate care for each person admitted.

B. Policies and procedures for operation of the facility shall be formulated and reviewed annually by the licensee of the facility. They shall include but not be limited to:

1. Purpose of the facility, to include scope and quality of services;
2. Ensuring compliance with all relevant federal, state, and local laws that govern operations of the facility;
3. Personnel policies and procedures, to include inservice training requirements;
4. The person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible;
5. Provision for annual review and evaluation of the facility's policies, procedures, management and operation;
6. Provision for a facility-wide quality improvement program to evaluate patient care. The program shall be ongoing, have statistical summaries, and have a written plan of implementation.
7. Patient rights and grievance procedures;
8. Functional safety and maintenance policies and procedures;
9. Incident reporting;

10. Consent must be informed, shall be obtained prior to the procedure, and shall include evidence of an explanation by a physician or allied health professional of the services offered and potential risks. Documentation of the informed consent must be filed in the patient's record.

SECTION 202. Administrator. (II)

An administrator shall be selected by the licensee and shall have the ability and authority to manage and administer the facility. Any change in the position of the administrator shall be reported immediately by the licensee to the Department in writing. An individual shall be appointed in writing to act in the absence of the administrator.

SECTION 203. Administrative Records.

The following administrative documents and references shall be on file in the facility:

- A. Current policies and procedures concerning the operation of the facility; (II)
- B. Current memorandums of agreement and credentialing documentation.
- C. A current copy of these regulations;
- D. Annual elevator safety inspections, if applicable;
- E. Annual heating, ventilation, and air conditioning inspection report.

SECTION 204. Personnel. (II)

Each facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients.

A. The licensee shall obtain written applications for employment from all employees. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate licensure, if applicable, and health and personal background of each employee.

B. Prior to performing job duties, all employees, to include volunteers who have direct patient contact within the clinic, shall have tuberculin skin testing conducted unless a previously positive reaction is documented in millimeters. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative (PPD) is to be used. For employees/volunteers who have no documentation of a negative PPD result during the preceding 12 months, then the two-step procedure (one PPD test with negative result followed one to three weeks later by another PPD test) is required to establish a reliable baseline. If employees/volunteers have complete documentation of a negative PPD during the preceding 12 months (may be a single PPD or a two-step PPD), then a single PPD is acceptable to establish the baseline for current employment.

1. Persons with negative tuberculin skin tests who have direct contact with patients shall have an annual tuberculin skin test.
2. There is no need to perform an initial or routine chest X-ray on employees or volunteers with negative tuberculin tests who are asymptomatic.
3. Personnel with a positive reaction to the skin test shall have no patient contact until certified non-contagious by a physician.
4. Employees and volunteers with reactions of 10mm and over to the pre-employment tuberculin test, those new employees/volunteers who have previously-documented positive reactions, those with newly-converted skin tests and those with symptoms suggestive of TB (e.g., cough, weight loss, night sweats, fever, etc.), shall be given a chest X-ray to determine whether TB disease is present. If TB disease is diagnosed, appropriate treatment shall be given and contacts examined.
5. Personnel who are known or suspected to have TB shall be required to be evaluated by a physician and will not be allowed to return to work until they have been certified non-contagious by the physician.
6. Preventive treatment of personnel with new positive reactions is essential, and shall be considered for all infected employees/volunteers who have patient contact, unless specifically contraindicated. Routine annual chest X-rays of persons with positive reactions do not prevent TB and therefore are not a substitute for preventive treatment nor are required.
 - a. Employees and volunteers who complete treatment, either for disease or infection, may be exempt from further routine chest radiographic screening unless they have symptoms of TB.
 - b. Positive reactors who are unable or unwilling to take preventive treatment need not receive an annual chest X-ray. These individuals must be informed of their lifelong risk of developing and transmitting TB to individuals in the institution and in the community. They shall be informed of

symptoms which suggest the onset of TB, and the procedure to follow should such symptoms develop.

7. Post-exposure skin tests should be provided for tuberculin negative employees/volunteers within 12 weeks after termination of contact for any suspected exposure to a documented case of pulmonary TB.

8. A person shall be designated in writing at each facility to coordinate TB screening of personnel and any other TB control activities.

C. All professional and allied health professional staff members shall be currently certified with American Red Cross or American Heart Association CPR and capable of recognizing symptoms of distress. A professional or allied health professional staff member who is legally qualified to perform advanced cardiac life support must be present while patients are undergoing abortion procedures/recovery in the facility. (I)

D. No employee or volunteer of the facility, while afflicted with any infected wounds, boils, sores, or an acute respiratory infection, or any other contagious disease or illness, shall work in any capacity in which there is a likelihood of such person transmitting disease to other individuals.

E. Each facility shall have and execute a written orientation program to familiarize each new staff member with the facility and its policies and procedures, to include, as a minimum, fire safety and other safety measures, medical emergencies, and infection control.

F. Inservice training programs shall be planned and provided for all employees and volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually:

1. Infection control, to include as a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as handwashing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members;
2. Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires;
3. Confidentiality of patient information and records, and protecting patient rights;
4. Licensing regulations.

G. Job Descriptions.

1. Written job descriptions that adequately describe the duties of every position shall be maintained.
2. Each job description shall include: position title, authority, specific responsibilities and minimum qualifications.
3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised.

H. A personnel file shall be maintained for each employee and for each volunteer. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's orientation, in-service education, appropriate licensure, if applicable, and TB skin testing.

SECTION 205. Clinical Staff (II)

A. Physicians, nurses, and allied health professionals shall constitute the clinical staff.

B. The clinical staff shall meet at least quarterly to review and analyze their clinical experiences; minutes shall be maintained of such meetings.

C. Physicians. (I)

1. Abortions shall be performed only by physicians who are licensed to practice medicine in this State and who are properly qualified by training and experience to perform pregnancy termination procedures.

2. The facility shall enter into a signed written agreement with at least one physician board-certified in obstetrics and gynecology (if not one on staff) who has admitting privileges at one or more local hospitals with OB/GYN services to ensure his/her availability to the staff and patients during all operating hours.

3. A physician must remain on the premises until all patients are stable, and are ready for discharge. A physician must sign the discharge order and be readily accessible and available until the last patient has been discharged.

D. Nursing.

1. Nursing care shall be under the supervision of a registered nurse currently licensed in this State.

2. A registered nurse shall be on duty to provide or supervise all nursing care of patients in preparation, during the termination procedure, the recovery period and until discharge by the attending physician.

3. Licensed practical nurses, working under appropriate supervision and direction of a registered nurse, may be employed as components of the nursing staff.

E. Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established.

F. If ultrasonography is conducted in the clinic, the procedure shall be conducted by a physician or by an ultrasound technician who shall have documented evidence of completion of a training course in ultrasonography.

SECTION 206. Consent of the Patient. (I)

A physician shall not perform an abortion without first obtaining a signed and dated consent of the pregnant woman pursuant to the provisions of Section 44-41-30 of the S.C. Code of Laws, 1976, as amended.

SECTION 207. Abortion Performed Upon Minors. (I)

No person may perform an abortion upon a minor unless consent is obtained pursuant to the provisions of Section 44-41-31 of the S.C. Code of Laws, 1976, as amended.

SECTION 208. Dissemination of Information. (I)

Clinics must comply with the Woman's Right to Know Act, Section 44-41-310 et seq., of the S.C. Code of Laws, 1976, as amended, and maintain an adequate supply of current printed material from the Department which has not been altered in content.

SECTION 209. Patients' Rights (II)

A. The facility shall have written policies and procedures to assure the individual patient the right to dignity, privacy, safety, and to register complaints with the Department. These patients' rights shall be approved by the licensee.

B. Each facility shall display in a conspicuous place a copy of the patients' rights. In addition, a copy signed by the patient shall be included in the medical record.

**PART III
PATIENT CARE**

SECTION 301. Policies and Procedures. (II)

Abortion clinics shall not serve patients whose needs exceed the resources and/or capabilities of the clinic. The facility shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients, to include but not limited to:

A. Admission criteria;

B. Physician and nurse responsibilities for the services offered;

C. Specific details regarding the pre-operative procedures performed, to include:

1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications;
 2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography required when gestational age is clinically estimated to be equal to or more than 14 weeks from the first day of the last menstrual period as established by the physician's performance of a bimanual physical examination. Policies and procedures should also indicate that ultrasound is recommended when gestational age is equal to or more than 12 weeks from the first day of the last menstrual period as established by the performance of a bimanual physical examination or if the physical examination and clinical evidence is inconclusive as to the gestational age.
- D. The actual abortion procedure, to include the use of:
1. IV's;
 2. Fluids;
 3. Analgesia/anesthesia. General anesthesia shall be administered only by a certified registered nurse anesthetist, anesthesiologist, or dentist anesthetist or physician anesthetist.
 4. Tissue examination/disposal.
- E. Post-procedure care/recovery room procedures to include emergency care;
- F. Provisions for the education of patient, family and others, as appropriate in pre and post-procedure care;
- G. Plans for follow-up of patient after discharge from the facility, to include arrangements for post-operative visit, and specific instructions in case of emergency;
- H. Management and appropriate referral of high-risk conditions;
- I. Transfer of patients who, during the course of pregnancy termination are determined to need care beyond that of the facility;
- J. Infection control and sanitation procedures to include duties and responsibilities of the infection control committee that shall include the development and implementation of specific patient care and administrative policies aimed at investigating, controlling and preventing infections in the facility;
- K. Registration of fetal death or death certificates, when applicable.

SECTION 302. Limitation of Services Offered by Abortion Clinics (I)

- A. Abortions performed in abortion clinics shall be performed only on patients who are within 18 weeks from the first day of their last menstrual period. Those beyond 18 weeks shall be performed in a hospital. A licensed ambulatory surgical facility that is also licensed as an abortion clinic may perform abortions on patients who are up to 26 weeks after the first day of their last menstrual period.
- B. Clinics performing abortions beyond 14 weeks from the first day of the last menstrual period must meet the requirements of Section 309.

SECTION 303. Pharmaceutical Services. (II)

Pharmaceutical services shall be provided in accordance with accepted professional practice and federal, state and local statutes and regulations.

A. Emergency Drugs:

1. Emergency Kit or Emergency Drugs. Each facility shall maintain an emergency kit or stock supply of drugs and medicines for the use of the physician in treating the emergency needs of patients. This kit or medicine shall be stored in such a manner as to prohibit its access by unauthorized personnel. A listing of contents by drawer or shelf shall be placed on the cabinet or emergency cart to allow quick retrieval. Contents shall correspond with the inventory list. Drugs and equipment must be available within the facility to treat, as a minimum, the following conditions: (I)
 - a. Cardiac arrest;
 - b. Seizure;
 - c. Asthmatic attack;
 - d. Allergic reaction;
 - e. Narcotic toxicity;

- f. Hypovolemic shock;
- g. Vasovagal shock.

2. Drug Reference Sources. Each facility shall maintain reference sources for identifying and describing drugs and medicines.

B. Administering Drugs and Medicines. Drugs and medicines shall not be administered to individual patients or to anyone within or outside the facility except by those authorized by law under orders of a physician duly licensed to prescribe drugs. Such orders shall be in writing and signed personally by the physician who prescribes the drug or medicine.

C. Medicine Storage. Medicines and drugs maintained in the facility for daily administration shall not be expired and shall be properly stored and safeguarded in enclosures of sufficient size that are not accessible to unauthorized persons. Refrigerators used for storage of medications shall maintain an appropriate temperature as determined by the requirements established on the label of medications. A thermometer accurate to ± 3 degrees Fahrenheit shall be maintained in these refrigerators. Only authorized personnel shall have access to storage enclosures. Controlled substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws.

D. Medicine Preparation Area. Medicines and drugs shall be prepared for administration in an area that contains a counter and a sink. This area shall be located in such a manner as to prevent contamination of medicines being prepared for administration.

E. Controlled Substances Registration.

1. If a stock of controlled drugs is to be maintained at the facility, a physician on the clinic staff shall obtain an individual practitioner South Carolina Controlled Substances Registration and a Drug Enforcement Administration (DEA) Registration as registrant for the facility. This physician shall be responsible for the proper safeguarding and handling of controlled substances within the facility, and shall be certain that all possible control measures are observed and that any suspected diversion or mishandling of controlled substances is reported immediately to the Bureau of Drug Control of the Department.

2. With a written power of attorney, this physician may grant permission to any other physician who possesses an individual practitioner South Carolina Controlled Substances Registration and a DEA Registration to administer, order for administration, or dispense any controlled substances maintained by the facility.

F. Records. Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received and/or administered.

G. Poisonous Substances. All poisonous substances must be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration. (I)

SECTION 304. Laboratory Services. (II)

A. Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88).

1. Facilities for collecting specimens shall be available on site.

2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88 standards.

B. Prior to the procedure, laboratory tests shall include a recognized urine pregnancy test unless the physician identifies fetal heart beats or fetal movements on physical examination. If positive, the following additional tests are required:

1. Urinalysis including albumin and glucose examination;

2. Hematocrit or hemoglobin;

3. Determination of Rh factor (including the Du variant when the patient is Rh negative); Rh (D) immune globulin (human) shall be administered, prior to discharge, to patients who are determined to be Rh negative.

C. Other laboratory tests to be administered:

1. Testing for Chlamydia and gonorrhea;

2. Syphilis serology shall be offered;
3. A Papanicolaou procedure shall be offered;
4. Referral for chest X-ray, if indicated;
5. Other tests as deemed appropriate by the physician.

D. Aspirated tissues shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy.

E. A written report of each laboratory test and examination shall be a part of the patient's record.

F. If a patient is bleeding profusely and a transfusion of red blood cells is necessary, she should be administered fluids and transported immediately to a hospital that routinely performs crossmatches and transfuses patients.

G. All laboratory supplies shall be monitored for expiration dates, if applicable.

H. Products of conception resulting from the abortion procedure must be managed in accordance with requirements for pathological waste pursuant to Department R.61-105, Infectious Waste Management Regulations. All contaminated dressings and/or similar waste shall be properly disposed of in accordance with R.61-105.

SECTION 305. Emergency Care. (I)

A. All staff and/or consulting physicians shall have admitting privileges at one or more local hospitals that have appropriate obstetrical/gynecological services or shall have in place documented arrangements approved by the Department for the transfer of emergency cases when hospitalization becomes necessary.

B. Equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital.

C. The facility shall inform, in writing, the local ambulance service which provides emergency care and transport of patients, of the location of the facility, and the nature of medical problems which may result from abortions.

SECTION 306. Equipment and Supplies. (II)

There shall be appropriate equipment and supplies maintained for the patients to include but not limited to:

- A. A bed or recliner suitable for recovery;
- B. Oxygen with flow meters and masks or equivalent; (I)
- C. Mechanical suction; (I)
- D. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways; (I)
- E. Emergency medications, intravenous fluids, and related supplies and equipment; (I)
- F. A clock with a sweep second hand;
- G. Sterile suturing equipment and supplies;
- H. Adjustable examination light;
- I. Containers for soiled linen and waste materials with covers;
- J. Refrigerator;
- K. Appropriate equipment for the administering of general anesthesia, if applicable.

SECTION 307. Consultation. (II)

Arrangements shall be made for consultation or referral services in the specialties of obstetrics/gynecology, anesthesiology, surgery, psychiatry, psychology, clinical pathology and pathology, clergy, and social services, as well as any other indicated field, to be available as needed.

SECTION 308. Quality Improvement. (II)

A. The facility shall establish and implement a written plan for a quality improvement program for patient care. The plan shall specify the individual responsible for coordinating the quality improvement program and shall provide for ongoing monitoring of staff and patient care services.

B. There shall be an ongoing process for monitoring and evaluating patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services.

C. Evaluation of patient care throughout the facility shall be criteria-based, so that certain actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified.

D. The quality improvement process shall incorporate quarterly review of a minimum of five per cent of medical records of patients undergoing procedures during a given quarter, but not less than five records shall be reviewed.

E. The quality improvement process shall include evaluation by patients of care and services provided by the facility. If the families of patients are involved in the care and services provided by the facility, the quality improvement process shall include a means for obtaining input from families of patients.

F. The administrator shall review the findings of the quality improvement program to ensure that effective corrective actions have been taken, including as a minimum, policy revisions, procedural changes, educational activities, and follow-up on recommendations, or that additional actions are no longer indicated or needed.

G. The quality improvement program shall identify and establish indicators of quality care, specific to the facility, that shall be monitored and evaluated.

H. The results of the quality improvement program shall be submitted to the licensee for review at least annually and shall include at least the deficiencies found and recommendations for corrections or improvements. Deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee.

SECTION 309. Requirements for Clinics Performing Abortions Beyond 14 Weeks. (I)

Clinics which perform abortions beyond 14 weeks from the first day of the last menstrual cycle shall, in addition to those requirements in all other sections of this regulation, have the following in place:

A. Physicians shall be board-certified or a candidate for board-certification in obstetrics and gynecology, general surgery, or family practice;

B. Physicians shall have admitting privileges at one or more local hospitals that have appropriate obstetrical/gynecological services;

C. Laryngoscopes, endotracheal tubes, and defibrillator;

D. Laboratory tests/procedures shall include:

1. White blood count and determination of blood type;
2. Sickle cell, when indicated;
3. Ultrasonogram.

PART IV MEDICAL RECORDS AND REPORTS

SECTION 401. Medical Records. (II)

Medical records shall be maintained for all patients examined or treated in the clinic. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. All information shall be centralized in the patient's medical record. All entries shall be legibly written or typed, dated and signed.

A. The record shall include as a minimum the following information:

1. A face sheet with patient identification data, to include but not be limited to: name, address, telephone number, social security number, date of birth, father's and mother's names when patient is

a minor, husband's name, and name, address and telephone number of person to be notified in the event of an emergency;

2. Signed consent for the procedure;
 3. Date of initial examination;
 4. Date of abortion;
 5. Referring and attending physicians' names and phone numbers, if applicable;
 6. Complete medical history to include medications currently being taken;
 7. Physical examination, to the extent necessary to determine the health status of the patient, within 15 days of the procedure, including detail of findings of pelvic examination and estimated gestational age, according to the first day of the last menstrual period;
 8. Results of diagnostic tests and/or examinations, e.g., X-ray, electrocardiography, clinical laboratory, pathology, consultations, ultrasound;
 9. Pre-operative diagnosis;
 10. Counselor's notes;
 11. Physician's orders;
 12. Complete record of abortion procedure to include:
 - a. Vital signs, i.e., temperature, pulse, respiration, and blood pressure, prior to and following the procedure;
 - b. Name of procedure performed;
 - c. Anesthetic agent utilized;
 - d. Name of attending physician performing the procedure;
 - e. Names of clinical assistants in attendance, to include other physicians, physician's assistants, anesthetists, nurses, or specially-trained technicians;
 - f. Signature of physician performing the procedure.
 13. Nurses' notes;
 14. Progress notes to include a post-anesthesia note if general anesthesia is utilized;
 15. Attending physician's description of gross appearance of tissue removed;
 16. Final diagnosis;
 17. Condition on discharge;
 18. Post-op orders and follow-up care;
 19. Documented verification that the woman has been presented printed materials as required in the Woman's Right-to-Know Act;
 20. In the case of an unemancipated minor or mentally incompetent person, a copy of the court order or written consent authorizing the abortion.
- B. The attending physician must complete and sign the medical record within 72 hours following discharge.

SECTION 402. Records Storage.

All records shall be treated as confidential and shall be stored in a safe location for a minimum of 10 years. When records are stored in a location other than the clinic, and upon closure of the clinic, for any reason, the medical records shall be stored in a safe location for that minimum period, with the Department informed of that location. The medium in which the records are stored, e.g., optical disk, microfiche, is a facility decision.

SECTION 403. Reports. (II)

- A. The following shall be reported to Vital Records and Public Health Statistics of this Department:
 1. Any abortion performed, to be reported by the performing physician on the standard form for reporting abortions, within seven days after the abortion is performed;

2. A fetal death when the fetus has completed or passed the age or weight requiring a report, pursuant to the standards in Department R. 61-19, Vital Statistics.

B. A record of each accident or incident occurring in the facility which involves patients, staff, or visitors, including medication errors and adverse drug reactions, shall be prepared immediately. Accidents or incidents resulting in serious injury shall be reported, in writing, to the Department within 10 days of the occurrence; if a death occurs, other than a fetal death, it shall be reported to the Department not later than the next Department work day (Monday through Friday). Accidents and incidents that must be reported include, but are not limited to:

1. Those leading to hospitalization;
2. Those leading to death, other than a fetal death;
3. Adverse drug reactions.

PART V FUNCTIONAL SAFETY AND MAINTENANCE

SECTION 501. Policies and Procedures.

A. Written policies and procedures shall be developed to enhance safety within the facility and on its grounds and to minimize hazards to patients, staff and visitors.

B. The policies and procedures shall include, but not be limited to:

1. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services;
2. Provisions for reporting and investigating accidental events regarding patients, visitors and personnel and corrective action taken;
3. Provisions for disseminating safety-related information to employees and users of the facility;
4. Provision for syringe and needle handling and storage.
5. Provisions for managing infectious waste from generation to disposal according to Regulation 61-105.

SECTION 502. Disaster Preparedness.

A. The facility shall have posted, in conspicuous places throughout the facility, a plan for evacuation of patients, staff, and visitors in case of fire or other emergency. (I)

B. A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

SECTION 503. Maintenance.

A. Facility Maintenance. A facility's structure, its component parts, and all equipment such as elevators, furnaces and emergency lights, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

B. Equipment Maintenance. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

PART VI INFECTION CONTROL AND SANITATION

SECTION 601. General.

Policies and procedures shall be established in writing to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection.

SECTION 602. Sterilization Procedures.

A. Adequate space shall be provided for storage, maintenance and distribution of sterile supplies and equipment.

B. Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust-proof and moisture-free units. They shall be properly labeled.

C. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features.

1. There must be documentation of each load run daily. A biological test of the autoclave shall be run daily and the results maintained on a log.

2. Each separate package of instruments to be sterilized must have internal and external chemical indicators.

3. The accuracy of instrumentation and equipment shall be provided by periodic calibration and/or preventive maintenance as necessary, but not less than annually, and a log maintained.

D. The policies and procedures shall indicate how the shelf life of a packaged sterile item is determined. Methods approved for use are:

1. Date of expiration being marked on the item; or

2. Event-related, i.e., day-to-day expiration, utilizing such wording as, "sterile unless the integrity of the package is compromised."

SECTION 603. Linen and Laundry.

A. An adequate supply of clean linen or disposable materials shall be maintained in order to insure change of linen on procedure tables between patients.

B. Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately. Storage shall be in covered containers.

C. A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

SECTION 604. Housekeeping.

A. General. A facility shall be kept neat, clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times.

B. Cleaning materials and supplies shall be stored in a safe manner. All harmful agents shall be locked in a closet or cabinet used for this purpose only.

C. Dry sweeping and dusting of walls and floors are prohibited.

SECTION 605. Refuse and Waste Disposal.

A. All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused.

B. Containers for garbage and refuse shall be covered and stored outside and placed on an approved platform to prevent overturning by animals, the entrance of flies or the creation of a nuisance. All solid waste shall be disposed of at sufficient frequencies in a manner so as not to create a rodent, insect or other vermin problem.

C. Immediately after emptying, containers for garbage shall be cleaned.

D. All waste meeting the definition of "infectious waste" as defined in Regulation 61-105 must be managed according to the requirements of that regulation.

SECTION 606. Outside Areas.

All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for insects, rodents and other pests. Outside stairs,

walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow and other impediments.

PART VII FIRE PROTECTION AND PREVENTION

SECTION 701. Fire-fighting Equipment and Systems.

A. All facilities located outside a fire protected area shall have a contract with the nearest fire department.

B. An evacuation plan shall be posted in prominent places and staff members shall be trained as part of their responsibilities to guide patients to the designated exits.

C. All fire protection and alarm systems and other fire fighting equipment shall be inspected and tested at least once each year, and more often if necessary to maintain them in serviceable condition.

D. Fire extinguishers of the proper type shall be installed in accordance with NFPA 10 (National Fire Protection Association) 10 requirements or as otherwise directed by fire authorities.

1. Fire extinguishers shall be kept in condition for instant use and shall be inspected monthly by facility staff with the date of inspection recorded on a tag affixed to the extinguisher.

2. Fire extinguishers shall be inspected and/or serviced annually by personnel licensed or certified to perform fire extinguisher servicing. Servicing/inspection records shall be kept on the fire extinguishers.

E. No portable electric, open flame, or unvented heaters shall be allowed in the facility.

F. Fire Drills.

1. A fire drill shall be conducted at least once every three months. New facilities shall conduct a fire drill within the first 48 hours of operation. Each employee shall participate in a fire drill at least twice each year.

2. Records of drills shall be maintained to report the date, time, description, and evaluation of the drill, to include the names of participating staff and time for total evacuation.

G. Corridor Obstructions. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions.

H. Corridor and Stairway Illumination. Corridors, stairs and other means of egress shall be lighted at all times with a minimum of one foot-candle at finish floor level along the path of travel.

SECTION 702. Alarms.

A fire alarm system shall be provided in accordance with the provisions of NFPA 72. The fire alarm system shall be tested monthly and each detector tested annually. Records of all tests shall be retained for at least one year.

SECTION 703. Gas Storage.

Gases (flammable and nonflammable) shall be handled and stored in accordance with the provisions of applicable NFPA codes.

PART VIII DESIGN AND CONSTRUCTION

SECTION 801. General.

Every facility must be planned, designed and equipped to provide adequate facilities for the care and comfort of each patient.

SECTION 802. Local and State Codes and Standards. (II)

A. Facilities shall comply with pertinent local and state laws, codes, ordinances and standards with reference to design and construction. Abortion clinics are categorized as a "business occupancy" as defined in the Standard Building Code. No facility will be licensed unless the Department has assurance that responsible local officials have approved the facility.

B. The Department uses as its basic codes: the Standard Building Code, Standard Plumbing Code, Standard Mechanical Code, and National Electrical Code. Buildings designed in accordance with the above mentioned codes will be acceptable to the Department, provided, however, that the requirements set forth in this regulation are also met.

SECTION 803. Submission of Plans and Specifications.

A. New Buildings, Additions or Major Alterations to Existing Buildings. (II)

1. When construction is contemplated either for new buildings, additions or major alterations to existing buildings, the facility must contact the Division of Health Facilities Construction of this Department to discuss code and regulation requirements that apply to that project. Plans and specifications shall be submitted to the Department for review. Where the Standard Building Code or other regulations require fire-rated walls or other fire-rated structural elements, these plans and specifications shall be prepared by an architect registered in the State of South Carolina and shall bear his/her seal.

2. All plans shall be drawn to scale with the title and date shown thereon. Construction work shall not be started until approval of the final drawings or written permission has been received from the Department. Any construction changes from the approved documents require approval by the Department.

B. Preliminary submission shall include the following:

1. Plot plan showing size and shape of entire site; orientation and location of proposed building; location and description of any existing structures, adjacent streets, highways, sidewalks, railroads, et cetera, properly designated; size, characteristics and location of all existing public utilities, including information concerning water supply available for fire protection;

2. Floor plans showing overall dimensions of buildings; locations, size and purpose of all rooms; location and size of doors, windows and other openings with swing of doors properly indicated; locations of smoke partitions and firewalls; locations of stairs, elevators, dumbwaiters, vertical shafts and chimneys;

3. Outline specifications listing a general description of construction including interior finishes and mechanical systems.

C. Final submission shall include the following: Complete working drawings and contract specifications, including layouts for plumbing, air conditioning, ventilation and electrical work and complete fire protection layout, if applicable.

D. In construction delayed for a period exceeding 12 months from the time of approval of final submission, a new evaluation and/or approval is required.

E. One complete set of as-built drawings shall be filed with DHEC.

SECTION 804. Licensure of Existing Structures. (II)

When an existing structure is contemplated for licensure it must meet the same building code requirements as a "new" facility (see Section 803.A). If an expansion or renovation to an existing facility is contemplated, the facility must contact the Division of Health Facilities Construction of this Department to discuss code and regulatory requirements that apply to that project. The following shall be submitted to the Department:

A. If the physical dimensions of the building are affected, a plot plan in accordance with Section 803.B.1;

B. A floor plan in accordance with Section 803.B.2;

C. Description of construction including outside walls, partitions, floor, ceiling and roof. The method of heating and cooling shall also be included.

NOTE: Those existing abortion clinics that have been identified by the Department, through submission of regular reports of abortions performed, may be licensed in their current buildings. However, upon initial licensure, these facilities will be required to submit a plan that will bring them into full compliance with this chapter within two years from date of licensure.

SECTION 805. Minor Alterations in Licensed Facilities.

When alterations that involve construction that may affect walls, ceilings, floors, or fire and life safety are contemplated, preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department for review and approval to insure that the proposed alterations comply with current safety and building standards and determine if an architect need be involved.

SECTION 806. Location.

A. Transportation. The facility must be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The facility shall have parking space to reasonably satisfy the needs of patients, staff, and visitors.

C. Communications. A telephone must be provided on each floor used by patients and additional telephones or extensions must be provided, as required, to summon help in case of fire or other emergency. Pay station telephones are not acceptable for this purpose.

SECTION 807. Physical Facilities.

A. An adequate number of examination/procedure rooms shall be provided. A procedure room shall be sized, shaped, and arranged to allow unfettered movement for all persons involved in the procedure.

B. Each procedure room shall be provided:

1. A suitable gynecological procedure table;

2. Equipment necessary to treat patients for hemorrhage, shock, cardiac arrest and other emergencies (an emergency "crash" cart in the immediate vicinity is acceptable); (I)

C. An area shall be provided for use by nurses in preparing medications for patients and keeping patient medical records. A room or cabinets shall be provided for storing medications and shall be kept locked except when medications are being prepared for administering. Narcotics shall be double-locked. An adequate supply of drugs shall be on hand at all times.

D. An adequate number of recovery room(s) or area(s) shall be provided. There shall be clear space on both sides and at the foot of each recovery bed/recliner to allow unencumbered movement by staff and patients.

1. There shall be a toilet room immediately accessible from the recovery area. This room shall contain a commode with grab bars or recessed hand-holds and handwashing lavatory, operable without the use of hands, soap dispenser with soap, and paper towel dispensers with paper towels, or hot air dryer;

2. There shall be a signal system for each patient bath and toilet that shall include an audible alarm that can be heard and location identified by staff;

3. There shall be a readily accessible safe and sanitary storage area for patients' clothing and personal effects;

4. There must be provisions to afford privacy upon request of a patient, e.g., curtains, screens, private room.

E. A room for the temporary storage of soiled linen and waste in covered containers shall be provided. This room shall be provided with at least 10 air changes per hour with all air continuously exhausted to the outside.

F. There must be an area to accommodate the sterilization procedures as described in Section 602. There shall be sufficient surgical instruments sterilized and available for each patient who presents herself for abortion. The area shall be arranged to prevent cross traffic of clean and dirty material. Air flow in this area shall be from the "clean" area toward the "dirty" area.

G. Suitable dressing room space shall be provided for physicians and nursing staff. Scrub facilities shall be provided and located conveniently to the procedure room(s).

H. Procedure and recovery room(s) shall be located on an exit access corridor that provides unimpeded, rapid access to an exit of the building. This exit must accommodate emergency transportation vehicles and equipment.

I. In multi-storied buildings where the facility is not located on the floor of entry to/exit from the building, there must be at least one elevator that serves the clinic floor(s). The elevator must accommodate emergency transportation equipment.

J. Adequate fixed or portable work surface areas shall be maintained for use in each procedure room.

K. Doors providing access into the facility and procedure room(s) shall be at least 36 inches wide to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment. All corridors shall be at least 48 inches wide.

L. Heating and ventilation.

1. Lighting, heating, and ventilation systems shall comply with local and state codes. There shall be approved equipment capable of maintaining a minimum temperature of 72 degrees Fahrenheit and a maximum temperature of 76 degrees Fahrenheit in patient areas.

2. The procedure room(s) and the recovery room(s) shall be provided a minimum of six air changes per hour. Air supplied to all areas shall be filtered through filters of at least 25 percent efficiency rating.

3. Mechanically operated systems shall be used to supply air to and exhaust air from soiled workrooms or soiled storage areas, janitor's closets, toilet rooms, and from spaces that are not provided with operable windows or outside doors.

M. The entrance shall be at grade level or above, be sheltered from the weather, and accommodate wheelchairs.

N. There shall be adequate storage areas for supplies and other storage. Sterile supplies shall be stored separate from other supplies.

O. One or more janitor's closets shall be provided throughout the facility as required to maintain a clean and sanitary environment. Each shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

P. A clean work area shall contain space for handwashing and clean storage and may include clean linen storage.

Q. There shall be at least two exits remote from each other.

R. Items such as drinking fountains, machines, and portable equipment or any other items shall not be located in the required exit corridors to restrict corridor traffic.

S. Thresholds and expansion joint covers shall be made sufficiently flush with the floor surface to accommodate wheeled service carts, wheelchairs, gurneys, etc.

T. All corridor glazing materials that extend within 18 inches of the floor shall be of safety glass, plastic, wireglass, or other material that will resist breaking and will not create dangerous cutting edges when broken. Safety glass or plastic glazing materials shall be used for any shower doors or bath enclosures.

U. Cubicle curtains and draperies shall be noncombustible or rendered flame retardant.

V. Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth and moisture resistant.

W. Wall bases in soiled equipment and material workrooms and other areas that are frequently subject to wet cleaning methods shall be tightly sealed and constructed without voids that can harbor insects.

X. Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

Y. Interior finish materials shall comply with the Standard Building Code requirements for "business occupancy."

Z. Adequate space shall be provided for reception, waiting, interviewing, administrative, and business office functions. Space provided for interviewing and admitting shall be located and designed to provide privacy.

SECTION 808. Water Supply and Plumbing. (II)

A. Water Supply. Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the facility and shall be adequate in volume and pressure for all purposes including fire fighting. Patient and staff handwashing lavatories shall be supplied with hot water that shall be thermostatically controlled to a temperature between 100 and 125 degrees Fahrenheit.

B. Plumbing.

1. All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of the Standard Plumbing Code.

2. All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies. There shall be, at a minimum, an approved double-check assembly on the water supply to the facility.

SECTION 809. Emergency Power and Lighting Requirements.

A. The facility shall be equipped with automatic emergency power adequate to maintain the operation of lighting for procedure rooms, egress, fire detection equipment, and alarms. (I)

B. There shall be sufficient safe lighting for all activities, including suitable lighting for corridors. (II)

Part IX. PREREQUISITES FOR INITIAL LICENSURE.

Prior to admission of patients to, and issuance of a license for new facilities or additional procedure rooms, the following actions must be accomplished:

A. Plans and construction must be approved by the Division of Health Facilities Construction of this Department.

B. The facility shall submit a completed application for license on forms that shall be furnished by the Division of Health Licensing. The following documents shall be submitted with the application:

1. Final construction approval of both water and wastewater systems by the appropriate District Environmental Quality Control Office of this Department (includes satisfactory laboratory reports of water samples).

2. Approval from the appropriate building official stating that all applicable local codes and ordinances have been complied with.

a. If the facility is located within town or city limits, approval by the local fire chief stating that all applicable requirements have been met, or

b. If the facility is located outside town or city limits, a written letter of agreement with the nearest fire department that will provide protection and respond in case of fire at the facility shall be obtained. This letter shall indicate that they have the equipment, personnel, and/or agreements with other departments to adequately respond to this type of facility.

3. Certification and laboratory test reports, provided by the manufacturer or supplier, that all carpeting purchased by the facility meets the requirements of the Standard Building Code.

4. Certification by the contractor that only the carpeting described in B.3 above was installed in the facility.

5. Certification by the manufacturer or supplier that all drapes and cubicle curtains purchased by the facility are flame or fire resistant or retardant.

6. Certification by the owner or contractor that only materials described in B.5 above were installed.

7. Certification by the manufacturer or supplier that all wall covering materials purchased by the facility are fire or flame resistant or retardant.

8. Certification by the contractor that only the materials described in 7 above were installed.

9. Certification by the engineer that all fire alarm and smoke detection systems have been installed according to plans and specifications, have been tested and operate satisfactorily.
 10. Certification by the contractor that the automatic sprinkler system, if required or installed, has been completed and tested in accordance with the approved plans and specifications and NFPA No. 13. Include a copy of the approval letter of the sprinkler shop drawings.
 11. Certification that all medical gas systems have been properly installed and tested.
- C. The facility must register as an infectious waste generator as outlined in Regulation 61-105.
 - D. Required personnel must be employed, available, trained, and capable of performing their duties.
 - E. The Division of Health Licensing shall inspect the facility and require compliance with these regulations.
 - F. The facility must pay the required licensing fee.

PART X. GENERAL.

Conditions arising that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

61–13. Standards for Licensing Intermediate Care Facilities for Individuals with Intellectual Disabilities.

(Statutory Authority: S.C. Code Section 44–7–260)

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SECTION 100—DEFINITIONS

For the purpose of these standards the following definitions shall apply:

A. Abuse. Physical Abuse or Psychological Abuse.

1. Physical Abuse. The act of intentionally inflicting or allowing to be inflicted physical injury on a client by an act or failure to act. Physical abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, burning, actual or attempted sexual battery, use of medication outside the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that a therapeutic procedure prescribed by a licensed physician or other legally authorized healthcare professional or that is part of a written individual care plan by a physician or other legally authorized healthcare professional is not considered physical abuse. Physical abuse does not include altercations or acts of assault between clients.

2. Psychological Abuse. The deliberate use of any oral, written, or gestured language or depiction that includes disparaging or derogatory terms to a client or within the client's hearing distance, regardless of the client's age, ability to comprehend, or disability, including threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

B. Active Treatment. An aggressive, consistent implementation of a program of specialized and generic training, treatment, and health services.

C. Administrator. The individual designated by the licensee to have the authority and responsibility to manage the facility and to be in charge of all functions and activities of the facility.

D. Adult. A person eighteen (18) years of age or older.

E. Airborne Infection Isolation (AII). A room designed to maintain Airborne Infection Isolation (AII), formerly called a negative pressure isolation room. An Airborne Infection Isolation (AII) room is a single-occupancy client-care room used to isolate persons with suspected or confirmed infectious tuberculosis (TB) disease. Environmental factors are controlled in Airborne Infection Isolation (AII) rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. Airborne Infection Isolation (AII) rooms may provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of six to twelve (6 to 12) air changes per hour (ACH), and direct exhaust of air from the room to the outside of the building or recirculation of air through a high efficiency particulate air (HEPA) filter.

F. Client. Any individual determined to have intellectual disability or a related condition, and resides and receives services in a licensed facility.

G. Control Station. An area of a facility which is the central focus of client management, nursing function, and service for a client living area. A control station may also be used for administrative functions by other disciplines which provide services to the clients of the facility. A control station shall not serve more than forty-four (44) beds.

H. Department. The South Carolina Department of Health and Environmental Control.

I. Designee. A physician, dentist, osteopath or podiatrist selected by a prescriber to sign orders for medication or treatment in the prescriber's absence.

J. Exploitation.

1. Causing or requiring a client to engage in activity or labor that is improper, unlawful, or against the reasonable and rational wishes of the client;

2. An improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a client by an individual for the profit or advantage of that individual or another individual; or

3. Causing a client to purchase goods or services for the profit or advantage of the seller or another individual through undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the client through cunning arts or devices that delude the client and cause him or her to lose money or other property.

4. Exploitation does not include requiring a client to participate in an activity or labor that is a part of a written plan of care or prescribed or authorized by the client's attending physician.

K. Facility. An Intermediate Care Facility for Persons with Intellectual Disability.

L. Incident. An unusual unexpected adverse event or accident resulting in harm, injury, or death of staff or clients, for example, medication errors, adverse medication reactions, client elopement.

M. Intellectual Disability. The significantly subaverage general intellectual functioning existing concurrently with deficits in adaptive behavior and manifested during the developmental period.

N. Interdisciplinary Team. A group designated by the facility to provide or supervise care, treatment, and services provided by the facility. The group normally includes the following persons: registered nurse, dietary, social services, direct care staff members, nurse aides, and activity professionals.

O. Intermediate Care Facility for Individuals with Intellectual Disabilities ("ICF-IID"). A facility that serves four (4) or more persons with intellectual disability or persons with related conditions and provides health or rehabilitative services on a regular basis to individuals whose mental and physical conditions require services including room, board, and active treatment for their intellectual disability or related conditions. For purposes of this regulation, the definitions of "Intermediate Care Facility for Individuals with Intellectual Disabilities" and "Habilitation Center for Persons with Intellectual Disability or Persons with Related Conditions" are the same and both terms are utilized interchangeably.

P. Licensee. The individual, corporation, organization, or public entity that has been issued a license to provide care, treatment, and services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

Q. Neglect. The failure or omission of a direct care staff member or direct care volunteer to provide the care, goods, or services necessary to maintain the health or safety of a client including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services. Failure to provide adequate supervision resulting in harm to clients, including altercations or acts of assault between clients, may constitute neglect. Neglect may be repeated conduct or a single incident that has produced or could result in physical or psychological harm or substantial risk of death. Noncompliance with regulatory standards alone does not constitute neglect.

R. Nonlegend Medication. A medication that may be sold without a prescription and that is labeled as stock or labeled for use by the consumer in accordance with the requirements of the laws of this state and the federal government.

S. Qualified Intellectual Disability Professional (QIDP). An individual who possesses the following minimal qualifications:

1. Has at least one (1) year of experience working directly with persons with intellectual disability or other developmental disabilities; and

2. Is a doctor of medicine or osteopathy, a registered nurse or an individual who holds at least a bachelor's degree in one of the following professional categories: occupational therapy; occupational therapy assistant; physical therapy; physical therapy assistant; psychology; sociology; speech-language pathology or audiology; recreation; dietetics; or human services.

T. Related Condition. A severe, chronic condition found to be closely related to intellectual disability or to require treatment similar to that required for persons with intellectual disability and must meet the following conditions:

1. Attributed to cerebral palsy, epilepsy, autism, or any other condition other than mental illness found to be closely related to intellectual disability because this condition results in impairment of

general intellectual functioning or adaptive behavior similar to that of persons with intellectual disability and requires treatment or services similar to those required for these persons;

2. Manifested before twenty-two (22) years of age;
3. Likely to continue indefinitely; and
4. Results in substantial functional limitations in three (3) or more of the following areas of major life activity: self-care, understanding and use of language, learning, mobility, self-direction, and capacity for independent living.

SECTION 200—LICENSE REQUIREMENTS (II)

201. Scope of Licensure

A. No person, private or public organization, political subdivision, or governmental agency shall establish, maintain, or represent itself (advertise or market) as an ICF-IID in South Carolina without first obtaining a license from the Department. Admission of clients or the provision of care, treatment, and/or services to clients prior to the effective date of licensure is a violation of S.C. Code Section 44-7-260(A). (I)

B. A license shall be effective for the period of time specified on its face by the Department.

C. A new facility, or one that has not been continuously licensed under these or prior standards, shall not admit clients until permission is granted by the Department.

D. Separate licenses are required for facilities not maintained on the same premises. Separate licenses may be issued for facilities maintained in separate buildings on the same premises. Each building of a licensed facility shall be staffed in accordance with Section 600.

202. License Application

Applicants for license shall file an application under oath on a form and frequency specified by the Department. An application shall be signed by the owner(s) if an individual or partnership; or in the case of a corporation, by two (2) of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction over it. The application shall set forth the full name and address of the facility for which the license is sought and owner(s); the names of persons in control thereof; and such additional information as the Department may require, including affirmative evidence of ability to comply with reasonable standards, rules, and regulations as may be lawfully prescribed. No proposed facility shall be named nor may an existing facility have its name changed to the same or similar name as a facility licensed in the state.

203. Compliance

An initial license shall not be issued to an applicant until the applicant demonstrates to the Department substantial compliance with the applicable licensing standards. A facility shall make a copy of the licensing standards accessible to all facility staff. In the event a licensee with an existing ICF-IID or other facility licensed by the Department applies for licensure for an additional ICF-IID or other facility, the currently licensed ICF-IID or other facility shall be in substantial compliance.

204. Compliance with Structural Standards

Facilities licensed at the time of promulgation of these regulations shall be allowed to continue utilizing the previously-licensed structure without modification.

205. Licensing Fee

Each applicant shall pay a license fee prior to the issuance of a license. The annual license fee shall be five dollars (\$5.00) per licensed bed. Such fee shall be made payable by check or credit card to the Department and is not refundable.

206. Change of License

A facility shall request issue of an amended license, by application to the Department, prior to any of the following circumstances:

- A. Change of ownership by purchase or lease;
- B. Change of facility's name or address;
- C. Addition of licensed beds; or
- D. Elimination of licensed beds.

207. Licensed Bed Capacity

A facility shall not exceed the bed capacity identified on the face of the license. A licensee shall obtain authorization from the Department before establishing new care, treatment, or services or occupying additional beds or renovated space. The midnight census of the facility shall not exceed the rated capacity of the license. (I)

208. Exceptions to Licensing Standards

The Department reserves the right to make exceptions to these standards where it is determined that the health and welfare of the community requires the services of the facility. When an “exception” applies to an existing facility, it will continue to meet the standards in effect at the time it was licensed.

SECTION 300—ENFORCEMENT OF REGULATIONS

301. General

The Department shall utilize inspections, investigations, consultations, or other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

302. Inspections and Investigations

A. Inspections shall be conducted prior to initial licensing of a facility. The Department, at its own determination, may also conduct subsequent inspections. (I)

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the South Carolina Code of Laws. (I)

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records at the time of the inspection. If photocopies are made for the Department inspector, they shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. Physical area of inspections shall be determined by the extent to which there is potential impact or effect upon clients as determined by the inspector. (I)

D. A facility found noncompliant with the standards of this regulation or governing statute shall submit an acceptable written plan of correction to the Department that shall be signed by the Administrator and returned by the date specified by the Department. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar); and
3. The actual or expected completion dates of those actions.

E. In accordance with S.C. Code Section 44–7–270, the Department may charge a fee for plan reviews, construction inspections, and licensing inspections.

SECTION 400—ENFORCEMENT ACTIONS

401. General

When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of a facility, the Department, upon proper notice to the licensee, may impose a monetary penalty, and deny, suspend, or revoke its license.

402. Violation Classifications

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health and safety of the persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition, one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of persons in the facility. The citation of a

Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section, as “(I)” or “(II).” Sections not annotated in that manner denote Class III violations. A classification at the beginning of a section and/or subsection applies to all subsections following, unless otherwise indicated.

E. In arriving at a decision to take enforcement action, the Department will consider the following factors: specific conditions and their impact or potential impact on the health, safety, or well-being of the clients; efforts by the facility to correct cited violations; behavior of the licensee that reflects negatively on the licensee’s character, such as illegal or illicit activities; overall conditions of the facility; history of compliance; any other pertinent conditions that may be applicable to current statutes and regulations including participating in, or offering, or implying an offer to participate in the practice generally known as rebates, kickbacks, or fee-splitting arrangements. (I)

F. When a decision is made to impose monetary penalties, the Department may utilize the following schedule as a guide to determine the dollar amount:

Frequency of violation of standard within a thirty-six (36) month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	\$200–1000	\$100–500	\$100
2nd	500–2000	200–1000	100–500
3rd	1000–5000	500–2000	200–1000
4th	5000	1000–5000	500–2000
5th	5000	5000	1000–5000
6th and more	5000	5000	5000

SECTION 500—POLICIES AND PROCEDURES (II)

A. Policies and procedures addressing each section of this regulation regarding client care, rights, and the operation of the facility shall be developed, implemented, and revised as needed in order to accurately reflect actual facility operation and shall be documented and maintained in the facility. The policies and procedures shall address the provision of any special care offered by the facility. Information shall include the means by which the facility shall meet the specialized needs of the affected clients, such as those who are physically or developmentally disabled, in accordance with any laws which pertain to that service offered. The facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures and such reviews shall be documented. These policies and procedures shall be accessible at all times in hard copy or electronically.

B. By its application, the licensee agrees to comply with all standards in this regulation. The policies and procedures shall describe the means by which the facility shall ensure the standards described in this regulation are met.

SECTION 600—STAFF AND TRAINING

601. General (II)

A. A facility shall have appropriate staff in numbers and training to meet the needs and conditions of the clients. Training and qualifications for the tasks each staff member performs shall be in compliance with all professional standards and applicable federal and state laws.

B. Prior to being employed or contracted as a staff member or direct care volunteer by a facility, a person shall undergo a criminal background check pursuant to S.C. Code Section 44-7-2910. (I)

C. The facility shall maintain accurate and current information regarding all staff members and volunteers of the facility, including at least: address, phone number, and health, work, and training

background. The facility shall assign duties and responsibilities to all staff members and volunteers in writing and in accordance with the facility's policy and the individual's capability.

602. Administrator (II)

- A. Each facility shall have a full-time Administrator.
- B. The facility Administrator shall be either a Qualified Intellectual Disability Professional (QIDP) or a licensed nursing home administrator and shall have the necessary authority and responsibility for management of the facility. Any change in the position of the Administrator shall be reported immediately by the governing board or owner to the Department in writing.
 - 1. For facilities utilizing a QIDP in this capacity, such notification shall include, at a minimum, the name of the appointed individual, effective date of the appointment, educational background, professional experience, and professional certificates and/or licenses.
 - 2. For facilities utilizing a licensed nursing home administrator in this capacity, such notification shall include, at a minimum, the name of the appointed individual, effective date of the appointment, and the number and expiration date of the current South Carolina Nursing Home Administrator's license or written verification of an emergency license.
- C. The Administrator shall exercise judgment that reflects that he or she is in compliance with these regulations and shall demonstrate adequate knowledge of these regulations.
- D. A staff member shall be designated, by name or position, in writing, to act in the absence of the Administrator, for example, a listing of the lines of authority by position title, including the names of the individuals filling these positions.
- E. The Administrator shall have sufficient freedom from other responsibilities and duties to carry out the functions associated with the position.
- F. The maximum number of facilities under the management of a single administrator will be determined based on the number of clients residing in the facilities, the extent of client needs, and the physical location of the facilities. Only facilities located within the same five (5) number zip code or no further than a twenty (20) miles radius of the facility shall be managed by a single administrator. No single administrator shall be responsible for more than a total of thirty-two (32) beds in multiple facilities unless approved by the Department.

603. Direct Care Staff (I)

- A. The facility shall maintain personnel adequate in number and skill in the facility at all times when clients are present to ensure safety and supervise clients in accordance with their individual program plans. When there are no clients in the facility, a responsible staff member shall be available by telephone.
 - 1. The facility's policy shall clearly define the authority, responsibility, and function of each category of personnel. (II)
 - 2. Personnel shall be assigned only those duties for which they are trained.
- B. The facility shall employ registered or practical nurses that are currently and continuously licensed to practice in South Carolina during the period of their employment. The facility shall maintain in the facility a copy of the license of each registered or practical nurse employed. Only licensed registered or practical nurses may perform duties requiring a registered or practical nurse. (II)

604. Staff (II)

- A. The facility shall employ or arrange for licensed nursing services which are sufficient to care for the client's health needs including individuals who are determined to need twenty-four-hour (24-hour) nursing care. If the facility utilizes only licensed practical nurses to provide health services, the facility shall have a contractual arrangement with a registered nurse to be available for verbal or onsite consultation to the licensed practical nurse in regard to the health aspects of the individual plans of care.
- B. The facility shall maintain a responsible direct care staff person on duty and awake on a twenty-four-hour (24-hour) basis (when clients are present) to respond to injuries and symptoms of illness and to handle emergencies in each facility building housing clients for whom a physician has ordered a medical care plan or clients who are aggressive, assaultive, or security risks.

C. The facility shall maintain at least one (1) staff member to eight (8) clients or a fraction thereof on duty on the first and second shift. The facility shall maintain one (1) staff member to sixteen (16) clients or a fraction thereof on duty on the third shift. In facilities serving less than sixteen (16) clients, the facility shall maintain one (1) additional staff member per shift for each eight (8) non-mobile clients or a fraction thereof present in the facility.

D. The facility shall provide the necessary professional services required to implement each client's individual program plan.

E. The facility shall require staff members who operate motor vehicles that transport clients to possess a valid driver's license.

F. If the facility has a volunteer program, a facility staff person shall be designated to direct the program. Volunteers shall consult with licensed staff prior to any changes in client care or treatment. The facility may elect to prohibit volunteers to work in the facility.

605. Inservice Training (I)

The facility shall require all staff members and volunteers to complete the necessary training to perform their duties and responsibilities. The facility shall document all inservice training. The following training shall be provided by appropriate resources, such as, licensed, registered, or certified persons; books; or electronic media, to all staff members prior to client contact and at a frequency determined by the facility, but at least annually unless otherwise specified by certificate, for example, cardiopulmonary resuscitation (CPR):

- A. Orientation of the facility organization and physical plant;
- B. Specific duties and responsibilities as outlined in the job description;
- C. Provisions of S.C. Code Sections 43-35-5, et seq., "Omnibus Adult Protection Act," and S.C. Code Sections 44-81-10, et seq.;
- D. "Bill of Rights for Residents of Long-Term Care Facilities" as well as other rights and assurances as required in this regulation;
- E. Confidentiality of client information and records;
- F. Emergency procedures and disaster preparedness to address various types of potential disasters such as evacuation, bomb threat, earthquake, flood, hurricane, tornado, and others within forty-eight (48) hours of initial client contact (See Section 1400);
- G. Fire response training (See Section 1702);
- H. CPR for designated staff members and direct care volunteers to ensure that there is a certified staff member or direct care volunteer present whenever clients are in the facility;
- I. Management and care of individuals with contagious and/or communicable disease, for example, hepatitis, tuberculosis, or HIV infection;
- J. Use of restraints that promote client safety, including alternatives to physical and chemical restraints, in accordance with the provisions of Section 1009 (for designated staff members only);
- K. OSHA standards regarding blood-borne pathogens;
- L. Infection control procedures; and
- M. Depending on the type of clients, care of persons specific to the physical or mental condition being cared for in the facility, such as, mental illness or aggressive, violent, and/or inappropriate behavioral symptoms, to include communication techniques (cueing and mirroring), understanding and coping with behaviors, safety, and activities.

606. Health Status (I)

A. All staff members and direct care volunteers who have contact with clients, including food service staff members and direct care volunteers, shall have a health assessment within twelve (12) months prior to hire. The health assessment shall consist of an evaluation of the individual's health status by a physician, registered nurse, or other legally authorized healthcare provider pursuant to written standing orders and/or protocol approved by a physician's signature. The health assessment shall also include tuberculin skin testing as described in Section 1503.

B. If a staff member or direct care volunteer is working at multiple facilities operated by the same licensee, copies of records for tuberculin skin testing and the pre-employment health assessment shall be accessible at each facility.

607. Volunteer Workers

A. Facilities shall require that volunteers sign in and out with staff of the facility upon entering or leaving the facility. Volunteers shall wear legible name and title badges that are visible at all times while on duty.

B. Volunteers and paid feeding assistants (as defined in the federal regulations on paid feeding assistants) shall not be included in the minimum staffing requirements of Section 604.

SECTION 700—REPORTING

701. Accidents and/or Incidents

A. A facility shall maintain a record of each accident and/or incident, including usage of mechanical or physical restraints, involving clients, staff members or volunteers, occurring in the facility or on the facility grounds. A facility's record of each accident and/or incident shall be documented, reviewed, investigated, and if necessary, evaluated in accordance with facility policies and procedures, and retained by the facility for six (6) years after the client's death, discharge, or transfer.

B. Accidents and/or incidents occurring to clients within the facility or on the facility grounds requiring reporting to the Department include, but are not limited to,:

1. Crime(s) against client;
2. Confirmed or suspected cases of abuse, neglect, or exploitation;
3. Medication error causing adverse reaction;
4. Hospitalization as a result of the accident and/or incident;
5. Elopement for more than twenty-four (24) hours or due to cognitive impairment;
6. Severe hematoma, laceration or burn requiring medical attention or hospitalization;
7. Fracture of bone or joint;
8. Severe injury involving use of restraints;
9. Attempted suicide; or
10. Fire.

C. A facility shall immediately report every serious accident and/or incident that results in client's death or significant loss of function or damage to a body structure, not related to the natural course of a client's illness or underlying condition or normal course of treatment, and resulting from an accident and/or incident occurring to client within the facility or on the facility's grounds to the client's next-of-kin or responsible party, the attending physician, and the Department via telephone, email, or facsimile within twenty-four (24) hours of the serious accident and/or incident.

D. A facility shall submit a written report of its investigation of every serious accident and/or incident to the Department within five (5) days of the serious accident and/or incident. A facility's written report to the Department shall provide at a minimum:

1. Facility name;
2. License number;
3. Type of accident and/or incident;
4. Date accident and/or incident occurred;
5. Number of clients directly injured or affected;
6. Client record number or last four (4) digits of Social Security Number;
7. Client age and sex;
8. Number of staff directly injured or affected;
9. Number of visitors directly injured or affected;
10. Name(s) of witness(es);
11. Identified cause of accident and/or incident;

12. Internal investigation results if cause unknown; and

13. Brief description of the accident and/or incident including the location of the occurrence and treatment of injuries.

E. A facility shall retain a report of every serious accident and/or incident with all of the information provided to the Department and the names, injuries, and treatments associated with each client, staff and/or visitor involved. A facility shall retain all serious accident and/or incident records for six (6) years after the client's death, discharge, or transfer.

F. The Administrator or his or her designee shall report every incident involving a client that leaves the premises for more than twenty-four (24) hours without notice to staff members of intent to leave to local law enforcement, the client's responsible party, and the Department. The Administrator or his or her designee shall immediately notify local law enforcement and the responsible party by telephone when a cognitively impaired client leaves the premises for any amount of time without notice to staff members.

G. The Administrator or his or her designee shall report changes in a client's condition, to the extent that serious health concerns and/or injuries, for example, fracture, behavioral changes or heart attack, are evident, to the attending physician and the responsible party immediately, not to exceed twenty-four (24) hours, consistent with the severity or urgency of the condition in accordance with facility policies and procedures. (I)

H. The Administrator or his or her designee shall report abuse and suspected abuse, neglect, or exploitation of clients to the Vulnerable Adults Unit of the South Carolina Law Enforcement Division (SLED) in accordance with S.C. Code Section 43-35-25.

702. Fire and Disasters (II)

A. The facility shall immediately notify the Department via telephone, email, or facsimile regarding any fire, regardless of size or damage that occurs in the facility, or any natural disaster in the facility which requires displacement of the clients or jeopardizes or potentially jeopardizes the safety of the clients.

B. The facility shall submit a complete written report regarding any fire or natural disaster to the Department to include the fire department reports, if any, within a time period as determined by the facility but not to exceed five (5) days.

703. Communicable Diseases and Animal Bites (I)

A. All cases of reportable diseases, animal bites, any occurrences such as epidemic outbreaks or poisonings, or other unusual occurrences that threaten the health and safety of clients or staff shall be reported in accordance with Regulation 61-20, Communicable Diseases.

B. The facility shall isolate any client who has a communicable disease which poses a threat to the health or safety of other clients, if ordered by the attending physician. If the attending physician determines the client cannot be managed at the facility or the physical layout prohibits isolation, the facility shall make arrangements for transfer of the client to an appropriate facility at the earliest practical time.

704. Emergency Placements

The facility shall notify the Department no later than the following workday when evacuees have been relocated to the facility by providing the names of the individuals received.

705. Facility Closure

A. Prior to the permanent closure of a facility, the licensee shall notify the Department in writing of the intent to close and the effective closure date. Within ten (10) days of the closure, the facility shall notify the Department of the provisions for the maintenance of the facility records as required by regulation, the identity of those clients displaced, and the relocated site. On the date of closure, the current original license shall be returned to the Department.

B. In instances where a facility temporarily closes, the licensee shall notify the Department in writing within fifteen (15) days prior to temporary closure. In the event of temporary closure due to an emergency, the facility shall notify the Department in writing within twenty-four (24) hours of the closure. At a minimum this notification shall include, but not be limited to, the reason for the temporary closure, the manner in which the records are being stored, the identification of those clients displaced, the relocated site, and the anticipated date of reopening. The Department shall consider,

upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards to the facility prior to its reopening.

706. Zero Census

In instances when there have been no clients in a facility for any reason, for a period of ninety (90) days or more, the facility shall notify, in writing, the Department no later than the one-hundredth (100th) day following the date of discharge or transfer of the last active client. If the facility has no clients for a period longer than one (1) year, and there is a desire to reopen, the facility shall reapply to the Department and shall be subject to all licensing requirements at the time of that application, including Certificate of Need review and construction-related requirements for a new facility. Instances of zero census do not relieve the facility of the requirement to pay licensing fees that may be due during that time.

SECTION 800—CLIENT RECORDS

801. Content (II)

A. A facility shall maintain adequate and complete records for each client. All entries shall be legibly written in ink or typed, dated, and signed, including title. If an entry is signed on a date other than the date it was made, the date of the signature shall also be entered. Although the use of initials in lieu of licensed nurses' signatures is not encouraged, initials shall be acceptable provided such initials can be readily identified by signature on each sheet on which the initials are used, or by signature on a master list which is maintained in the record at all times.

B. A minimum client record shall include the following:

1. Identification data:

a. Name, county, date of birth, sex, marital status, religion, county of birth, father's name, mother's maiden name, husband's or wife's name (if applicable), health insurance number, social security number, diagnosis, case number dates of care, name of the person providing information, and contact information for person(s) to be notified in case of emergency.

b. Admission agreement specifying available services and costs, and documentation of the explanation of the client bill of rights and grievance procedures.

c. Name and telephone number of attending physician.

d. Date and time of admission.

2. Consent form for treatment signed by the client or his or her legal representative.

3. Record of physical examination:

a. Physical examination, to include but not be limited to, diagnosis and identification of special conditions or care required, completed within one (1) month prior to or within forty-eight (48) hours after admission.

b. Physician's orders for medication, treatment, care, and diet, which must be reviewed and reordered at least once every three (3) months by the physician.

4. Individual Program Plan. An individual program plan shall be formulated or adopted within thirty (30) days of admission. This plan shall be updated as necessary, but at least annually, to reflect the current problems and needs of each client.

5. Social services. A social history, psychosocial assessment, and progress notes shall be documented and updated as necessary.

6. Activity services. An activity assessment and progress notes shall be documented and updated as necessary.

7. Dietary services. A dietary assessment and progress notes shall be documented and updated as necessary.

8. Nursing care record. Record of all pertinent factors pertaining to the client's condition.

9. Assessments and progress notes regarding psychological, behavioral, and therapeutic services shall be documented and updated as necessary by the interdisciplinary team.

10. Record of all physicians' visits subsequent to admission. Progress notes shall be entered after each visit to or by the physician. Physician's orders for medications, treatment, care, and diet shall be written in ink and signed by the prescriber or his or her designee.

11. Discharge summary.

802. Physician Orders

A. All physician orders for medication and treatment shall be recorded in the client's record, signed and dated by the physician or nurse receiving the orders. All orders, including verbal orders, shall be signed and dated by the prescribing physician or his or her designee within forty-eight (48) hours. (I)

B. No one, except a licensed nurse or pharmacist, may accept verbal orders from physicians for medication or nursing treatment and care. Verbal orders in other specialized departments or services, as authorized in facility policy and procedures, may be accepted by those departments or services, for example, orders pertaining to physical therapy may be received by a physical therapist. (I)

C. The use of a rubber stamp signature or electronic representation shall be acceptable under the following conditions:

1. The physician whose signature the rubber stamp represents is the only one who uses it; and

2. The physician places in the administrative office of the facility a signed statement to the effect that he or she is the only one who has the rubber stamp and is the only one who will use it.

D. The use of rubber stamp signatures shall not be permitted on orders for "controlled substances."

803. Individual Program Plan (II)

The facility shall provide an individual program plan for each client that is developed by the interdisciplinary team made up of the professions, disciplines, and service areas necessary to identify each client's needs and design appropriate programs, and shall be signed and dated by the client or his or her responsible party and a staff member on the interdisciplinary team. The individual program plan shall include the identified needs, the specific objectives to meet these needs, and the methods and schedules for implementing the designed programs. The individual program plan shall be updated and/or revised as changes in client needs occur, but not less than semi-annually by the interdisciplinary team.

804. Record Storage

A. Records of clients are the property of the facility and shall not be removed without court order. Access to the medical record shall be granted to the legal guardian or any individual legally authorized in writing to act on behalf of the client.

B. On discharge, transfer, or death of a client, the medical records shall be completed within fifteen (15) days and filed in an inactive file in an orderly manner. Records shall be retained in a safe storage area or electronically and none shall be disposed of less than six (6) years after discharge, transfer, or death of a client.

C. Facilities that microfilm before six (6) years have expired shall film the entire record.

D. In the event of change of ownership, all client records shall be transferred to the new owner(s). (II)

E. Prior to the closing of a facility for any reason, the facility shall arrange for preservation of records to ensure compliance with these regulations. The facility shall notify the Department, in writing, describing these arrangements.

SECTION 900—ADMISSION AND RETENTION (I)

A. A facility shall make admission decisions based on a preliminary evaluation of the client that is conducted or updated by the facility or outside sources. The preliminary evaluation shall contain background information as well as current assessments of functional, developmental, behavioral, social, health, and nutritional needs and if the client is likely to benefit from placement in the facility.

B. A facility shall admit only those persons having a diagnosis of intellectual disability or other related condition and be in need of a continuous program of training directed toward:

1. The acquisition of behaviors and skills needed to function with greater independence; and/or

2. The prevention or deceleration of the loss of current functions.

C. Within one (1) month prior to or within forty-eight (48) hours after admission, all first time clients shall have a physical examination including the tuberculosis testing requirements of Section 1504.

D. Within one (1) month prior to or within forty-eight (48) hours of client admission, a dietitian, occupational therapist, or speech therapist shall conduct an assessment to determine the diet and food consistency the client can manage.

SECTION 1000—CLIENT CARE AND SERVICES

1001. Client Care Policies

A. A facility shall designate a committee to develop client care policies. (II)

B. The facility's client care policy committee shall include the Administrator and designated professional representatives from the healthcare, dietary, pharmaceutical, social services, and psychological areas. (II)

C. A facility's review of client care policies shall occur at least once every two (2) years and shall cover at least the following:

1. Admission and transfer;
2. Dietary services;
3. Habilitation services;
4. Pharmaceutical services;
5. Physician services;
6. Nursing services;
7. Client rights; and
8. Behavior management.

D. Actual practices and procedures shall be in accordance with facility policy. (II)

E. A facility shall retain minutes of meetings of the client care policy committee relating to policies, procedures, or evaluations of the facility.

1002. Training and Habilitation

A. A facility shall provide each client with developmental training utilizing assessment-based programs to ensure achievement and maintenance of his or her highest level of self-care independence. A facility shall encourage and assist each client to achieve his or her highest level of independence. (I)

B. A facility shall provide each client with developmental training and/or assistance in the activities of daily living as his or her needs indicate.

C. A facility shall provide training and assistance on a continuum of care from the basic skills of proper body alignment and joint movement to preparation for independent community living.

1003. Client Activities

A. A facility shall provide a regular and ongoing program of varied, meaningful activities designed to meet the needs and interests of each client and to promote his or her physical, social, and emotional well-being. A facility shall provide activities that include appropriate group activities and activities for individuals with particular interests and needs. A facility shall make activities available to give the clients an opportunity for participation. A facility shall not force clients to participate in any activity. A facility shall provide activities in accordance with the client's individual program plan.

B. A facility shall utilize community resources and volunteers to the fullest possible extent.

C. A facility shall provide flexible visiting hours and encourage visitation by relatives and friends, with minimal restrictions. A facility shall grant reasonable exceptions to visiting hours.

D. A facility shall provide ample space, supplies, and equipment for all pertinent activities. Examples include: books, magazines, newspapers, games, arts and crafts, radio, and television.

E. If a facility implements a pet therapy program, the following guidelines shall be met:

1. Pets utilized for the program shall be free of fleas, ticks, and intestinal parasites, and have been screened by a veterinarian prior to client contact, and shall present no apparent threat to the health, safety, and well-being of the clients;

2. Pets utilized for the program shall be inoculated or vaccinated as required by law, with written verification of current inoculations on file at the facility; and

3. Pets shall be properly cared for and housed, if applicable.

1004. Therapeutic and Behavioral Services

A. A facility shall provide therapeutic services such as physical therapy, occupational therapy, and speech therapy based on each client's individual needs. A facility shall provide these therapies based upon the interdisciplinary team's recommendation and shall be administered by qualified persons. A facility shall obtain a physician's order for physical therapy evaluation and/or treatment.

B. A facility shall provide psychological and behavioral management services for clients as needed and recommended by the facility's interdisciplinary team.

1005. Physician Services

A. An annual physical examination by a physician, physician assistant, or nurse practitioner shall be performed on each client in addition to preventative and general care as deemed necessary by the attending physician.

B. The attending physician shall review all prescribed medications at least once every three (3) months.

C. Physician's progress notes shall be recorded as needed and shall be consistent with the observed condition of the client.

D. Special exams or consultations. A facility shall develop written policies and procedures regarding the acceptance of unsigned radiological, laboratory, or other consultative reports requested by a physician.

E. A facility shall not, under any circumstances, restrict client, guardian, or representative choice in attending physician coverage provided the physician is licensed to practice in South Carolina and agrees to provide medical services required by facility policy and applicable regulations.

F. A facility shall have at least one (1) licensed physician available on call at all times.

1006. Dental Services

A. Within one (1) month of client admission, a physician, dentist, or registered nurse shall conduct an oral assessment on each client to determine the condition of gums and teeth.

B. The facility shall provide clients with daily dental care assistance as necessary.

C. A facility shall maintain names of dentists who can render emergency and other dental treatments. A facility shall encourage clients to utilize dental services of their choice.

1007. Oxygen Therapy

A. A facility shall provide oxygen for the treatment of clients when ordered by a physician or other legally authorized healthcare provider. (I)

B. A facility shall post "No Smoking" signs conspicuously when oxygen is dispensed, administered, or stored. A facility shall appropriately secure all cylinders in an upright position.

1008. Personal Hygiene (II)

Each client shall be assured of good personal hygiene, clean clothing, removal or trimming of facial hair, trimming of nails, and freedom from offensive body odors.

1009. Safety Restraints for Behavioral or Medical Conditions (I)

A. A facility shall develop written policies and procedures on restraints that may be used.

B. The client's individual program plan and/or the physician's order shall include the length of time the restraint is to be used, but use of restraints shall not be used for more than twelve (12) consecutive hours.

C. The facility may employ safety restraints only:

1. As an integral part of an individual program plan intended to manage and eliminate the behaviors for which the restraint is utilized; or

2. As an emergency measure with a physician's order at the time they are applied; or
3. As a health-related protection prescribed by a physician.

D. If a client residing in a facility without twenty-four (24) hour nursing personnel requires continuous physical restraint for more than twenty-four (24) hours, the client shall be transferred to a facility which provides the specialized services required and which employs twenty-four (24) hour nursing personnel.

SECTION 1100—RIGHTS AND ASSURANCES

A. A facility shall comply with all current state, federal, and local laws and regulations concerning client care, treatment, procedures, and/or services, client rights and protections, and privacy and disclosure requirements, such as, S.C. Code Section 44–81–10, Bill of Rights for Residents of Long-Term Care Facilities, and S.C. Code Sections 43–35–5, et seq., Omnibus Adult Protection Act. (I)

B. A facility shall prominently display inside the facility all posted notices required in the Bill of Rights for Residents of Long-Term Care Facilities, the Omnibus Adult Protection Act, and other notices as required by law.

C. A facility shall have a grievance and complaint procedure to be exercised on behalf of the clients to enforce the Bill of Rights for Residents of Long-Term Care Facilities that includes the address and telephone number of the Department and a provision prohibiting retaliation against the client should the grievance right be exercised. Clients shall be made aware of this procedure and it shall be posted adjacent to the Bill of Rights for Residents of Long-Term Care Facilities.

SECTION 1200—MEDICATION MANAGEMENT

1201. General (I)

A. Medications, including controlled substances, medical supplies, and those items necessary for the rendering of first aid, shall be properly managed in accordance with state, federal, and local laws and regulations. Such management shall address the securing, storing, and administering of medications, medical supplies, first aid supplies, and biologicals, their disposal when discontinued or expired, and their disposition at discharge, transfer, or death of a client.

B. Applicable medication-related reference materials such as Physicians' Desk Reference and information on the use of medications shall be readily available at each staff work area in order to provide staff members with adequate information concerning medications. At least one (1) such reference in the facility shall have been published within the previous year and none shall be older than three (3) years.

1202. Medication and Treatment Orders (I)

A. Medication and treatment, to include oxygen, shall be administered to clients only upon orders (to include standing orders) of a physician or other legally authorized healthcare provider.

B. All orders (including verbal) shall be received only by licensed nurses or other legally authorized healthcare providers, and shall be authenticated and dated by a physician or other legally authorized healthcare provider within forty-eight (48) hours. This restriction shall not be construed to prohibit the issuance and acceptance of verbal orders in other specialized departments or services in accordance with facility policies and procedures, for example, orders pertaining to respiratory therapy modalities may be given to respiratory therapy personnel and physical therapy orders to physical therapists.

C. Physicians' orders for medication, treatment, care, and diet shall be reviewed and reordered no less frequently than every three (3) months.

D. All medication orders that do not specifically indicate the number of doses to be administered or the length of time the medication is to be administered shall automatically be stopped in accordance with facility policies and procedures.

1203. Administering Medication (I)

A. Medications shall be administered in accordance with orders from the attending physician, dentist, or other individual legally authorized to prescribe medications.

B. Medications and medical supplies ordered for a specific client shall not be provided to or administered to any other client.

C. Medications shall be administered in accordance with state practice acts by individuals licensed to administer medications, including a licensed respiratory care practitioner. The administration of medication shall include, but not be limited to,:

1. Removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container);
2. Verifying the dosage with the physician's orders;
3. Giving the individual dose to the proper client;
4. Monitoring the ingestion or application of the dose; and
5. Promptly recording on the medical administration records, as it is administered, the date, time, dose given, mode of administration, and identification of the individual who administered the medication.

D. Doses of medication shall be administered by the same licensed nurse or other legally authorized healthcare provider who prepared them for administration. Preparation of doses for more than one (1) scheduled administration shall not be permitted.

E. Self-administration of medications by clients shall be permitted only on the specific written orders of the client's attending physician or other legally authorized healthcare provider, verified by observation of the client by a licensed nurse, and recorded on the medication administration records by that same person. Facilities may elect to prohibit self-administration. The facility shall not allow clients to self-administer controlled substances.

F. The facility shall maintain a daily documented review of all scheduled controlled substances, Schedules II, III, IV, and V, by nurses including verification that the count was correct, and if incorrect, an explanation of the discrepancy and any corrective actions taken. The review shall include controlled substances in an unsealed emergency medication kit or cart.

G. Non-licensed facility staff members may administer nonlegend drugs, such as, aspirin, milk of magnesia, mineral oil, medicated shampoo, provided that these staff members have been trained to perform these tasks in the proper manner by individuals licensed to administer medications and the training is documented and maintained in the record of the non-licensed staff member.

1204. Pharmacy Services (I)

A. The facility shall maintain a written agreement with a consulting pharmacist to direct, supervise, and be responsible for pharmacy services in the facility in accordance with accepted professional principles and appropriate state, federal, and local laws and regulations.

B. At least once every three (3) months the pharmacist shall:

1. Review the medication profile for each client for potential adverse reactions, allergies, interactions and laboratory modifications. The attending physician shall be advised of recommended changes in the medication regimen, medication therapy duplication, incompatibilities or contraindications;
2. Review medication storage areas and emergency medication kits;
3. Review all medications in the facility for expiration dates and ensure the removal of discontinued or expired medications from use;
4. Verify proper storage of medications and biologicals in the facility and make recommendations concerning the handling, storing, and labeling of medications;
5. Examine the controlled substances records and affirm to the Administrator that this inventory is correct; and
6. Assess the facility's pharmaceutical services to ensure the services have been properly implemented and maintained and submit to the Administrator a written report of each pharmaceutical assessment including recommendations.

C. In addition to the services enumerated in Section 1204.B, the pharmacist shall participate in the formulation of pharmacy service policies and procedures and coordinate pharmacy services.

D. Facilities that maintain stocks of legend medications and biologicals for client use within the facility shall obtain and maintain from the South Carolina Board of Pharmacy a valid, current, non-dispensing drug outlet permit, displayed in a conspicuous place in the facility.

1205. Medication Containers (I)

A. The labeling of medications and biologicals shall be based on currently accepted professional principles. Labels shall identify, at a minimum, the name of the medication or biological, strength, and lot number. As appropriate, labels shall include client name and any identifying number. The prescribing physician's name and directions for use shall be on the label. If a physician or other authorized healthcare provider changes the dosage of a medication, the medication shall be returned to the pharmacy for relabeling. In lieu of this procedure, it is acceptable to attach a label to the container that states, "Directions changed; refer to MAR and physician or other authorized healthcare provider orders for current administration instructions."

B. Medication containers that have been damaged, compromised, or without labels, or that have damaged, incomplete, or makeshift labels, are considered to be misbranded and are prohibited and shall be destroyed in accordance with Section 1209.

C. Medications for each client shall be maintained in the original container(s) including unit dose systems. Opening blister packs to remove medications for destruction or adding new medications for administration, except under the direction of a pharmacist, is prohibited.

1206. Medication Storage (I)

A. Medications shall be stored and safeguarded in a locked medicine preparation room or locked cabinet at or near the staff work area to prevent access by unauthorized individuals. Medication carts utilized for storage shall be locked when not in use. Expired or discontinued medications shall not be stored with current medications. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life.

B. Medications requiring refrigeration or freezing shall be stored in a refrigerator or freezer as appropriate at the temperature range established by the manufacturer used exclusively for that purpose in the medicine preparation room, or in a locked refrigerator used exclusively for medications. Food and drinks shall not be stored in the same refrigerator or freezer in which medications and biologicals are stored. Refrigerators and freezers shall be provided with a thermometer accurate to plus or minus two (2) degrees Fahrenheit.

C. Medications shall be stored:

1. Under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety, and security;

2. In accordance with manufacturer's directions and in accordance with all applicable state, federal, and local laws and regulations;

3. Separately from poisonous substances, such as cleaning and germicidal agents, or body fluids;

4. In a manner that provides for separation between topical and oral medications, and which provides for separation of each client's medication; and

5. In medicine preparation rooms or cabinets that are well-lighted and of sufficient size to permit orderly storage and preparation of medications. Keys to the medicine preparation room, cabinet, refrigerator or medication cart at the staff work area shall be under the control of a designated licensed nurse.

D. Nonlegend medications that can be obtained without a prescription such as aspirin, milk of magnesia, and mineral oil, may be retained and shall be labeled as stock in the facility for administration as ordered by a physician or other legally authorized healthcare provider.

E. The medications prescribed for a client shall be protected from use by any other individuals. For those clients who have been authorized by a physician or other legally authorized healthcare provider to self-administer medications, such medications shall be stored in accordance with facility policies and procedures.

F. Prescribed and over-the-counter medications may be maintained at bedside upon physician orders if kept in an individual cabinet or compartment that is locked, such as the drawer of the client's night stand, in the room of each client who has been authorized in writing to self-administer by a physician or other legally authorized healthcare provider, in accordance with facility policies and procedures.

G. Medications listed in Schedule II of the Federal “Controlled Substances Act” shall be stored in separately locked, permanently affixed, compartments within a locked medicine preparation room, cabinet, or medication cart, unless otherwise authorized by a change in the state or federal law pertaining to the unit dose or multi-dose system.

1207. Medication Control and Accountability (I)

A. Records of receipt, administration, and disposition of all medications shall be maintained in sufficient detail to enable an accurate reconciliation. The pharmacist or designee shall verify that drug records are in order and that an account of all drugs is maintained.

B. Medications that have been discontinued may be secured in the staff work area with a written order by the attending physician. Such medications shall not be held beyond a ninety (90) day period unless so ordered by the physician or other legally authorized healthcare provider, but in no case held beyond the expiration date of the medication.

C. Separate control sheets shall be maintained on any controlled substances listed in Schedules II, III, IV, and V, State and Federal “Controlled Substances Act.” This record shall contain the following information: date, time administered, name of client, dose, signature of individual administering, name of physician or other legally authorized healthcare provider ordering the medication and all scheduled controlled substances balances (See Section 1203.F).

1208. Emergency Medications (I)

If the facility determines a need for an emergency medication kit or cart, the kit or cart shall comply with the provisions of Regulation 61–4, Controlled Substances.

1209. Disposition of Medications (I)

A. Upon discharge of a client, unused medications, biologicals, medical supplies, and solutions may be released to the client, family member, or responsible party, unless prohibited by facility policies and procedures, the attending physician, or other legally authorized healthcare provider.

B. When client medications, biologicals, medical supplies, or solutions have deteriorated or exceeded their expiration date or there are partially unused medications, or medication containers are misbranded, they shall be destroyed by a licensed nurse or other legally authorized healthcare provider.

C. When non-controlled legend drugs, biologicals, medical supplies, and solutions are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the name of the individual performing the destruction and witnessed by a licensed nurse or pharmacist.

D. The destruction of controlled substances shall be accomplished pursuant to the requirements of Regulation 61–4.

SECTION 1300—VITAL STATISTICS

1301. General

Facilities shall comply with Regulation 61–19, Vital Statistics, with regard to vital statistics.

1302. Death Certificates

Facilities shall file death certificates in accordance with R.61–19 and the South Carolina Code of Laws.

SECTION 1400—EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1401. Disaster Preparedness (II)

A. All facilities shall develop, by contact and consultation with their county emergency preparedness agency, a suitable written plan for actions to be taken in the event of a disaster and/or emergency evacuation. In the event of mass casualties, the facility shall provide resources as available. The facility shall update its plan annually or as needed, and shall rehearse it at least annually. The facility shall maintain a record of the rehearsal, including its date and time, a summary of actions and recommendations, and the names of the participants.

B. The disaster and emergency evacuation plan shall include, but not be limited to:

1. A sheltering plan to include:
 - a. Facility occupancy at the time of the disaster;

b. Name, address, and phone number of the sheltering facility or facilities to which the clients will be relocated during a disaster; and

c. A letter of agreement signed by an authorized representative of each sheltering facility which shall include: the number of relocated clients that can be accommodated; sleeping, feeding, and medication plans for the relocated clients; and provisions for accommodating relocated staff members and volunteers. The letter shall be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Horry, Jasper, and Georgetown counties, at least one (1) sheltering facility shall be located in a county other than these counties.

2. A transportation plan, to include agreements with entities for relocating clients, which addresses:

a. The relocation needs of the clients and staff contingent upon the type of disaster or emergency confronted;

b. Procedures for providing appropriate medical support, food, water, and medications during relocation based on the needs and number of the clients; and

c. Estimated time to accomplish the relocation during normal conditions; and

d. Primary and secondary routes to be taken to the sheltering facility.

3. A staffing plan for the relocated clients, to include:

a. How care will be provided to the relocated clients, including licensed and nonlicensed staff members that will meet the staffing requirements of Section 604 for clients who are relocated;

b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility; and

c. A co-signed statement by an authorized representative of the sheltering facility if staffing, bedding, or medical supplies are to be provided by the sheltering facility.

C. In instances where there are proposed changes in licensed bed capacity, the disaster or emergency evacuation plan shall be updated to reflect the new licensed bed capacity and submitted to the Department along with the application for bed capacity change.

D. Only those facilities located in the coastal counties of Beaufort, Charleston, Colleton, Horry, Jasper, or Georgetown may request exemption from an emergency evacuation order.

1. Facilities in the above counties may elect to seek an exemption from having to evacuate the facility in the event the Governor issues a Mandatory Evacuation Order for an impending hurricane. Facilities located in these counties may request an exemption from an emergency evacuation order if the facility has previously submitted the following to the Department:

a. A Critical Data Sheet, updated annually, that certifies emergency power supply is available for a minimum of seventy-two (72) hours, a seventy-two (72) hour supply of food, water, and medical supplies is on site, and that adequate staff will be available and on duty to provide continual care for the clients;

b. A copy of the engineer's report concerning the wind load the facility should withstand; and

c. A current approved evacuation plan prior to a declared emergency.

2. Once the prerequisites are met and an emergency has been declared, the facility shall draw down the census of the facility and then contact the Department to request an exemption from the evacuation order.

3. A facility shall comply with the mandatory evacuation order unless an exemption from evacuation of the facility for a specific storm has been received from the Department.

1402. Emergency Call Numbers

A facility shall post emergency call data in a conspicuous place and shall include at least the telephone numbers of fire and police departments, ambulance service, and the poison control center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members and volunteers to be notified in case of emergency.

1403. Continuity of Essential Services (II)

A facility shall maintain a written plan to be implemented to ensure the continuation of essential client support services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the workforce resulting from inclement weather or other causes.

SECTION 1500—INFECTION CONTROL AND ENVIRONMENT

1501—Staff Practices (I)

Staff and volunteer practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable regulations and guidelines of the Occupational Safety and Health Administration, for example, the Bloodborne Pathogens Standard; the Centers for Disease Control and Prevention, for example, Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee; Regulation 61-105; and other applicable state, federal and local laws and regulations.

1502. Tuberculosis Risk Assessment (I)

A. All facilities shall conduct an annual tuberculosis risk assessment in accordance with CDC guidelines to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification, such as low risk or medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and clients and the frequency of screening. A risk classification shall be determined for the entire facility. In certain settings, such as, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, client population, job type, or location within the setting, may have separate risk classifications.

1503. Staff Tuberculosis Screening (I)

A. Tuberculosis Status. Prior to date of hire or initial client contact, the tuberculosis status of direct care staff shall be determined in the following manner in accordance with the applicable risk classification:

B. Low Risk:

1. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All staff (within three (3) months prior to contact with clients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

C. Medium Risk:

1. Baseline two-step TST or a single BAMT: All staff (within three (3) months prior to contact with clients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic testing (with TST or BAMT): Annually, of all staff who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff about symptoms of TB disease (including the staff and/or direct care volunteers responses), documenting the questioning of the staff about the presence of symptoms of TB disease, and instructing the staff to report any such symptoms immediately to the Administrator or director of nursing. Treatment for latent TB infection (LTBI)

shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

D. Baseline Positive or Newly Positive Test Result:

1. Staff with a baseline positive or newly positive test result for *M. tuberculosis* infection (such as TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, such as, cough, weight loss, night sweats, or fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). These staff members will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (such as the Department's TB Control program).

2. Staff with positive TST results (regardless of when that conversion was first documented) shall document that conversion, document a subsequent negative chest radiograph, and receive a negative assessment for signs and symptoms of TB before they may be hired or admitted, as appropriate.

3. Staff who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician, and permitted to return to work only with approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician.

1504. Client Tuberculosis Screening (I)

A. Tuberculosis Status. Prior to admission, the tuberculosis status of a client shall be determined in the following manner in accordance with the applicable risk classification:

B. For Low Risk and Medium Risk:

1. Admission/Baseline two-step TST or a single BAMT: All clients within one (1) month prior to admission unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly-admitted client has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered within one (1) month prior to admission to the facility to serve as the baseline.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for clients upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all clients who have had exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

C. Baseline Positive or Newly Positive Test Result:

1. Clients with a baseline positive or newly positive test result for *M. tuberculosis* infection (such as TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, such as, cough, weight loss, night sweats, or fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). Routine repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician. These clients will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (such as the Department's TB Control program).

2. Clients with positive TST results (regardless of when that conversion was first documented) shall document that conversion, document a subsequent negative chest radiograph and receive a negative assessment for signs and symptoms of TB before they may be admitted, as appropriate.

3. Clients who are known or suspected to have TB disease shall be transferred from the facility if the facility does not have an Airborne Infection Isolation room (See Section 100.E), required to

undergo evaluation by a physician, and permitted to return to the facility only with approval by the Department's TB Control program.

1505. Housekeeping (II)

A. A facility and its grounds shall be uncluttered, clean, and free of vermin and offensive odors. A facility shall maintain sufficient cleaning supplies and equipment at all times. Housekeeping shall at a minimum include:

1. Cleaning each specific area, including storage areas, of the facility. Accumulated waste material shall be removed daily or more often if necessary;
2. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area. Cleaning and disinfection shall be appropriate to the area and the equipment's purpose or use and shall include client room preparation for new occupants;
3. Storage and/or use of chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be secure and inaccessible to clients;
4. Cleaning of all exterior areas, such as, porches and ramps, and removal of safety impediments such as snow, ice, and standing water; and
5. Keeping facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.

B. Dry dusting and dry sweeping are prohibited.

1506. Clean and Soiled Linen and Clothing (II)

A. Clean Linen and Clothing.

1. Proper storage facilities shall be provided for keeping clean linen, restraints, and client clothes in sanitary condition prior to use. Clean linen and clothing storage rooms shall be used only for the storage of clean linen and clothing. Clean linen and clothing shall be separated from storage of other materials.
2. A supply of clean, sanitary linen and clothing shall be available at all times.
3. Clean linen and clothing shall be transported in a sanitary manner, such as, covered.

B. Soiled Linen and Clothing.

1. A soiled linen storage room shall be provided.
2. Soiled linen and clothing shall neither be sorted, rinsed, nor washed outside the laundry service area.
3. Provisions shall be made for collecting and transporting soiled linen and clothing.
4. Soiled linen and clothing shall be kept in enclosed or covered nonabsorbent containers or washable laundry bags.
5. Soiled linen and clothing shall not be transported through client rooms, kitchens, food preparation or storage areas.
6. If linen chutes are used, the soiled linen and clothing shall be enclosed in bags before placing in the chute.
7. Facilities shall utilize Standard Precautions in the handling of all soiled linen and clothing. Labeling or color-coding of bagged soiled linen and clothing is sufficient provided all on-site or off-site handlers recognize the containers as requiring compliance with Standard Precautions.

1507. Contaminated Dressings and Pathological Waste (I)

A. A facility shall dispose of all contaminated dressings, pathological, and other similar waste by incineration or other approved means. A facility shall clearly identify containers for contaminated waste as such and shall not be accessible by unauthorized persons.

B. A facility shall dispose of dressings and contaminated wastes in client rooms only if such wastes are placed in a closed, clearly identified container, double bagged, and removed from the client room after attending the client.

1508. Refuse Disposal

A. A facility shall deposit all garbage and refuse in suitable watertight containers. A facility shall dispose of rubbish and garbage in accordance with local requirements.

B. A facility shall cover and store refuse containers outside on an approved platform constructed of concrete, wood, or asphalt and secured in such a manner so as to prevent overturning by animals, the entrance of flies, or the creation of a nuisance. A facility shall thoroughly clean garbage and trash containers as necessary to prevent the creation of a nuisance.

1509. Cleaning and Use of Equipment and Supplies

A facility shall disinfect or sterilize medical equipment coming into contact with clients after each use to maintain such equipment in a clean and sanitary condition. Disposable materials and equipment shall be used by one (1) client only, in accordance with manufacturer's recommendations and then disposed of in an acceptable manner. (II)

SECTION 1600—MEAL SERVICE

1601. General (II)

A. Facility meal service programs shall be inspected and approved by the Department, and shall be regulated, inspected, and permitted pursuant to Regulation 61-25, Retail Food Establishments. Facilities preparing food on-site and licensed for sixteen (16) beds or more subsequent to the promulgation of these regulations shall have kitchen equipment which meets the requirements of R.61-25. Existing facilities with sixteen (16) licensed beds or more may continue to operate with equipment currently in use; however, only certified or classified equipment shall be used when replacements are necessary. Those facilities with fifteen (15) beds or less shall be regulated pursuant to R.61-25 with certain exceptions in regard to food equipment (may utilize non-certified or non-classified food equipment).

B. When meals are catered to a facility, such meals shall be obtained from a retail food establishment permitted by the Department, pursuant to R.61-25.

C. If food is prepared at a central kitchen and delivered to separate facilities or separate buildings and/or floors of the same facility, the method of transportation shall be in compliance with all applicable sections of R.61-25 and approved by the Department.

D. Food shall be prepared by methods that conserve the nutritive value, flavor and appearance. The food shall be palatable, properly prepared, and sufficient in quantity and quality to meet the daily nutritional needs of the clients in accordance with written dietary policies and procedures.

E. Efforts shall be made to accommodate the religious, cultural, and ethnic preferences of each client and consider variations of eating habits, unless the orders of a physician or other legally authorized healthcare provider contraindicate.

F. Nourishment stations, if provided, shall contain a handwashing sink equipped for handwashing, equipment for serving nourishment between scheduled meals, refrigerator, and storage cabinets.

G. At least one (1) dietary refrigerator shall be provided on each client floor and shall have a thermometer accurate to plus or minus two (2) degrees Fahrenheit. In addition, if a refrigerator(s) is in a client room for food storage, the same thermometer requirement applies.

H. Medications, nursing supplies, or biologicals shall not be stored in the dietary department or any refrigerator or storage area utilized by the dietary department.

I. The preparation of meals shall only be conducted in areas of the facility that have been approved by the Department. Extended operations of a facilities meal service program shall not be located in rooms used for other purposes, for example, sleeping, living, laundry.

1602. Food and Food Storage (II)

A. At least a three (3) day supply of staple foods and a two (2) day supply of perishable foods shall be maintained on the premises. Supplies shall be appropriate to meet the requirements of the menu and prescribed special or therapeutic diets.

B. All food in the facility shall be from food sources approved or considered satisfactory by the Department, and shall be clean, wholesome, free from spoilage, free from adulteration and misbranding, and safe for human consumption. Home canned food usage shall be prohibited. (I)

1603. Food Equipment and Utensils (II)

Drinking containers made of porous materials shall not be used unless the containers have smooth liners which can be easily cleaned. These containers and/or liners shall be sanitized at least weekly or

more often as necessary and identified for individual client use. Disposable containers shall be replaced at least weekly.

1604. Meals and Services

A. The dining area shall provide a comfortable and relaxed environment. Table service shall be planned in an attractive and colorful manner for each meal.

B. A minimum of three (3) nutritionally-adequate meals in each twenty-four-hour (24-hour) period shall be provided for each client unless otherwise directed by the client's physician or other legally authorized healthcare provider. Clients shall be allowed to choose between a variety of foods offered. Personal preferences as to the times clients receive their meals may be honored. This may include offering smaller, more frequent meals, or snacks, or postponing meals to honor a client's request, such as, to sleep or not to eat. The condition of the client shall dictate the manner in which meal service is adjusted to suit personal preferences. Meal service systems, such as, four (4) meal plans and/or buffet dining, may be offered in order to facilitate the client receiving a variety of foods. (II)

C. Not more than fourteen (14) hours shall elapse between the scheduled serving of the evening meal and breakfast the following day. (II)

EXCEPTION: There may be up to sixteen (16) hours between the scheduled serving of the evening meal and breakfast the following day if approved by the client's attending physician and the client, and if a nourishing snack is provided after the evening meal.

D. Food shall be cut, chopped, ground or blended to meet individual needs.

E. The same menu items shall not be repetitively served during each seven (7) day period except to honor specific, individual client requests. Substitutes of similar nutritive value shall be offered to clients who refuse food served.

F. Food and snacks shall be available and offered between meals at no additional cost to the clients. Individual client food and snack preferences shall be honored when reasonable. (II)

1605. Meal Service Staff (II)

A. Sufficient staff members shall be available to serve food and to provide individual attention and assistance, as needed.

B. The facility shall maintain trained staff members to supervise the preparation and serving of the proper diet to the clients including having sufficient knowledge of food values in order to make appropriate substitutions when necessary.

C. Clients shall not be permitted to engage in food preparation unless the following criteria are met:

1. The individual program plan of the client has indicated food preparation as suitable and/or beneficial to the client; and

2. The client is directly supervised by staff members, for example, a staff member in the food preparation area with the client.

D. Meal service staff shall have the responsibility of accompanying the food to the floor, when necessary.

1606. Diets (II)

A. All diets shall be prescribed, dated and signed by the physician and be prepared in conformance with physicians' orders giving consideration to individual client preferences.

B. The necessary equipment for preparation of client diets shall be available and utilized.

C. A diet manual published within the previous five (5) years shall be available and shall address at a minimum:

1. Food sources and food quality;

2. Food protection storage, preparation and service;

3. Meal service staff health and cleanliness;

4. Dietary Reference Intakes (DRIs) of the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences food serving recommendations; and

5. Menu planning, including plans appropriate to special needs, such as, diabetic, low-salt, low-cholesterol, or other diets appropriate for clients.

1607. Menus

A. Menus shall be planned and written at a minimum of four (4) weeks in advance and dated as served. The current week's menu, including routine and special diets and any substitutions or changes made, shall be readily available. At least the current day's menu shall be posted in one (1) or more conspicuous places in a public area. All substitutions made on the master menu shall be recorded in writing. Cycled menus shall be rotated so that the same weekly menu is not duplicated for at least a period of two (2) weeks.

B. Each menu shall be approved in writing by a dietitian before meals are prepared and served.

C. A file of tested recipes, adjusted to appropriate yield, shall correspond to items on the posted menus.

1608. Ice and Drinking Water (II)

A. Ice shall be prepared on-site from a water system in accordance with Regulation 61-58, State Primary Drinking Water Regulations, or shall come from a source permitted under Regulation 61-54, Wholesale Commercial Ice Manufacturing. Ice shall be available and precautions taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside the ice container in an inverted self-draining position and allowed to air dry. The ice scoop and holding tray shall be sanitized daily.

B. Potable drinking water shall be available and accessible to clients at all times.

C. The use of common cups shall be prohibited.

D. Ice delivered to client areas in bulk shall be in nonporous, covered containers that shall be cleaned after each use.

E. Drinking fountains of a sanitary angle jet design shall be properly regulated and maintained. There shall be no possibility of the mouth or nose becoming submerged. If drinking fountains are not provided, single service cups shall be used.

SECTION 1700—FIRE PREVENTION

1701. Arrangements for Fire Department Response and Protection (I)

A. A facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, a suitable written plan for actions to be taken in the event of fire and other emergencies. All employees shall be made familiar with these plans and instructed as to required action.

B. A facility shall meet all of the requirements prescribed by the South Carolina State Fire Marshal.

C. Where a facility is located outside of a service area or range of a public fire department, a facility shall make arrangements to have the nearest fire department respond in case of fire. A facility shall keep a copy of the agreement on file in the facility.

1702. Fire Response Training (I)

A. Each employee of the facility shall receive within twenty-four (24) hours of initial client contact and annually thereafter instructions covering:

1. The fire plan;
2. The fire evacuation plan, including routes and procedures;
3. How to report a fire;
4. How to use the fire alarm system;
5. Location and use of fire-fighting equipment;
6. Methods of containing a fire; and
7. Specific responsibilities of the individual.

B. A facility shall maintain records of training including the date, names of participating individuals, and a description of the training.

1703. Fire Drills (I)

- A. A facility shall conduct a fire drill for each shift at least once every three (3) months.
- B. A facility shall maintain records of drills including the date, time, shift, and names of individuals participating, description of the drill, and evaluation.
- C. Fire drills shall be designed and conducted to:
 - 1. Ensure that all personnel are capable of performing assigned tasks or duties;
 - 2. Ensure that all personnel know the location, use, and operation of fire-fighting equipment;
 - 3. Ensure that all personnel are thoroughly familiar with the fire plan; and
 - 4. Evaluate the effectiveness of plans and personnel.

SECTION 1800—DESIGN AND CONSTRUCTION

1801. General (II)

A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each client. Facility design shall be such that all clients have access to required services.

1802. Codes and Standards (II)

A. A facility shall be approved for code compliance by local officials (zoning and building) prior to licensure by the Department.

B. Facility design and construction shall comply with applicable provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

C. Unless specifically required otherwise by the Department, all facilities shall comply with the codes and regulations applicable at the time its license was issued.

D. Any facility that closes, has its license revoked, or surrenders its license and applies for re-licensure at the same site shall be considered a new building and shall meet the current codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for re-licensing.

1803. Submission of Plans (II)

A. Plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina. Unless directed otherwise by the Department, a facility shall submit plans at the schematic, design development, and final stages. All plans shall be drawn to scale. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the Owner shall employ a registered architect and/or engineer for observation. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic inspections throughout each project.

B. Plans and specifications shall be submitted to the Department for new construction and for a project that has an effect on:

- 1. The function of a space;
- 2. The accessibility to or of an area;
- 3. The structural integrity of the facility;
- 4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);
- 5. Doors;
- 6. Walls;
- 7. Ceiling system assemblies;
- 8. Exit corridors;
- 9. Life safety systems; or
- 10. Increases the occupant load or licensed capacity of the facility.

C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, or other, that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.

E. Any construction work which violates codes or standards shall be required to be brought into compliance.

1804. Construction Permits

All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

1805. Client Rooms

A. Facilities with sixteen (16) or more beds shall provide cubicle curtains with built-in curtain tracks in all multiple bed rooms which will shield each client completely. Curtains shall be flameproof.

B. Beds must be placed at least three (3) feet apart. (II)

C. At least one (1) private room shall be provided in each control station area for purposes of medical isolation, incompatibility, personality conflicts, or other.

1806. Control Station

A control station shall serve not more than forty-four (44) beds, unless additional services and facilities are provided. In order to permit a control station to serve more than forty-four (44) beds, a facility shall furnish justification showing how the additional beds served will not adversely affect the healthcare provided to each client.

1807. Utility Rooms

A. Soiled Utility Room. Facilities with sixteen (16) or more beds shall provide at least one (1) soiled utility room per control station which contains a clinical sink, work counter, handwash sink, waste receptacle and soiled linen receptacle.

B. Clean Utility Room. Facilities with sixteen (16) or more beds shall provide at least one (1) clean utility room per control station which contains a counter with a handwash sink and space for the storage and assembly of supplies for nursing procedures.

C. A soiled linen holding, and clean linen holding room shall be provided in facilities with sixteen (16) or more beds.

SECTION 1900—FIRE PROTECTION EQUIPMENT AND SYSTEMS (I)

1901. Fire Alarms and Sprinklers

A. A facility shall include a partial, manual, automatic, and supervised fire alarm system. A facility shall arrange the fire alarm system to transmit an alarm automatically to a third party by an approved method. A facility shall provide a fire alarm system that notifies all occupiable areas and floors of the building by audible and visual alarm. A facility shall provide a fire alarm system that shuts down central recirculating systems and outside air units that serve the area(s) of alarm origination at a minimum.

B. A facility shall include all fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems that connect to the main fire alarm system and triggers the system when activated.

C. A facility shall include a sprinkler system.

D. A facility shall include a fire alarm pull station in or near each control station.

1902. Emergency Generator Service

A. Facilities shall provide certification that construction and installation of the emergency generator service, when provided, complies with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

B. An emergency generator shall deliver emergency electrical service during interruption of the normal electrical service to the distribution system as follows:

1. Exit lights and exit directional signs;
2. Exit access corridor lighting;
3. Lighting of means of egress and staff work areas;

4. Fire detection and alarm systems;
5. Client care areas;
6. Signal system;
7. Equipment necessary for maintaining telephone service and all life safety systems;
8. Elevator service that will reach every client floor where rooms are located other than the ground floor;
9. Fire pump;
10. Equipment for heating client rooms;
11. Public restrooms;
12. Essential mechanical equipment rooms;
13. Battery-operated lighting and a receptacle in the vicinity of the emergency generator;
14. Alarm systems, water flow alarm devices, and alarms required for medical gas systems; and
15. Client records when solely electronically based.

SECTION 2000—PREVENTATIVE MAINTENANCE

A facility shall keep the structure, component parts, amenities and equipment in good repair and operating condition. Repairs and the replacement of component parts, including repairs to equipment requiring routine testing, shall be documented and retained by the facility. A facility shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

SECTION 2100—EQUIPMENT AND SYSTEMS

2101. Gases (I)

A. Gases, flammable and nonflammable, shall be handled and stored in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

B. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place in an upright position. In "Smoke-Free" facilities, "No Smoking" signs shall not be required in, and in the vicinity of, client rooms where oxygen is being administered provided all four (4) of the following conditions are met:

1. Smoking is prohibited;
2. The facility's nonsmoking policy is strictly enforced;
3. "Smoke-Free" signs are strategically placed at all major entrances; and
4. The facility has "No Smoking" signs in, and in the vicinity of, client rooms where oxygen is stored as well as all other required areas.

2102. Furnishings and Equipment (I)

A. A facility shall maintain the physical plant free of fire hazards or impediments to fire prevention.

B. A facility shall not permit portable electric or unvented fuel heaters.

C. Fireplaces and fossil-fuel stoves, or wood-burning, shall have partitions or screens or other means to prevent burns. Fireplaces shall be vented to the outside. A facility shall not use unvented gas logs. Gas fireplaces shall have a remote gas shutoff within the room and not inside the fireplace.

D. A facility shall require all wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows to be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant.

SECTION 2200—WATER SUPPLY, HYGIENE, AND TEMPERATURE CONTROL (II)

A. Plumbing fixtures that require hot water and which are accessible to clients shall be supplied with water that is thermostatically controlled to a temperature of at least one hundred (100) degrees Fahrenheit and not to exceed one hundred twenty (120) degrees Fahrenheit at the fixture.

B. The water heater or combination of heaters shall be sized to provide at least six (6) gallons per hour per licensed bed at the temperature range indicated in Section 2200.A.

C. Hot water supplied to the kitchen equipment and utensil washing sink shall be supplied as required by R.61-25.

D. Hot water provided for washing linen shall not be less than one hundred sixty (160) degrees Fahrenheit. Should chlorine additives or other chemicals which contribute to the margin of safety in disinfecting linen be a part of the washing cycle, the minimum hot water temperature shall not be less than one hundred ten (110) degrees Fahrenheit, provided hot air drying is used.

SECTION 2300—ELECTRICAL

2301. General (I)

A facility shall maintain all electrical installations and equipment in a safe, operable condition in accordance with the applicable codes and shall be inspected at least annually by a licensed electrician, registered engineer, or certified electrical inspector.

2302. Panelboards (II)

A facility shall label the panelboard directory to conform to the room numbers and/or designations.

2303. Lighting

A. A facility shall provide adequate lighting in spaces occupied by persons, machinery, and equipment within buildings, approaches to buildings, and parking lots. (II)

B. A facility shall provide adequate artificial light and sufficient illumination for reading, observation, and activities. A facility shall provide general lighting in all parts of every client room and at least one (1) light fixture for night lighting in every client room. A facility shall provide a reading light for each client.

C. A facility shall provide switched lighting in all client sleeping rooms. Switches shall be located at the client sleeping room door.

D. A facility shall provide lighting in hallways, stairs, and other means of egress at all times.

2304. Receptacles (II)

A. A facility shall provide duplex grounding type receptacles in each client room with one (1) duplex receptacle at the head of each bed in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

B. Each client bed location shall have a minimum of two (2) duplex receptacles.

C. Each client bed location shall be supplied by at least two (2) branch circuits.

D. Duplex receptacles for general use shall be installed approximately fifty (50) feet apart in all corridors and within twenty-five (25) feet of the ends of corridors.

2305. Ground Fault Protection (I)

A. A facility shall have ground fault circuit-interrupter protection for all outside receptacles and bathrooms.

B. A facility shall have ground fault circuit-interrupter protection for any receptacle within six (6) feet of a sink or any other wet location. If the sink is an integral part of the metal splashboard grounded by the sink, the entire metal area is considered part of the wet location.

2306. Exit Signs (I)

A. A facility shall identify all required exits and ways to access thereto with electronically-illuminated exit signs bearing the word "Exit" in red letters.

B. A facility shall mark changes in egress direction with exit signs with directional arrows.

C. A facility shall maintain exit signs in corridors that indicate two (2) directions of exit, where appropriate.

SECTION 2400—HEATING, VENTILATION, AND AIR CONDITIONING (HVAC) (II)

A. A facility shall not install a HVAC supply or return grille within three (3) feet of a smoke detector. (I)

- B. A facility shall not install HVAC grilles in floors.
- C. Return air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. The system shall not discharge in a manner that would be an irritant to clients, staff, or visitors.
- D. A facility shall have each shower, bath, and restroom with either operable windows or have approved mechanical ventilation.

SECTION 2500—GENERAL CONSTRUCTION REQUIREMENTS

2501. Common Areas (II)

- A. A facility shall provide a minimum of thirty (30) square feet per bed of living, recreational, and dining area combined, excluding bedrooms, halls, kitchens, bathrooms, and rooms not available to clients.
- B. A facility shall provide all required care, treatment, and services in a manner that does not require clients to ambulate from one site to another outside the building(s), nor impedes clients from ambulating from one site to another due to the presence of physical barriers.
- C. A facility shall ensure methods of visual and auditory privacy between client and staff, volunteers, or visitors.
- D. A facility shall provide physical space for private client, family, and/or responsible party visiting.
- E. A facility shall provide accommodations for family privacy after a client's death.

2502. Client Rooms

A. With the exception of furniture (unless otherwise allowed by facility policy), a client shall have the choice of bringing familiar items from home as part of the furnishing to his or her room, such as, wall pictures, paintings, vases, or other. Each client room shall be equipped with the following as a minimum for each client:

- 1. A comfortable single bed having a mattress with moisture-proof cover, sheets, blankets, bedspread, pillow, and pillowcases. Roll-away type beds, cots, bunkbeds, and folding beds shall not be used. It is permissible to utilize a recliner in lieu of a bed or remove a client bed and place the mattress on a platform or pallet provided the physician or other authorized healthcare provider has approved it and the decision is documented in the plan of care. (II)

EXCEPTION: In the case of a married couple sharing the same room, a double bed is permitted if requested. For all other requirements, this shall be considered a bedroom with two (2) licensed beds. A roll-away type bed or cot may be temporarily used for family or responsible party staying overnight with the client.

- 2. A facility shall provide a closet or wardrobe, a bureau consisting of at least three (3) drawers, and a compartmentalized bedside table or nightstand to adequately accommodate each client's personal clothing, belongings, and toilet articles. Built-in storage is permitted.
 - 3. A comfortable chair shall be available for each client occupying the room. In facilities licensed prior to the promulgation of this regulation, if the available square footage of the client room will not accommodate a chair for each client or if the provision of multiple chairs impedes client ability to freely and safely move about within their room, the facility shall provide at least one (1) chair and have additional chairs available for temporary use in the client's room by visitors.
- B. If hospital-type beds are used, there shall be at least two (2) lockable casters on each bed, located either diagonally or on the same side of the bed.
 - C. Beds shall not be placed in corridors, solaria, or other locations not designated as client room areas. (I)
 - D. No client room shall contain more than two (2) licensed beds. (II)
 - E. No client room shall be located in a basement.
 - F. Access to a client room shall not be by way of another client room, toilet, bathroom, or kitchen.
 - G. A facility shall provide equipment such as bedpans, urinals, and hot water bottles, necessary to meet client needs. Permanent positioning of a portable commode at bedside shall only be permitted if

the room is private, the commode is maintained in a sanitary condition, and the room is of sufficient size to accommodate the commode. (II)

H. Side rails may be utilized when required for safety and when ordered by a physician or other authorized healthcare provider. When there are special concerns, such as, clients with Alzheimer's disease and/or related dementia, side rail usage shall be monitored by staff members as per facility policies and procedures. (I)

I. In semi-private rooms, when personal care is being provided, arrangements shall be made to ensure privacy in accordance with Section 1805.A.

J. A facility shall provide at least one (1) private room for assistance in addressing client compatibility issues, client preferences, and accommodations for clients with communicable disease.

K. Infants and small children shall not be assigned to a room with an adult client unless requested by clients and families.

2503. Client Room Floor Area

A. Each client room shall have an outside window. This window shall not open onto a common area screened porch. (I)

B. The client room floor area is a usable or net area and does not include wardrobes (built-in or freestanding), closets, or the entry alcove to the room. The following is the minimum floor space allowed: (II)

1. Rooms for only one (1) client: at least eighty (80) square feet for the licensed bed (there shall be compliance with the minimum square footage requirements of Section 2503.B.2 in instances when family members or responsible party routinely utilize a separate bed for overnight stays with the client);

2. Rooms for more than one (1) client: at least sixty (60) square feet per licensed bed.

C. There shall be at least three (3) feet between beds. (II)

2504. Visitor Accommodations

A. If provided, visitor designated or guest rooms shall not be utilized by clients, prospective clients, or staff members of the facility.

B. No supervisory care shall be given to visitors of the facility, for example, first aid response by staff, tray service, or other supervisory care.

C. Visitors shall be made aware of those provisions and accommodations available so that they may serve themselves, such as, towels, sheets, soap, or other provisions.

D. Any conduct of the visitors which may have an adverse effect on the clients or facility must be promptly and prudently handled, such as client or staff abuse.

E. Those visiting, as well as the clients with whom they are visiting, shall be made fully aware of the conditions under which their stay is acceptable.

F. A facility shall provide adequate space of privacy for the family and significant others at the time of a client's death.

2505. Baths and Restrooms (II)

A. A facility shall have an appropriate number of restrooms to accommodate clients, staff, and visitors. A facility shall have one (1) toilet for each four (4) licensed beds or a fraction thereof and one (1) bathtub or shower for each twelve (12) licensed beds or a fraction thereof.

B. A facility shall have accessible restrooms during all operating hours.

C. A facility shall equip all restrooms with at least one (1) toilet fixture, toilet paper installed in a holder, a lavatory supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle. A facility shall provide soap, bath towels, and washcloths to each client as needed. A facility shall not store bath linens assigned to specific clients in centrally located restrooms.

D. A facility shall have approved grab bars securely fastened on at least one (1) side of all toilet fixtures used by clients.

E. A facility shall provide privacy at toilet fixtures and urinals.

F. A facility shall provide restrooms for persons with disabilities in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

G. A facility shall completely cover all restroom floors with an approved, nonabsorbent covering. A facility shall have restroom walls with nonabsorbent, washable surfaces to the highest level of splash.

2506. Control Stations

A. A facility shall provide control stations for nursing and/or other direct care staff. A facility shall design and construct (or set up) control stations in a manner conducive to the type of care provided by the facility or that specific area of the facility and the types of clients served.

B. At or near each control station, there shall be a telephone, an area for maintaining client records and making entries, and a toilet and handwashing sink.

C. At or near each control station, a facility shall make provisions for the following:

1. Secured storage of medications, which may be accomplished by the use of a separately secured medication cart, container, cabinet, or room, provided:

a. The method or methods used are of sufficient size to allow for neat, clean, and orderly storage of medications;

b. Separations are provided for the storage of each client's medications; and

c. Separations are provided for oral and topical medications.

2. Work space or area for the preparation of medications, which may be a counter, table top, or a separate room, to include being a part of a separate medication room.

D. A facility shall not allow a control station to serve more than forty-four (44) beds.

E. A facility shall not have any client room located more than 150 feet from the control station serving that client room.

F. A facility shall have utility areas or rooms for separate storage of clean and soiled supplies and equipment at or near each control station. A facility shall require each utility area to contain a handwashing sink, work counter, waste receptacle, and space for the storage of supplies.

2507. Doors (II)

A. A facility shall have opaque doors on restrooms for the purpose of privacy.

B. A facility shall require all glass doors, including sliding or patio type doors, to have a contrasting or other indicator that causes the glass to be observable, for example, a decal located at eye level.

C. Doors that have locks shall be unlockable and openable with one action.

D. A facility shall have provisions for emergency entry if client room doors are lockable.

E. Any locked room door in the facility shall have the ability to unlock and open from inside the room.

2508. Elevators (II)

A facility shall have elevators inspected and tested upon installation, prior to first use, and annually thereafter by a certified elevator inspector.

2509. Handrails and Guardrails (II)

A. A facility shall provide handrails on at least one (1) side of each corridor.

B. A facility shall provide guardrails forty-two (42) inches high on all porches, walkways, and recreational areas (such as decks and the like) elevated thirty (30) inches or more above grade in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

2510. Janitor's Closet (II)

A facility shall have at least one (1) lockable janitor's closet per forty-four (44) licensed beds. Facilities having multiple housing units shall have at least one (1) lockable janitor's closet per each housing unit. A facility shall equip each closet with a mop sink or receptor and space for the storage of supplies and equipment.

2511. Storage Areas

A. A facility shall provide adequate general storage areas for client, staff, and volunteer belongings and equipment. A facility shall provide at least ten (10) square feet of general storage per bed throughout the facility.

B. A facility shall provide separate storage for beds, wheel chairs, and other equipment.

C. A facility shall not store supplies and equipment directly on the floor. A facility shall not store supplies and equipment susceptible to water damage or contamination under sinks or other areas with a propensity for water leakage. (II)

2512. Telephone Service

A. A facility shall make at least one (1) telephone available and easily accessible on each floor of the facility for use by clients and/or visitors for their private, discretionary use. Telephones shall be portable to accommodate bedridden or ambulatory-impaired clients. Telephones capable of only local calls are acceptable for this purpose, provided other arrangements exist to provide client and visitor discretionary access to a telephone capable of long-distance service.

B. A facility shall provide at least one (1) telephone on each floor for staff members and volunteers to conduct routine business of the facility and to summon assistance in the event of an emergency.

2513. Location

A. Transportation. A facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. A facility shall have a parking area to reasonably satisfy the needs of clients, staff members, volunteers, and visitors.

C. Access to firefighting equipment. A facility shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

2514. Outdoor Area

A. A facility shall enclose all unsafe, unprotected physically hazardous outdoor areas with a fence or natural barrier the size, shape, and density to effectively impede travel to the hazardous area. The outdoor hazardous areas of a facility include, but are not limited to, steep grades, cliffs, open pits, high voltage electrical equipment, high speed or heavily traveled roads, roads exceeding two (2) lanes excluding turn lanes, ponds, and swimming pools. (I)

B. A facility shall have a gate in any fence required as part of a fire exit from the building and the gate in the fence shall unlock in case of emergency in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal. (I)

C. A facility shall protect mechanical or equipment rooms open to the outside of the facility from unauthorized individuals. (II)

SECTION 2600—SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2700—GENERAL

Conditions which have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Amended by State Register Volume 16, Issue No. 3, eff March 27, 1992; State Register Volume 34, Issue No. 6, eff June 25, 2010; State Register Volume 40, Issue No. 5, Doc. No. 4564, eff May 27, 2016; State Register Volume 40, Issue No. 6, Doc. No. 4564, eff June 24, 2016 (errata).

Code Commissioner's Note

Pursuant to 2011 Act No. 47, § 14(B), the Code Commissioner substituted "intellectual disability" for "mental retardation" and "person with intellectual disability" or "persons with intellectual disability" for "mentally retarded".

61-15. CERTIFICATION OF NEED FOR HEALTH FACILITIES AND SERVICES.

(Statutory Authority: 1976 Code §§ 44-7-110 through 44-7-340)

Editor's Note

The following constitutes the history for 61-15, 101 through 802.

HISTORY: Amended by State Register Volume 17, Issue No. 6, eff June 25, 1993; State Register Volume 27, Issue No. 6, Part 1, eff June 27, 2003.

Executive Order No. 2020-11 (SCSR 44-4 EO 2020-11), effective March 19, 2020, relating to additional emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order No. 2020-50 (SCSR 44-8 EO 2020-50), effective August 2, 2020, extended by Executive Order No. 2020-53 (SCSR 44-8 EO 2020-53), effective August 10, 2020, Executive Order No. 2020-56 (SCSR 44-9 EO 2020-56), effective August 25, 2020, Executive Order No. 2020-59 (SCSR 44-9 EO 2020-59), effective September 9, 2020, and Executive Order No. 2020-62 (SCSR 44-10 EO 2020-62), effective September 24, 2020, relating to additional emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order No. 2020-63 (SCSR 44-10 EO 2020-63), effective October 2, 2020, extended by Executive Order No. 2020-65 (SCSR 44-10 EO 2020-65), effective October 9, 2020, Executive Order No. 2020-67 (SCSR 44-11 EO 2020-67), effective October 24, 2020, Executive Order No. 2020-70 (SCSR 44-11 EO 2020-70), effective November 8, 2020, and Executive Order No. 2020-72 (SCSR 44-12 EO 2020-72), effective November 23, 2020, relating to additional emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order No. 2020-73 (SCSR 44-12 EO 2020-73), effective November 25, 2020, extended by Executive Order No. 2020-75 (SCSR 44-12 EO 2020-75), effective December 8, 2020, Executive Order 2020-77 (SCSR 45-1 EO 2020-77), effective December 20, 2020, Executive Order 2021-03 (SCSR 45-1 EO 2021-03), effective January 7, 2021, Executive Order 2021-07 (SCSR 45-2 EO 2021-07), effective January 22, 2021, Executive Order 2021-08 (SCSR 45-2 EO 2021-08), effective February 6, 2021, and Executive Order 2021-10 (SCSR 45-3 EO 2021-10), effective February 21, 2021, relating to modifying amending emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order 2021-11 (SCSR 45-3 EO 2021-11), effective March 1, 2021, relating to modifying amending emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order 2021-12 (SCSR 45-3 EO 2021-12), effective March 5, 2021, extended by Executive Order No. 2021-13 (SCSR 45-3 EO 2021-13), effective March 8, 2021, Executive Order No. 2021-15 (SCSR 45-4 EO 2021-15), effective March 23, 2021, Executive Order No. 2021-18 (SCSR 45-4 EO 2021-18), effective April 7, 2021, Executive Order No. 2021-20 (SCSR 45-5 EO 2021-20), effective April 22, 2021, and Executive Order No. 2021-22 (SCSR 45-5 EO 2021-22), effective May 7, 2021, relating to modifying amending emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order 2021–23 (SCSR 45–5 EO 2021–23), effective May 11, 2021, extended by Executive Order 2021–25 (SCSR 45–6 EO 2021–25), effective May 22, 2021, relating to modifying amending emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61–15 and 61–16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

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PART A QUESTIONNAIRE—APPLICATION

CHAPTER 1 PURPOSE, APPLICABILITY AND DEFINITIONS

SECTION 101. Purpose

The purpose of these Regulations is to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State.

SECTION 102. Applicability.

1. A person or health care facility as defined in this Regulation is required to obtain a Certificate of Need from the Department of Health and Environmental Control before undertaking any of the following:

- a. The construction or other establishment of a new health care facility;
- b. A change in the existing bed complement of a health care facility through the addition of one or more beds or change in the classification of licensure of one or more beds;
- c. An expenditure by or on behalf of a health care facility in excess of two million dollars (\$2,000,000) which, under generally acceptable accounting principles consistently applied, is considered a capital expenditure except those expenditures exempted in Section 104. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the development, acquisition, improvement, expansion, or replacement of any plant or equipment must be included in determining if the expenditure exceeds the prescribed amount;
- d. capital expenditure by or on behalf of a health care facility which is associated with the addition or substantial expansion of a health service for which specific standards or criteria are prescribed in the South Carolina Health Plan;
- e. If no capital expenditure is made, the offering of any health service by or on behalf of a health care facility which has not been offered by the facility in the preceding twelve months and for which specific standards or criteria are prescribed in the South Carolina Health Plan. For purposes of this section, operating costs include expenditures incurred by the health care facility and any person or other entity on behalf of the health care facility to establish a new service. A person or other entity shall not be allowed to incur costs thereby attempting to enable a health care facility to avoid Certificate of Need review and establish a new service as described above;
- f. The acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of six hundred thousand dollars (\$600,000);

2. An applicant may not split or combine one expenditure into two or more expenditures for the purpose of avoiding Certificate of Need review, nor may the Department be allowed to lump projects together arbitrarily to bring them under Certificate of Need review.

3. When any question exists, a potential applicant shall forward a letter requesting a formal determination by the Department as to the applicability of the Certificate of Need requirements to a particular project. Such a letter shall contain a detailed description of the project including the extent of modifications, changes in services and total costs. Additional information may be requested as may be reasonably necessary to make such applicability determination. The Department shall respond within sixty (60) calendar days of receipt of the necessary information.

4. These provisions do not apply to acquisitions or changes of ownership of health care facilities, services, and equipment that are already in existence, operational, and providing services in a particular service area, and which have undergone the review and obtained the approval that was appropriate under the law at the time they first entered the relevant service area, so long as the facility or service is not being relocated. For facilities, services, and equipment which have previously undergone Certificate of Need review, the Certificate of Need must be fulfilled prior to a change of ownership.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

Editor's Note

Executive Order No. 2020-11 (SCSR 44-4 EO 2020-11), effective March 19, 2020, relating to additional emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend the monetary thresholds set forth in Section 102 of Regulation 61-15 for items requiring Certificate of Need Review, to the extent necessary and applicable, so as to permit healthcare facilities to make those capital expenditures and acquire medical equipment deemed necessary to prevent, diagnose, treat, or monitor the progression of COVID-19.

Executive Order No. 2020-50 (SCSR 44-8 EO 2020-50), effective August 2, 2020, extended by Executive Order No. 2020-53 (SCSR 44-8 EO 2020-53), effective August 10, 2020, Executive Order No. 2020-56 (SCSR 44-9 EO 2020-56), effective August 25, 2020, Executive Order No. 2020-59 (SCSR 44-9 EO 2020-59), effective September 9, 2020, and Executive Order No. 2020-62 (SCSR 44-10 EO 2020-62), effective September 24, 2020, relating to additional emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend the monetary thresholds set forth in Section 102 of Regulation 61-15 for items requiring Certificate of Need Review, to the extent necessary and applicable, so as to permit healthcare facilities to make those capital expenditures and acquire medical equipment deemed necessary to prevent, diagnose, treat, or monitor the progression of COVID-19.

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SECTION 103. Definitions.

1. Affected person means the applicant, a person residing within the geographic area served or to be served by the applicant, persons located in the health service area in which the project is to be located and who provide similar services to the proposed project, persons who before receipt by the Department of the proposal being reviewed have formally indicated an intention to provide similar services in the future, persons who pay for health services in the health service area in which the project is to be located and who have notified the Department in writing of their interest in Certificate of Need applications, the State Consumer Advocate and the State Ombudsman. Persons from another state who would otherwise be considered "affected persons" are not included unless that state provides for similar involvement of persons from South Carolina in its Certificate of Need process. A person may not file a request for final review in opposition to the staff decision on a Certificate of Need unless the person provided written notice to the Department during the staff review that he is an affected person and specifically states his opposition to the application under review. Affected persons may request in writing to be notified of a Department decision by regular mail or electronic mail in lieu of certified mail.

2. Ambulatory surgical facility means a distinct, free-standing, self-contained entity that is organized, administered, equipped and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures and/or services for which patients are scheduled to arrive, receive surgery or related care, treatment, procedures and/or services and be discharged on the same day. The owner or operator makes the facility available to other providers who comprise an organized professional staff.

3. Arrangement for financing means a financial commitment, i.e. enforceable contract.

4. Board means the State Board of Health and Environmental Control.

5. Children and adolescents in need of mental health treatment in a residential treatment facility means a child or adolescent under age eighteen who manifests a substantial disorder of cognitive or emotional process, which lessens or impairs to a marked degree that child's capacity either to develop or to exercise age-appropriate or age-adequate behavior. The behavior includes, but is not limited to, marked disorders of mood or thought processes, severe difficulties with self-control and judgment including behavior dangerous to self or other, and serious disturbance in the ability to care for and relate to others.

6. Competing applicants means two or more persons and/or health care facilities as defined in this regulation who apply for Certificates of Need to provide similar services and/or facilities in the same service area and whose applications if approved would exceed the need for this facility or service. An application shall be considered competing if it is received by the Department no later than fifteen (15) calendar days after a Notice of Affected Persons is published in the State Register for one or more applications for similar services and/or facilities in the same service area. All applications received by the Department within fifteen (15) days of publication of the Notice of Affected Persons in the State Register for the first application(s) will be considered to be competing. Any applications received by the Department later than the fifteenth day following publication of the Notice of Affected Persons in the State Register for the first application(s) will not be considered to be competing with the(se) application(s).

7. Department means the Department of Health and Environmental Control.

8. Facility for chemically dependent or addicted persons means a facility organized to provide outpatient or residential services to chemically dependent or addicted persons and their families based on an individual treatment plan including diagnostic treatment, individual and group counseling, family therapy, vocational and educational development counseling, and referral services.

9. Fees mean the Department may charge and collect fees to cover the cost of operating the program. The fees for review of certificate of need projects include: (a) initial filing fee; (b) application fee; and (c) issuance fee.

a. Initial filing fee is five hundred dollars (\$500), which must be submitted as a non-refundable initial payment at the time the application is submitted.

b. Application fee is one half of one percent (.5%, .005) of the total project cost (as defined in Section 103.25) which is payable when the application is deemed complete under Section 303. The application fee shall not exceed seven thousand dollars (\$7,000).

c. Issuance fee is seven thousand five hundred dollars (\$7,500) payable upon the granting of a Certificate of Need to any project whose total project cost (as defined in Section 103.25) is greater than one million four hundred thousand dollars (\$1,400,000). Should the project not be approved, the issuance fee will not be assessed.

10. Freestanding or Mobile technology means medical equipment owned or operated by a person other than a health care facility for which the total cost is in excess of that prescribed in these regulations and for which specific standards or criteria are prescribed in the South Carolina Health Plan.

11. Good cause is defined as:

a. presentation of significant and relevant information not previously considered by the Department;

b. demonstration that there have been significant changes in factors or circumstances relied upon by the Department in reaching its decision;

c. demonstration that the Department has materially failed to follow its adopted procedures in reaching its decision; or

d. such other basis for a public hearing as the Department determines constitutes good cause.

12. Health care facility for the purposes of Certificate of Need means acute care hospitals, psychiatric hospitals, alcohol and substance abuse hospitals, nursing homes, ambulatory surgical facilities, rehabilitation facilities, residential treatment facilities for children and adolescents, intermediate care for the persons with intellectual disability, inpatient hospice facilities, radiation therapy facilities and any other facility for which Certificate of Need review is required by state law.

13. Health service means clinically related, diagnostic, treatment, or rehabilitative services, and includes alcohol, drug abuse, and mental health services for which specific standards or criteria are prescribed in the South Carolina Health Plan.

14. Hospital means a facility organized and administered to provide services to accommodate two or more non-related persons for the diagnosis, treatment and care of such persons over a period exceeding 24 hours and provides medical or surgical care or nursing care of illness, injury, or infirmity and may provide obstetrical care, and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.

15. Institutional health services means health services provided in or through health care facilities and includes the entities in or through which such services are provided.

16. Like equipment with similar capabilities means medical equipment in which functional and technological capabilities are identical to the equipment to be replaced; and the replacement equipment is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use; and does not constitute a material change in service or a new service.

17. Nursing home means a facility with an organized nursing staff to maintain and operate organized facilities and services to accommodate two or more unrelated persons over a period exceeding twenty-four hours which is operated either in connection with a hospital or as a freestanding facility for the express or implied purpose of providing nursing care for persons who are not in need of hospital care.

18. Person means an individual, a trust or estate, a partnership, a corporation including an association, joint stock company, insurance company, and a health maintenance organization, health care facility, a state, a political subdivision or an instrumentality including a municipal corporation of a state, or any legal entity recognized by the State.

19. Psychiatric Hospital means an institution which is primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.

20. Residential treatment facility for children and adolescents means a facility operated for the assessment, diagnosis, treatment, and care of two or more “children and adolescents in need of mental health treatment” which provides:

- a. a special education program with a minimum program defined by the South Carolina Department of Education.
- b. recreational facilities with an organized youth development program; and
- c. residential treatment for a child or adolescent in need of mental health treatment.

21. Solely for research means a service, procedure, or equipment which has not been approved by the Food and Drug Administration (FDA) but which is currently undergoing review by the FDA as an investigational device. FDA research protocol and any applicable Investigational Device Exemption (IDE) policies and regulations must be followed by a facility proposing a project ‘solely for research.’

22. To develop when used in connection with health services, means to undertake those activities which on their completion will result in the offering of a new institutional health services or the incurring of a financial obligation in relation to the offering of such a service.

23. To offer when used in connection with health services means that the health care facility holds itself out as capable of providing or as having the means for the provision of, specified health services.

24. Total project cost is the estimated total capital cost of a project including land cost, construction, fixed and moveable equipment, architect’s fee, financing cost, and other capital costs properly charged under generally accepted accounting principals as a capital cost. The determination of project costs involving leased equipment of buildings will be calculated based on the total value (purchase price) of the equipment or building being leased.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

Code Commissioner’s Note

Pursuant to 2011 Act No. 47, § 14(B), the Code Commissioner substituted “intellectual disability” for “mental retardation” and “person with intellectual disability” or “persons with intellectual disability” for “mentally retarded”.

SECTION 104. Exemption Determinations.

1. The following are exempt from Certificate of Need review, but prior to undertaking these projects, a written determination from the Department is required:

- a. The replacement of like equipment for which a Certificate of Need has been issued and the replacement does not result in a material change in service or a new service.
- b. The acquisition by a health care facility of medical equipment to be used solely for research, the offering of an institutional health service by a health care facility solely for research, or the obligation of a capital expenditure by a health care facility to be made solely for research if it does not: (a) affect the charges of the facility for the provision of medical or other patient care services other than the services which are included in the research; (b) change the bed capacity of the facility; or (c) substantially change the medical or other patient care service of the facility. FDA research protocol and any applicable Investigational Device Exemption (IDE) policies and regulations must be followed by the facility. A written description of the proposed research project must be submitted to the department in order for the department to determine if the above conditions are met. A Certificate of Need is required to continue use of the equipment or service after the equipment or service is no longer being used solely for research;
- c. The permanent reduction in bed capacity, including the permanent closure of a health care facility.

2. In order to request an exemption, the following information must be provided to the Department in writing at a minimum:

- a. A complete description of the proposed project, including, but not limited to, location of the project, and total project costs,
- b. Other documentation requested by the Department in order to determine compliance with these regulations;
- c. Additional information as may be reasonably necessary for the Department to make a determination.

3. If an exemption is granted, it is valid for a period of twelve (12) months from the date of issuance. If the proposal is not implemented within this twelve-month period, the exemption becomes void and another exemption must be requested in order for the applicant to undertake the proposal.

4. The following projects are exempt from Certificate of Need review but do not require a written determination from the Department: the offices of a licensed private practitioner whether for individual or group practice. This exemption shall not apply to: (1) the construction or other establishment of a new health care facility, as in Section 102.1.a; or (2) the acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of six hundred thousand dollars (\$600,000), as in Section 102.1.f.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 105. Determinations of Non-Applicability.

1. Certificate of Need review is not applicable to the following, but prior to undertaking the proposed project, a written determination of non-applicability from the Department is required:

a. Replacement of like equipment with similar capabilities as defined by the Department in Section 103.16.

b. Acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is not in excess of six hundred thousand dollars (\$600,000). A written determination of non-applicability is only required when any question exists as to whether or not the total project cost is below the six hundred thousand dollars (\$600,000) threshold.

2. The following information must be provided to the Department in writing at a minimum:

a. A complete description of the proposed project, including, but not limited to, location of the project, total project costs, capital and/or operational cost;

b. Other documentation requested by the Department in order to determine compliance with these regulations;

c. Additional information as may be reasonably necessary to make a determination.

3. If a determination of non-applicability is granted, it is valid for a period of twelve (12) months from the date of issuance. If the proposal is not implemented within this twelve (12) month period, the non-applicability determination becomes void and another determination must be requested in order to undertake the proposal.

4. Certificate of Need review is not applicable to the following projects and a written non-applicability determination from the Department is not required prior to undertaking these projects:

a. Health care facilities owned and operated by the federal government;

b. Any federal health care facility sponsored and operated by this State;

c. Educational and penal institutions maintaining infirmaries for the exclusive use of their respective student bodies and inmate populations;

d. Facilities owned and operated by the South Carolina Department of Mental Health and the South Carolina Department of Disabilities and Special Needs, except an addition of one or more beds to the total number of beds of the departments' health care facilities existing on July 1, 1988;

5. Certificate of Need review is not applicable to the following projects and a written non-applicability determination from the Department is not required. However, written notification shall be provided to DHEC Division of Health Facilities Construction prior to undertaking the following projects:

a. An expenditure by or on behalf of a health care facility for non-medical projects, such as refinancing existing debt, parking garages, laundries, roof replacement, computer systems, telephone systems, and heating and air conditioning systems;

b. The upgrading of medical facilities, which do not involve additional square feet to the facility or additional health services;

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 106. South Carolina Health Plan.

1. With the advice of the health planning committee, the Department shall prepare a South Carolina Health Plan for use in the administration of the Certificate of Need Program. The plan at a minimum must include:

- a. an inventory of existing health care facilities, beds, specified health services, and equipment.
- b. projections of need for additional health care facilities, beds, health services, and equipment;
- c. standards for distribution of health care facilities, beds, specified health services, and equipment including scope of services to be provided, utilization, and occupancy rates, travel time, regionalization, other factors relating to proper placement of service, and proper planning of health care facilities; and
- d. a general statement as to the project review criteria considered most important in evaluating Certificate of Need applications for each type of facility, service and equipment, including a finding as to whether the benefits of improved accessibility to each such type of facility, service and equipment, may outweigh the adverse affects caused by the duplication of any existing facility, service or equipment.

2. The South Carolina Health Plan must address and include projections and standards for specified health services and equipment which have a potential to substantially impact health care cost and accessibility. Nothing in this provision shall be construed as requiring the Department to approve any project which is inconsistent with the South Carolina Health Plan.

3. Upon approval by the health planning committee, the South Carolina Health Plan must be submitted at least once every two years to the Board for final revision and adoption. Once adopted by the Board, the Plan may later be revised through the same planning and approval process, public review and comment, including four regional public hearings before adoption or revision of the Plan. Prior to revising the plan, the Department will publish a notice in the State Register, announcing a period for public comments and scheduling public hearings to receive public comments.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

CHAPTER 2 APPLICATION PROCEDURES

SECTION 201. Public Notification

Within twenty days prior to submission of an application, the applicant shall publish notification that an application is to be submitted to the Department in the legal section of a daily newspaper serving the area where the project is to be located for three consecutive days. The notification must contain at least the following information: 1) that a Certificate of Need is being applied for; 2) a description of the scope and nature of the project; and 3) the estimated project capital cost. No application may be accepted for filing by the department unless accompanied by documentation from the newspaper that publication has been made for three consecutive days within the prior twenty day period.

SECTION 202. Application.

1. Two copies of the application shall be forwarded to the Department in the following format and shall contain the following information as applicable. The application will be on 8 ½ × 11-inch paper, one side only, and 3-hole punched on the left side.

2. Application

- a. Proposal Page and Part A. Questionnaire (See Appendix)
- b. Part B. Additional Information

(1) Document that the applicant has published notification of this project in a local newspaper as required by Section 201 of these Regulations.

(2) Describe the project setting forth the proposed change in services or facilities in as much detail as possible. State whether the project will change the existing licensed or survey bed capacity, will encompass the development of a new service, or result in the discontinuance of an existing service. If a new facility is proposed, list all services to be provided.

(3) Provide the total cost of the project, indicating design fees, land cost, interest cost, construction cost, equipment cost, and any other cost involved in the project. Provide an estimate of the construction cost from a licensed architect or engineer; in the case of equipment, valid/current estimate from a vendor is acceptable.

(4) State the specific location of the facility or service and/or equipment, including, where applicable, specific areas of an existing facility to be affected by the project. Provide room numbers of all patient rooms affected. Sufficient detail should be provided to allow the Department to visually inspect the site. The number of private and semi-private patient rooms shall be identified.

(5) Provide details regarding any proposed construction and/or renovations. Discuss alternatives to new construction and why these alternatives were rejected. For a multi-floor project, construction and/or renovation must be described, by floor, to include any additions and/or deletions made to each floor. Provide evidence that the applicant has adequately planned for any temporary move or relocation of any department, facility, or services, which may be necessary during the construction period. Document that plans exist to assure adequate protection (from fire, noise, dust, etc.) and continuation of all services during the proposed construction period.

(6) If a replacement facility or ancillary service is being constructed, describe plans for disposition of the existing facility or ancillary service area upon completion of the project.

(7) Provide a timetable for development and completion of the project to include, at a minimum, the date of site acquisition, date of architectural contract, architectural design schedule, date of closing for financing, date of valid construction contract, date that all necessary permits (grading, building, sewer, etc.) will be obtained, and date of start of construction. The timetable shall be presented in one month increments commencing with the month following receipt of the Certificate of Need and ending with the execution of a contract or purchase order for equipment only projects.

(8) Provide the following ownership information:

(a) Proposed name of facility;

(b) Name and address of licensee or prospective licensee. (Note: The licensee is defined as the legal entity who, or whose governing body, has the ultimate responsibility and authority for the conduct of the facility or service; the owner of the business. The licensee must be the entity to whom the Certificate of Need is issued.)

(c) Complete title of the licensee's governing body.

(d) Name, title and mailing address of presiding officer of the governing body.

(e) Name and mailing address of all persons and/or legal entities having any ownership interest or owner's equity of the licensee to include a schedule of percent and type ownership claim of each.

(f) Name and mailing address of all persons and/or legal entities claiming liabilities of the licensee or of the facility or service for which this Certificate of Need is requested to include a schedule of percent and type of claim of each.

(g) Provide a listing which identifies all officers of the licensee.

(h) Is the land and/or building on/in which the proposed facility or service is to be conducted owned by the applicant. _____ YES _____ NO. If no, provide information on the land and building similar to that required in (b) through (g) above.

(i) Has the licensee engaged an entity other than an employee of the licensee to manage or operate the facility or service? _____ YES _____ NO. If yes, provide information similar to that required in (b) through (g) above.

(j) Is there any agreement, contract, option, understanding, intent or other arrangement that will effect a change in any of the information requested and/or provided in (b) through (g) above. _____ YES _____ NO. If yes, provide information similar to that required in (b) through (g) above.

(k) Provide a complete listing of all existing licensed health care facilities and/or services and Certificates of Need in which the proposed licensee currently has an ownership interest, to

include names and addresses of each facility or service. In the cases of Certificates of Need for undeveloped facilities and services, provide the name, address, and telephone number of a contact person representing the authority which issued the Certificate of Need.

(7) Should the licensee be a subsidiary corporation, provide a diagram of the licensee's relationship to the parent corporation and list the name and address of the parent corporation as well as the corporation which has ultimate control. In addition, please provide the name and mailing address of all persons and/or legal entities having ownership interest of five percent or more or any person with any agreement, contract, option, arrangement, or intent to acquire ownership interest of five percent or more, of all corporations in the corporate organizational structure which have ultimate control of the licensee.

(9) Provide documentation that the applicant has sought cooperative agreements such as transfer agreements with other facilities, as applicable.

(10) Indicate the means by which a person will have access to the facility's services (i.e. physician referral, self admission, etc). Identify the specific facilities or agencies the applicant expects to receive referrals from (i.e. hospitals, home health agencies, etc). Describe any limitations placed on admissions.

(11) Demonstrate that the proposed project is needed or projected as necessary to meet an identified need of the public. This shall address at a minimum: identification of the target population; the degree of unmet need; projected utilization of the proposed facility or service; utilization of existing facilities and services; past utilization of existing similar services within the facility; and justification that the proposed project will not unnecessarily duplicate existing entities. The applicant must show all assumptions, data sources, and methodologies used. The applicant must use population statistics consistent with those generated by the State Demographer, State Budget and Control Board.

(12) Discuss alternative facilities and/or services considered including the advantages and disadvantages of each alternative. Include a statement as to why this project alternative was adopted.

(13) Discuss any serious problems, such as costs, availability, or accessibility in obtaining care of the type proposed, experienced by patients in the absence of this project.

(14) Where a project affects an increase or decrease in bed capacity, provide annual occupancy rates for the facility based on licensed beds, for the past three years by category (i.e. general acute, psychiatric, obstetric, nursing home, etc.).

(15) Identify the method of financing the cost of the project, including the start-up costs. Provide documentation that the applicant can obtain such financing. Alternative sources and/or methods of financing must be identified and the method chosen demonstrated to be the most feasible option.

(16) For an addition to an existing facility or service, provide a current annual budget and at least a three fiscal year projected budget for both the overall facility and the proposed project. The projections must be developed by an accountant. For a new facility or service, provide a projected annual budget for not less than three fiscal years following the completion of the proposed project. The projections must be attested to by an accountant. These budgets must at a minimum include how proposed charges, proposed cost of service, utilization, depreciation, reimbursement rates and contractual adjustments were calculated. Any assumptions made in the application must be specifically noted.

(17) Provide a list of proposed charges for the project. The charges provided may be used for comparison with the average charges in the final completion report as required in Section 607.3.b.

(18) Document that the proposed project is economically feasible, both immediately and long-term. In the case of existing facilities, indicate what impact the proposed project will have on patient charges and cost per unit of service.

(19) State how the project will foster cost containment and improve quality of care through the promotion of such services as ambulatory and home health care, preventive health care, promotion of shared services, economies of scale, and design and construction economies.

(20) In the case of projects involving additional long-term care beds, discuss how the plans of other agencies, organizations, or programs responsible for providing and financing long-term care have been considered.

(21) Provide a three-year projected manpower budget in full-time equivalents (FTE's) detailing the existing and proposed nursing, other professional, and non-professional personnel required for the staffing of the new project.

(22) Provide the number of existing and proposed medical staff by specialty, to include physicians employed by, or with admission privileges to, the facility. Include the name of the Chief of the Medical Staff, if available.

(23) Indicate those physicians who have expressed a willingness to utilize the proposed services or to refer patients to the facility for the provision of services.

(24) Discuss the availability of health manpower resources for the provision of the proposed services, including the contemplated program and plan for recruiting and training personnel.

(25) Describe the previous experience of the applicant in the proposed health care field. If the applicant has no prior experience, specify the anticipated sources of technical assistance, either from specific individuals or organizations.

(26) Discuss the impact of the project on the clinical training programs of health professional schools, particularly the extent to which these schools will have access to the services for training.

(27) Provide documentation of policies and procedures to assure the quality of healthcare services by addressing patient safety and quality indicators, as applicable. Documents may include, but are not limited to, measures of patient care, patient safety, healthcare-acquired infections and the following of best practices established by recognized organizations. Applicable quality standards in the South Carolina Health Plan must be addressed.

(28) Provide any additional information that would assist the department in evaluating this project.

c. Part C. Programmatic Documents

Provide adequate programmatic documents in support of the various elements of the proposed project. These documents will include as appropriate:

(1) An Indigent Care Plan as required by the Board of Health and Environmental Control. It shall address at a minimum, the following:

(a) The existing and proposed admission and treatment policies of the facility or agency with regard to race, sex, creed, national origin, and ability to pay.

(b) The proposed admission and treatment policies of the facility or agency with respect to admission and care of indigent patients including those patients unable to pay at the time of admission and those whose benefits expire while in the care of the facility or agency.

(c) In existing facilities or agencies, provide the amount, in dollars and percent of gross revenues, that the facility or agency provided in indigent care during the past three fiscal years. NOTE: Indigent care does not include bad debt; contractual adjustments; or care which is reimbursed by a governmental program (Medicare, Medicaid, county indigent program), church, or philanthropic organization.

(d) Provide the proposed amount of indigent care the facility or agency projects to provide during the existing fiscal year and next fiscal year. This projection should be expressed in both dollars and a percent of gross revenues.

(e) A discussion of why the above figures are adequate or inadequate for the needs of the community; the need of indigent care within the proposed service area; and any solutions, remedial plans or proposals by the facility or agency to better address the indigent care problem in the service area. Include any initiatives or undertakings the facility or agency has begun to address the indigent care problem in the proposed service area.

(f) Describe any Board or Advisory Board established to implement or control the indigent problem at the facility or agency. Include the Board's functions, responsibilities, and limitations.

(2) A map of sufficiently large scale to be meaningful, indicating the location of the project site and its geographical area.

(3) A plot plan of the project site showing existing buildings, roads, parking areas, walks, service and entrance courts, existing utilities (electricity, telephone, water, railroads, sewer, gas, etc.) and other natural land features necessary for adequate analysis of site conditions.

(4) A legal description of the project site indicating its physical characteristics and existing easements.

(5) A square foot program of space and/or equipment elements, and scale drawings describing the existing space and proposed alterations and additions.

(6) Documentation from the appropriate zoning authorities that the proposed site is or can be zoned for the intended use.

(7) Documentation from appropriate sources that utilities supplied to the site are adequate for the project to include electricity, gas, water, and sewerage.

(8) Endorsement from the community that the project is desirable. This may include but is not limited to members of the medical community, citizen's groups, governmental elected officials, and other health and social service disciplines in the community.

(9) Documentation that the proposed project has been approved by the health facility's planning committee and governing body.

(10) For the facilities or services not licensed by the Department of Health and Environmental Control, provide documentation of coordination and support from the appropriate licensing agency.

d. Part D. Assurances

The applicant must furnish written assurance of each of the following where applicable:

(1) That the applicant has or will have a fee simple title or such other estate or interest in the site including necessary easements and rights-of-way, sufficient to assure use and possession for the purpose of the construction and operation of the facility.

(2) That approval by the department of the final drawings and specifications, which will be prepared by an architect and/or engineer legally registered under the laws of the State of South Carolina, will be obtained.

(3) That the applicant will submit to the Department for prior approval, changes that substantially alter the scope of work, function, utilities, major items of equipment, safety or cost of the facility during construction.

(4) That the applicant will cause the project to be completed in accordance with the Certificate of Need application.

(5) That the applicant will cause the project to be completed in accordance with approved plans and specifications by maintaining competent and adequate architectural and engineering services throughout the construction administration phase of the project. That, at the completion of the project, the architect of record shall be required to issue a statement that to the best of his knowledge and belief, based upon available records, supplemental documents, and periodic observation of the work, the project was constructed according to those documents approved by the Department.

(6) That the facility will be operated and maintained in accordance with the standards prescribed by law and regulations for the maintenance and operation of such facilities.

(7) That the applicant understands that the Certificate of Need shall become void at the end of the specified time period from the date of issuance unless otherwise extended under Chapter 6 of these regulations.

(8) That the Department or its authorized representatives may at any time during the course of construction and upon the completion of the project make an on-site inspection of the construction and equipment to check for compliance of the construction in accordance with the application for which the Certificate of Need was issued.

(9) That the controlling interest in any health care facility shall not be sold or leased or otherwise disposed of unless the Certificate of Need has been fulfilled.

(10) That the applicant will notify the Department in writing that the contractual agreement has been completed. For a construction project, the letter shall indicate that a construction contract specifying the beginning and completion dates of the project, has been signed by both parties. For services projects, the letter must indicate that equipment purchase orders with estimated delivery dates have been properly negotiated.

(11) That the applicant will notify the Department in writing of the date that a new or expanded service has been implemented, completed or terminated.

(12) That the applicant will provide monthly progress reports and a final completion report which contain the information required by Section 607 of these regulations.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

CHAPTER 3
DISPOSITION OF APPLICATION

SECTION 301. Submission of Application.

Two copies of the application along with a non-refundable filing fee of five hundred dollars (\$500) shall be forwarded to the Bureau of Health Facilities and Services Development, S.C. Department of Health and Environmental Control, 2600 Bull Street, SC, 29201. Applicants are encouraged to involve the Department in the development of proposed projects prior to the submission of an application.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 302. Additional Information.

1. After receipt of an application with proof of publication in a local newspaper and the five hundred dollars (\$500) non-refundable filing fee, the Department shall publish in the State Register a notice that an application has been accepted for filing. The Department shall notify the applicant in writing when the application is not acceptable for filing.

2. Within thirty (30) calendar days from acceptance of an application, the Department will request any additional information pertinent to the project as may be deemed necessary to make the application complete. Should additional information be required for an application to be considered complete, the applicant will have thirty (30) calendar days from the date of the request to submit the requested information. If the applicant does not submit the requested information within thirty (30) calendar days, the application will be deemed to have been withdrawn.

3. Should the applicant within such thirty (30) calendar day period submit incomplete additional information, the Department will have thirty (30) calendar days in which to request further information. If the information requested is not received by the Department within thirty (30) calendar days of this second request, the application will be deemed to have been withdrawn.

4. If any deadline provided for in this section falls on a weekend or State holiday, the deadline will be extended until the next calendar day that is not a weekend or State holiday.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 303. Payment of Filing and Application Fees.

1. When the application is determined to be complete, the Department shall invoice the applicant, by certified mail, for the certificate of need application fee. The applicant shall have fifteen (15) calendar days from the date of receipt of the invoice to pay the fee by valid check or credit card made payable to the S.C. Department of Health and Environmental Control. Should the application fee not be received within fifteen (15) calendar days from receipt of the Department's invoice by the applicant, the application will be considered withdrawn.

2. If any deadline provided for in this section falls on a weekend or State holiday, the deadline must be extended until the next calendar day that is not a weekend or State holiday.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 304. Relative Importance Criteria.

1. Upon determination by the Department that an application is complete, the Department shall notify the applicant, by certified mail, of the relative importance of the project review criteria to be used in reviewing the application. The applicant will have thirty (30) calendar days from the date of receipt of this notice to submit any additional information. If, subsequent to this notice, the Department determines that the relative importance of the review criteria has changed, the Department must again notify the applicant by certified mail. The applicant will have thirty (30) calendar days from receipt of the revised notice to submit any additional information.

2. The staff may reorder the relative importance of the project review criteria no more than one time during the review period. The staff's reordering of the relative importance of the project review criteria does not extend the review period.

3. When an application has been appealed, the Department may not change the weight of the importance of the project review criteria.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 305. Review Time Frames.

1. Upon determination by the Department that the application is complete, and receipt of the application fee, the Department shall publish in the State Register a notice that the review cycle for the project has begun. Any affected person who has notified the Department in writing that they desire to be notified of the beginning of the review period be sent a copy of the notification.

2. The Department will make a decision on the complete application no earlier than thirty (30) calendar days but no later than 120 calendar days of the date of publication in the State Register unless a public hearing is held. Notice of a Department decision must be sent by certified mail, return receipt requested to the applicant and affected persons who have requested in writing to be notified.

a. If a public hearing is held pursuant to Section 306, the Department will render its decision no later than 150 calendar days from the date the affected persons are notified that the application is complete.

b. [Reserved]

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 306. Public Hearing.

A public hearing must be requested in writing by an "affected person" as defined in these regulations within thirty (30) calendar days of the notification of the beginning of a review. Where such a hearing is requested, prior notice of the hearing will be provided to "affected persons." The written notification of the hearing shall include the proposed schedule for the review, time, date, and place of such hearing. The public hearing shall provide an opportunity for any person to present information relevant to the application.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 307. Department Review.

1. The Department may not issue a Certificate of Need unless an application is in compliance with the South Carolina Health Plan as described in this regulation, project review criteria, and other regulations which must be identified by the Department. The Department may refuse to issue a Certificate of Need even if an application is in compliance with the South Carolina Health Plan but is inconsistent with project review criteria or departmental regulations. The Department must identify any regulation that is used as a basis for denying an application that is in compliance with the South Carolina Health Plan.

2. In the case of competing applications, the Department shall award a Certificate of Need, if appropriate, on the basis of which, if any, most fully complies with the requirements, goals, and purposes of the Certificate of Need program, South Carolina Health Plan, project review criteria, and any regulations developed by the Department.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 308. Department Decision.

On the basis of staff review of the record established by the Department, including but not limited to, the application, comments from affected persons and other persons concerning the application, data, studies, literature and other information available to the Department, the staff of the Department shall make a proposed decision to grant or deny the Certificate of Need.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 309. Certificate of Need Issuance Fee.

Projects with a total project cost greater than one million four hundred thousand dollars (\$1,400,000) will require payment of a Certificate of Need issuance fee of seven thousand five hundred dollars (\$7,500) upon the granting of the certificate of need. An invoice will be enclosed with the certificate which will be sent by certified mail. The Department must receive payment within fifteen (15) calendar days from receipt of the certificate by the applicant for the certificate of need to remain valid.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 310. Project Changes During Review Period.

If an applicant amends his application during the review process, the Department will determine whether or not the amendment is substantial and constitutes a new application. If the change results in an increase in cost, the fees will be adjusted accordingly.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 311. Validity of Certificate of Need Issued

The Certificate of Need, if issued, is valid only for the project described in the application including location, beds and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application, except as may be modified in accordance with these regulations. Implementation of the project or operation of the facility or medical equipment that is not in accordance with the Certificate of Need application or conditions subsequently agreed to by the applicant and the Department may be considered a violation of this Regulation.

SECTION 312. Prohibited Contact.

1. After a Certificate of Need application has been filed with the Department, state and federal elected officials are prohibited from communicating with the Department with regard to the Certificate of Need application at any time. This prohibition does not include written communication of support or opposition to an application. Such written communication must be included in the administrative record.

2. From the date of publication of notice in the local newspaper that an application is being filed and until the date final review is requested under Section 401 of these regulations:

a. members of the Board and persons appointed by the Board to hold a final review conference on staff decisions may not communicate directly or indirectly with any person in connection with the application; and

b. no person shall communicate, or cause another to communicate, as to the merits of the application with members of the Board and persons appointed by the Board to hold a final review conference on staff decisions.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

CHAPTER 4 APPEALS

SECTION 401. Appeal of Decision.

1. A Department decision involving the issuance, denial, or revocation of a certificate of need may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; Title 1, Chapter 23; and Title 44, Chapter 7.

2. Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1; Title 1, Chapter 23; and Title 44, Chapter 7.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 402. [Reserved]

Editor's Note

Former R. 61-15 § 402 was titled "Staff Reconsideration".

SECTION 403. Deleted by State Register Volume No. 36, Issue No. 5, eff May 25, 2012.

Editor's Note

Former R 61-15 § 403 was titled "Contested Case Hearing".

SECTION 404. Deleted by State Register Volume No. 36, Issue No. 5, eff May 25, 2012.

Editor's Note

Former R 61-15 § 404 was titled "Judicial Review".

CHAPTER 5 GENERAL PROVISIONS

SECTION 501. Findings of the Department.

In the case of any proposed new institutional health service for the provision of health services to inpatients, the Department shall not grant a Certificate of Need, or otherwise make a finding that such proposed new institutional health service is needed, unless:

1. The capital and operating costs of the proposal and their potential impact on patient charges are reasonable;
2. Superior alternatives to such services in terms of cost, efficiency, or appropriateness do not exist and that the development of such alternatives is not practicable;
3. In the case of new construction, alternatives to new construction (e.g., modernization or sharing arrangements) have been considered;
4. Patients will experience serious problems in terms of costs, availability or accessibility, or such other problems as may be identified by the Department, in obtaining care of the type proposed in the absence of the project; and
5. In the case of a proposed addition of beds for the provision of nursing care service, the addition is consistent with the plans of other State agencies responsible for provision and financing of long-term care (including home health) services.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 502. Periodic Reports

For the purpose of health planning, health care facilities and others who provide services that require a Certificate of Need or who have been exempted, shall on an annual basis submit information requested on the applicable Joint Annual Report.

SECTION 503. Distribution of Procedures Criteria

The Department shall distribute copies of its proposed and adopted review procedures and criteria, and proposed revisions to statewide health agencies and organizations, any agency which establishes rates for health care facilities in the state, and other persons upon request.

SECTION 504. Review Under Applicable Plan.

All decisions on Certificate of Need applications shall be made based on the currently approved South Carolina Health Plan in effect at the time such application is accepted. Should a new plan be adopted during any phase of the review or appeals process, the applicant shall have the option of withdrawing the application and resubmitting under the newly adopted plan or continuing the review or appeal process under the plan in use when the application was submitted. In cases where

applications are withdrawn and resubmitted under the newly adopted South Carolina Health Plan within forty-five (45) calendar days of the date of withdrawal, no additional filing fee shall be required.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

CHAPTER 6
VOIDANCE AND EXTENSION OF CERTIFICATES OF NEED

SECTION 601. Voidance and Extension Procedures.

1. The Certificate of Need shall become void twelve months (one year) from the date of issuance. The Department may void a Certificate of Need if requested by the applicant, or if the Department determines that the Certificate of Need has not fully implemented within one year from the date issued. Implementation may be evidenced by, but not limited to, a properly negotiated valid construction contract or appropriate purchase order for service projects.

2. A Certificate of Need must be issued with a timetable submitted by the applicant, and approved by the Department, to be followed for completion of the project. The holder of the Certificate of Need must submit quarterly progress reports documenting compliance with the aforementioned timetable. Failure to meet the timetable results in the revocation of the Certificate of Need by the Department unless the Department determines that extenuating circumstances beyond the control of the holder of the Certificate of Need are the cause of the delay. If the applicant has not met the approved timetable, documented evidence that extenuating circumstances beyond the control of the holder of the Certificate of Need should be provided to the Department. This information can also be included in a request for an extension as provided in Section 602.

3. The Department may grant up to two extensions of up to nine months each. In order to obtain an extension, the applicant must have demonstrated substantial progress and must either be complying with the approved timetable or have submitted documentation satisfactory to the Department that extenuating circumstances beyond the control of the applicant have prevented compliance with the timetable. After the nine month extension period, the Certificate of Need will expire and become void.

4. However, the Board may grant further extensions of the Certificate of Need of up to nine months each if it determines that substantial progress has been made. A request to the Board must be made at least three months prior to the expiration of the Certificate of Need and must contain justification for such extension.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 602. Extension Request.

1. A Certificate of Need extension shall be requested by the applicant at least thirty (30) calendar days before the expiration date and shall contain such information as the Department may reasonably require.

2. This information shall include at least the following:

a. A detailed description of any changes in the configuration, costs, services, or scope of the project.

b. A detailed description and documentation of any progress on the project including preparation of construction drawings, the securing of necessary funds and building permits, and commencement of any construction.

c. An estimated timetable for commencement and completion of all remaining components of the project.

d. Documentation of compliance with the approved timetable or documented evidence that extenuating circumstance beyond the control of the applicant if the timetable was not met.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 603. Criteria for Extension

The following criteria shall be used to determine whether substantial progress has been made by the applicant:

1. Site procurement: The applicant should have made definitive progress toward permanent acquisition of the intended site. Such progress may include purchase of property previously under option or consummation of long-term lease agreements.

2. Architectural Progress: The facility architect should have been employed and definitive progress should be made toward development of final drawings.

3. Financial Status: the applicant should document definitive progress toward finalizing any necessary loans or lease-purchase arrangements.

4. The applicant should provide reasonable assurance that the project will be under construction or implemented within the requested extension time frame.

SECTION 604. Non-Transferability of Certificate of Need.

A Certificate of Need is nontransferable. A Certificate of Need or rights there under may not be sold, assigned, leased, transferred, mortgaged, pledged, or hypothecated, and any actual transfer or attempt to make a transfer of this sort results in the immediate voidance of the Certificate of Need. Any of the aforementioned transactions involving an entity directly or indirectly holding a Certificate of Need before fulfillment of the Certificate of Need results in the transfer and the subsequent voidance of the Certificate of Need. Fulfillment of the Certificate of Need occurs, although not limited to, the submission of an adequate final completion report as determined by the Department. Anyone having their Certificate of Need voided shall not be eligible to apply for a new Certificate for a period of one (1) year without Board approval.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 605. Project Changes After Receipt of Certificate of Need.

If an applicant amends or alters his project after receipt of a Certificate of Need, the Department will decide whether or not the amendment is substantial and thereby constitutes a new project.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 606. Total Project Cost.

In issuing a Certificate of Need, the Department shall specify the approved total project cost. A project is only approved for the amount specified in the Certificate of Need. The Department will review cost overruns on an individual basis.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 607. Periodic Reporting of Certificate of Need Implementation.

1. The applicant is required to submit a quarterly progress report that corresponds with the timetable included in the Certificate of Need application beginning ninety (90) calendar days after receipt of the Certificate of Need. Failure to meet the timetable results in the revocation of the Certificate of Need by the Department unless a determination is made by the Department that circumstances beyond the control of the holder of the Certificate of Need are the cause of the delay.

2. The applicant shall report on, if applicable: (1) costs incurred on the project; (2) construction activity; (3) program or service activity; and (4) any deviations from the submitted application with supporting documentation.

3. After the project has been fully implemented, the applicant shall provide the Department with a final completion report that contains, at a minimum:

- a. An audited cost report that shows all expenditures on the approved project;
- b. A list of average charges and costs for the services approved in the application and documented by affidavit, certification or other proof;
- c. A registered architect's or engineer's signed statement of final construction costs;
- d. An equipment listing and inventory for the project;
- e. A program and/or service narrative describing the final project configuration; and
- f. An explanation of any deviation from the approved application with justification, or a signed statement from the applicant that the project was implemented as outlined in the application.

4. Records relating to the project shall be maintained by the applicant for seven (7) years following the completion of the project and these records shall be made available to the Department's auditors for inspection as needed.

5. The Department may audit any project for consistency with the information provided in the Certificate of Need application. Undertaking a project that is not in accordance with the approved application or conditions or amendments subsequently agreed to by the applicant and the Department may be considered a violation of this article.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

CHAPTER 7
PENALTIES FOR NON-COMPLIANCE

SECTION 701. Penalties.

Undertaking any activity requiring certificate of need review, as defined in Section 102 of these regulations, without prior approval of the Department or failing to comply with any of the above stated regulations shall be grounds for the denial, suspension, or revocation of the Certificate of Need, or other penalties, under the provisions of Sections 44-7-320 through 44-7-340 of the Code of Laws of South Carolina, as amended. Any violation of this regulation is subject to provisions set forth in the statute.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 702. [Reserved]

Editor's Note

Former R 61-5 §702 was titled "Penalties".

CHAPTER 8
PROJECT REVIEW CRITERIA

SECTION 801. Applicability and Weighting.

1. The criteria listed in Section 802 are to be used in reviewing all projects under the Certification of Need program. These criteria have been grouped under the following general categories:

Need for the Proposed Project (Section 802.1 through 802.4)

Economic Consideration (Section 802.5 through 802.19)

Health System Resources (Section 802.20 through 802.25)

Site Suitability (Section 802.26 through 802.30)

Special Consideration (Section 802.31 through 802.33)

2. The Department shall notify the applicant of the relative importance of the project review criteria to be used in reviewing the application. The relative importance assigned to each specific criterion is established by the Department depending upon the importance of the criterion applied to the specific project. The relative importance must be consistent for competing projects.

3. A project does not have to satisfy every criterion in order to be approved, but no project may be approved unless it is consistent with the South Carolina Health Plan. A project may be denied if the Department determines that the project does not sufficiently meet one or more of the criteria.

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

SECTION 802. Criteria for Project Review.

1. Need:

The proposal shall not be approved unless it is in compliance with the South Carolina Health Plan.

2. Community Need Documentation:

a. The target population should be clearly identified as to the size, location, distribution, and socioeconomic status (if applicable).

b. Projections of anticipated population changes should be reasonable and based upon accepted demographic or statistical methodologies, with assumptions and methodologies clearly presented in

the application. The applicant must use population statistics consistent with those generated by the state demographer, State Budget and Control Board.

c. The proposed project should provide services that meet an identified (documented) need of the target population. The assumptions and methods used to determine the level of need should be specified in the application and based on a reasonable approach as judged by the reviewing body. Any deviation from the population projection used in the South Carolina Health Plan should be explained.

d. In the case of a reduction, relocation, or elimination of a facility or service, the applicant should address the need that the population presently has for the service, the extent to which that need will be met by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination, or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, the elderly, handicapped persons, and other underserved groups, to obtain needed health care.

e. Current and/or projected utilization should be sufficient to justify the expansion or implementation of the proposed service.

3. Distribution (Accessibility):

a. Duplication and modernization of services must be justified. Unnecessary duplication of services and unnecessary modernization of services will not be approved.

b. The proposed service should be located so that it may serve medically underserved areas (or an underserved population segment) and should not unnecessarily duplicate existing services or facilities in the proposed service area.

c. The location of the proposed service should allow for the delivery of necessary support services in an acceptable period of time and at a reasonable cost.

d. The proposed facility should not restrict admissions. If any restrictions are applied, their nature should be clearly explained.

e. The applicant must document the means by which a person will have access to its services (e.g. outpatient services, admission by house staff, admission by personal physician).

f. The applicant should address the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, the elderly, handicapped persons, and other medically underserved groups, are likely to have access to those services being proposed.

g. The facility providing the proposed services should establish provisions to insure that individuals in need of treatment as determined by a physician have access to the appropriate service, regardless of ability to pay.

h. Potential negative impact of the proposed project upon the ability and/or resources of existing providers to serve medically underserved groups must be considered.

4. Acceptability:

a. The proposal and applicant should have the support of "affected persons" (including local providers and the target population). The lack of opposition should not be considered support for the purposes of these criteria.

b. Where documented opposition exists to a proposal, such opposition will be considered along with the application.

c. Possible transfer agreements should be confirmed and an intent to negotiate these arrangements should be documented by all parties.

d. The applicant should document the initiation of any other required reviews or agency check-offs.

5. Financial Entries and Assumptions:

All financial entries and assumptions contained in the application must be provided by an accountant who stands behind the reliability of this financial information.

6. Projected Revenues:

a. The proposed charges should be comparable to those charges established by other facilities for similar services within the service area or state. The applicant should document how the proposed charges were calculated.

b. The projected levels of utilization should be reasonably consistent with those experienced by similar facilities in the service area and/or state. In addition, projected levels of utilization should be consistent with the need level of the target population.

c. The projected collection and reimbursement rates should be reasonably consistent with those experienced/utilized by similar facilities.

d. Failure to provide contingency plans for any known factor which would jeopardize the stability of the revenue projections shall be grounds for rejection of the budget.

7. Projected Expenses:

Projections of construction costs, start-up costs, operating costs, debt service, depreciation, manpower costs, etc. should be consistent with those experienced by similar facilities offering a similar level and scope of services (with proper consideration given to such factors as inflation, cost of capital, etc.).

8. Beginning Cash Flow:

The applicant must have documented the availability of resources or sources of funds sufficient to cover capital requirements and start-up costs. The schedule of utilization and net revenues must be detailed with assumptions explicitly present.

9. Net Income:

The project should show an improvement in its net revenue position over time, especially the first three years, until a steady, positive net income trend is attained. Any projected deviations from this pattern should be explained.

10. Debt Service:

a. Debt service (interest cost plus payment toward principal) should not be so large as to cause a negative net income.

b. Characteristics of the debt (interest, prepayment arrangements, etc.) should be consistent with those arrangements used by other health service entities in the State and consistent with accepted good business practices in terms of assumption and retirement of debt.

c. The applicant must document the impact the project will have on the facility's proposed level of patient charges.

11. Methods of Financing:

a. Possible alternatives should be identified.

b. Reasons for the selection of the proposed funding method should be stated and reasonable.

12. The applicant should demonstrate an ability to obtain the desired capital. The applicant must provide at least conditional commitment from an appropriate institution.

13. Record of the Applicant (Owner and/or Administrator):

a. The applicant's record should be one of successful operation with adequate management experience.

b. The applicant should have a demonstrated ability to obtain necessary capital financing.

c. If the applicant has no prior experience, sources of assistance should be specified (i.e. technical assistance from specific individuals or organizations).

d. The applicant's record or his representative's record of cooperation and compliance with State and Federal regulatory programs will be considered.

14. Ability to Complete the Project:

a. The applicant should have demonstrated that the project can be initiated and completed within the proposed time frame specified in the application.

b. The financial schedules and time frames contained in the application should be consistent with those usually experienced in the development of similar facilities or services.

15. Financial Feasibility:

The applicant must have projected both the immediate and long-term financial feasibility of the proposal. Such projection should be reasonable and based upon accepted accounting procedures.

16. Cost Containment (Minimizing Costs):

a. The applicant should have identified and sought alternative sources and/or methods of funding and demonstrated that the method chosen was the most feasible option.

b. If the applicant had the option of lease or purchase, with all other factors being equal, he should demonstrate that his choice is the least costly in the long run.

c. The impact of the project upon the applicant's cost to provide services and the applicant's patient charges should be reasonable. The impact of the project upon the cost and charges of other providers of similar services should be considered if the data are available.

17. Efficiency:

The proposed project should improve efficiency by avoiding duplication of services, promoting shared services and fostering economies of scale or size.

18. Physical Design:

The proposed project should foster economies of design by use of design characteristics such as improved access and circulation within the facility, the relationship of services within the facility, and the use of shared space for centralized supply, storage, and common activities.

19. Alternative Methods:

a. The applicant should have considered any available or more effective alternatives which exist to the proposed service such as the use of less costly alternatives, outpatient services, shared services, or extended hours of service.

b. For new construction projects, modernization of existing facilities should be considered as an alternative, and the rejection of this alternative by the applicant should be justified.

20. Staff Resources:

a. The applicant should have a reasonable plan for the provision of all required staff (physicians, nursing, allied health and support staff, etc.).

b. The applicant should demonstrate that sufficient physicians are available to insure proper implementation (e.g. utilization and/or supervision) of the project.

c. If the applicant presently owns existing facilities or services, he/she should demonstrate a satisfactory staffing "track record."

d. Alternative uses of resources for the provision of other health services should be identified and considered.

21. Support Services and Equipment:

a. Support services and equipment necessary to implement and sustain the proposed service should be identified, accessible and of sufficient capacity.

b. Where possible, projects should utilize equipment already available and accessible to the population to be served.

22. Distribution:

The existing distribution of the health service(s) should be identified and the effect of the proposed project upon that distribution should be carefully considered to functionally balance the distribution to the target population.

23. Adverse Effects on Other Facilities:

a. The impact on the current and projected occupancy rates or use rates of existing facilities and services should be weighed against the increased accessibility offered by the proposed services.

b. The staffing of the proposed service should be provided without unnecessarily depleting the staff of existing facilities or services or causing an excessive rise in staffing costs due to increased competition.

24. Adverse Effects on Training Programs:

The proposed delivery of health services should not adversely affect the ability of local health professional training programs to meet their clinical needs.

25. Access:

If the proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools in the area will have access to the services for training purposes should be clearly delineated in the proposal.

26. Zoning:

The proposed site must comply with local zoning regulations. Documentation should be provided from the appropriate zoning authorities that the proposed site is or can be zoned for the intended use.

27. Utilities:

The utilities necessary for the facility to operate should be available on site or the application should state provisions made for bringing these utilities on site or providing alternatives such as wells or sewage treatment plants. Applicants should document the availability of needed utilities. The cost of such provisions should be detailed in the financial section of the application.

28. Site Size:

Documentation should be provided that all of the property intended for use is available to the applicant. Consideration may also be given to the suitability of the proposed site for any expansion of services included in the applicant's long-range plans.

29. Environmental Hazard:

The proposed facility should not be located on a site where environmental conditions would either create a health hazard or aggravate an existing health condition in individuals served by the facility.

30. Square Footage:

Space allocations should conform to applicable local, state, and federal regulations or minimum standards. For all projects, state or other applicable licensing standards must be met by the proposal.

31. Medically Underserved Groups:

a. The applicant should address the contribution of the proposed service in meeting the health needs of members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (e.g. low income persons, racial and ethnic minorities, women, the elderly, and handicapped persons), particularly those needs identified in the applicable South Carolina Health Plan as deserving of priority.

b. The extent to which medically underserved populations currently use the applicant's services should be considered in comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved.

c. Consideration of the documented performance of the applicant in meeting its obligation, if any, under any applicable Federal regulations requiring provision of uncompensated care, indigent care plan, community service, or access by minorities and handicapped persons to programs receiving Federal financial assistance (including the existence of any civil rights access complaints against the applicant) should be given.

d. Consideration should be given to the extent to which Medicare, Medicaid, and medically indigent patients are served by the applicant.

32. Other Entities:

Consideration should be given to the special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas. These entities may include medical and other health professions schools, multidisciplinary clinics and specialty centers.

33. Elimination of Safety Hazards

The Department shall issue a Certificate of Need for a proposed capital expenditure if it is required to eliminate or prevent imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations; or to comply with State Licensure standards, or to comply with accreditation or certification standards which must be met to receive reimbursement under Title XVIII of the Social Security Act or payments under a State Plan for medical assistance

approved under Title XIX of that Act, provided the Department has determined that the facility or service for which the capital expenditure is proposed is needed and the obligation of the capital expenditure is consistent with the South Carolina Health Plan. Those portions of a proposed project which are not required to eliminate or prevent safety hazards or to comply with licensure, certification, or accreditation standards shall be reviewed against each of the applicable criteria for project review.

APPENDIX:

APPLICATION FOR CERTIFICATION OF NEED FOR A HEALTH FACILITY OR SERVICE

Proposal Prepared By:

Name: _____ Title _____

Organization: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Telephone Number _____

Email: _____ Fax Number: _____

The Applicant hereby certifies that the information contained in this Application, including all assurances and attachments, are correct to the best of his knowledge and belief.

Applicant's Signature: _____

Date: _____

Forward to:

Bureau of Health Facilities and Services Development
S.C. Department of Health and Environmental Control
2600 Bull Street
Columbia, S.C. 29201

NOTE: A "complete" application shall include a written narrative report by the applicant (Regulation 61-15, Section 202).

PART A - QUESTIONNAIRE

1. Name of Facility

2. Address, City, County, State, Zip Code

3. Type of Facility (Circle)

- | | | |
|----------------------------|-----------------------------|--------------------------------|
| A. Hospital | B. Nursing Home | C. Psychiatric Facility |
| D. Rehabilitation Facility | E. Substance Abuse Facility | F. Ambulatory Surgery Facility |
| G. Other (Specify) | | |

4. Purpose of Review (Circle)

- | | | |
|------------------------------------|------------------------|----------------------------------|
| A. New Facility | B. Change of Licensure | C. Addition to Existing Facility |
| D. Renovation of Existing Facility | E. Change of Services | |
| F. Other (Specify) | | |

5. Management

- | | | |
|--------------------------|-----------------------------------|----------|
| A. Name of Administrator | B. Address, City, State, Zip Code | |
| C. Telephone: | D. Fax Number | E. Email |

6. Licensee

A. Name of Licensee

B. Address, City, State, Zip Code

7. Ownership or Control of the Facility

(Attach a list of names and addresses of the owners of the facility, indicating percent of ownership of each owner, the person responsible for the proposal, and the attorney(s) representing the proposal). Circle the appropriate information regarding ownership.

A. Individual B. Partnership C. Corporation D. Proprietary

E. Non-Profit F. Government (Specify)

G. Other: (Specify)

8. Proposed Site of the Property

A. Owned B. Leased

C. Length of Site Lease

D. Option E. Length of Option

F. Name and Address of Owner(s) of Real Property

9. Total Bed Capacity for Which Application is Made

Existing Facilities

	New Facility Only	Existing Beds	# Gained or Lost	Bed Total
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Type of Beds

A. Medical/Surgical

B. Obstetrics

C. Pediatrics

D. Substance Abuse

E. Psychiatric

F. Rehabilitation

G. Nursing Care

H. RTFs

I. ICU/CCU

J. Other

K. TOTAL

10. Construction and Site

A. Type of Construction B. Number of Buildings Pertaining to Project

C. Number of Stories Pertaining to Project D. Size of the Site in Acres

E. Size of the Project Site in Acres F. Square Footage of the Project

G. Anticipated Date of Beginning Construction H. Anticipated Date of Licensing or Project Completion

I. Anticipated Date for Submission of Final Completion Report

11. Zoning of Construction Site

12. Costs (Provide Estimated Signed Cost Statement from Either the Architect or Engineer)

A. Land Cost B. Construction Cost

C. Architect's/Engineer's Fee D. Equipment Costs (to include taxes)

1) Fixed Equipment

2) Movable Equipment

E. Financing Cost During Construction F. Other Costs (Specify)

G. Total Project Cost H. Construction and Equipment Cost

- 1) Per Square Foot
 - 2) Per Bed
-

HISTORY: Amended by State Register Volume 36, Issue No. 5, eff May 25, 2012.

61-16. MINIMUM STANDARDS FOR LICENSING HOSPITALS AND INSTITUTIONAL GENERAL INFIRMARIES.

(Statutory Authority: 1976 Code Sections 44-7-110 through 44-7-394, 44-37-40, 44-37-50, and 63-7-40.)

Editor's Note

The following constitutes the history for 61-16, 101 through 3001.

HISTORY: Amended by State Register Volume 16, Issue No. 4, eff April 24, 1992.

Executive Order No. 2020-11 (SCSR 44-4 EO 2020-11), effective March 19, 2020, relating to additional emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order No. 2020-50 (SCSR 44-8 EO 2020-50), effective August 2, 2020, extended by Executive Order No. 2020-53 (SCSR 44-8 EO 2020-53), effective August 10, 2020, Executive Order No. 2020-56 (SCSR 44-9 EO 2020-56), effective August 25, 2020, Executive Order No. 2020-59 (SCSR 44-9 EO 2020-59), effective September 9, 2020, and Executive Order No. 2020-62 (SCSR 44-10 EO 2020-62), effective September 24, 2020, relating to additional emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order No. 2020-63 (SCSR 44-10 EO 2020-63), effective October 2, 2020, extended by Executive Order No. 2020-65 (SCSR 44-10 EO 2020-65), effective October 9, 2020, Executive Order No. 2020-67 (SCSR 44-11 EO 2020-67), effective October 24, 2020, Executive Order No. 2020-70 (SCSR 44-11 EO 2020-70), effective November 8, 2020, and Executive Order No. 2020-72 (SCSR 44-12 EO 2020-72), effective November 23, 2020, relating to additional emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order No. 2020-73 (SCSR 44-12 EO 2020-73), effective November 25, 2020, extended by Executive Order No. 2020-75 (SCSR 44-12 EO 2020-75), effective December 8, 2020, Executive Order 2020-77 (SCSR 45-1 EO 2020-77), effective December 20, 2020, Executive Order 2021-03 (SCSR 45-1 EO 2021-03), effective January 7, 2021, Executive Order 2021-07 (SCSR 45-2 EO 2021-07), effective January 22, 2021, Executive Order 2021-08 (SCSR 45-2 EO 2021-08), effective February 6, 2021, and Executive Order 2021-10 (SCSR 45-3 EO 2021-10), effective February 21, 2021, relating to modifying amending emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order 2021-11 (SCSR 45-3 EO 2021-11), effective March 1, 2021, relating to modifying amending emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order 2021-12 (SCSR 45-3 EO 2021-12), effective March 5, 2021, extended by Executive Order No. 2021-13 (SCSR 45-3 EO 2021-13), effective March 8, 2021, Executive Order No. 2021-15 (SCSR 45-4 EO 2021-15), effective March 23, 2021, Executive Order No. 2021-18 (SCSR 45-4 EO 2021-18), effective April 7, 2021, Executive Order No. 2021-20 (SCSR 45-5 EO 2021-20), effective April 22, 2021, and Executive

Order No. 2021-22 (SCSR 45-5 EO 2021-22), effective May 7, 2021, relating to modifying amending emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

Executive Order 2021-23 (SCSR 45-5 EO 2021-23), effective May 11, 2021, extended by Executive Order 2021-25 (SCSR 45-6 EO 2021-25), effective May 22, 2021, relating to modifying amending emergency measures and regulatory relief regarding COVID-19, authorized the South Carolina Department of Health and Environmental Control (DHEC) to suspend, for the duration of the present emergency, any necessary and applicable provisions of Regulations 61-15 and 61-16, which restrict the use of unlicensed beds or space, the conversion of single and double occupancy patient rooms to account for higher patient capacity, or the establishment of wards, dormitories, or other spaces not designated as patient rooms.

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SECTION 100
DEFINITIONS

SECTION 101. Definitions.

For the purpose of these Standards, the following definitions shall apply:

- A. Administrator: The individual designated by the governing body or owner who is in charge of and responsible for the administration of the facility.
- B. Annual (Annually): A time period that requires an activity to be performed at least every twelve to thirteen (12 to 13) months.
- C. Contact Investigation: Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify Latent TB Infection (LTBI) or TB disease, and treatment of these persons, as indicated.
- D. Department: The South Carolina Department of Health and Environmental Control.
- E. Facility: Hospitals and institutional general infirmaries licensed by the Department, shall be defined and classified as follows:
 - 1. General Hospital: A facility with an organized medical staff to maintain and operate organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and care of such persons overnight and provides medical and surgical care of acute illness, injury or infirmity and may provide obstetrical care, and in which all diagnoses, treatment or care are administered by or performed under the direction of persons currently licensed to practice medicine, surgery, or osteopathy in the State of S.C.
 - 2. Specialized Hospital: A facility which has an organized medical staff, maintains and operates organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and/or care of such persons overnight and which provides a specialized service for one type of care, such as, maternity, orthopedics, pediatrics, E.E.N.T., psychiatry, etc., and in which all diagnoses, treatment or care are under the direction of persons currently licensed to practice medicine, surgery, osteopathy in the State of S.C.
 - 3. Institutional General Infirmiry: A facility which is established within the jurisdiction of a larger nonmedical institution and which maintains and operates organized facilities and services to accommodate two or more nonrelated students, residents or inmates with illness, injury or infirmity for a period exceeding 24 hours for the diagnosis, treatment and care of such persons and which provides medical, surgical and professional nursing care, and in which all diagnoses, treatment and

care are performed under the direction of persons currently licensed to practice medicine and surgery in the State of S.C.

4. Long Term Acute Care Hospital (LTACH): A general hospital which has been classified and certified as a long term acute care hospital designed to provide extended medical and rehabilitative care for patients who are clinically complex and have acute or chronic conditions. In a LTACH patients have an average length of stay of 25 days or more.

5. Critical Access Hospital (CAH): A general hospital designated by the state as such through the Medicare Rural Hospital Flexibility Program, in accordance with 42CFR485 Subpart F.

6. Privately-Owned Educational Institutional Infirmary: These facilities may be established within the jurisdiction of a larger nonmedical institution which maintains and operates organized facilities and services to accommodate two or more nonrelated students, faculty, and staff with illness, injury, or infirmity for a period exceeding twenty-four hours for the diagnosis, treatment, and care of such persons and which provides medical, surgical, and professional nursing care, and in which all diagnoses, treatment, and care are performed under the direction of persons currently licensed to practice medicine and surgery in South Carolina. However, privately-owned education infirmaries also may care for patients who are not students, faculty, or staff when the privately-owned education infirmary has agreed to provide such care to this class or patients prior to January 1, 2007 pursuant to 44-7-261.

F. Designee: A physician, dentist, osteopath, podiatrist, physician's assistant, or advanced practice registered nurse who has staff privileges, selected by a prescriber to sign verbal orders for medication or treatment in the prescriber's absence.

G. Dietitian: An individual who is registered by the Commission on Dietetic Registration and currently licensed as a dietitian by the South Carolina Department of Labor, Licensing and Regulation.

H. Existing Facility: A facility which was in operation and/or one which began the construction or renovation of a building, for the purpose of operating the facility, prior to the adoption of these standards. The licensing standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under these Standards.

I. Health Assessment: An evaluation of the health status of a staff member or volunteer by a physician, other legally authorized healthcare provider, or registered nurse, pursuant to written standing orders and/or protocol approved by a physician's signature.

J. Licensee: The individual, corporation, organization, or public entity that has been issued a license to provide care, treatment, and services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

K. Live Birth: The complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which after such expulsion or extraction, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions and respirations are to be distinguished from fleeting respiratory efforts or gasps.

L. License: A certificate issued by the Department to the licensee that authorizes the operation of a hospital or institutional general infirmary.

M. Legally Authorized Healthcare Provider: An individual authorized by law and currently licensed in South Carolina to provide specific medical treatments, care, or services to staff members and/or patients, e.g., advanced practice registered nurses, physician assistants.

N. New Facility: A facility which began operation and/or one which began construction or renovation of a building for the purpose of operating the facility after the adoption of these standards.

O. Nurse: A registered nurse, licensed practical nurse, or vocational nurse as those terms are defined by each party state's practice laws.

P. Patient: Any individual who is receiving treatment or services at the facility.

Q. Quarterly: A time period that requires an activity to be performed at least four (4) times a year within intervals ranging from eighty-one to ninety-nine (81 to 99) days.

R. External Medical Surge: Providing medical care services in an area outside of the licensed inpatient hospital building(s). For purposes of External Medical Surge, these locations are called Alternate Care Sites.

S. Internal Medical Surge: An emergency situation when a facility needs to set up and utilize beds beyond its licensed bed capacity in an area within the licensed inpatient facility building(s).

T. Inpatient Dialysis: Dialysis which, because of medical necessity, is furnished to an End-Stage Renal Disease (ESRD) patient on a temporary inpatient basis in a hospital.

U. Emergency Care: The treatment which is usually and customarily available at the respective hospital and that must be provided immediately to sustain a person's life, to prevent serious permanent disfigurement or loss or impairment of the function of a bodily member or organ, or to provide for the care of a woman in active labor and the infant.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; SCSR 42-5 Doc. No. 4740, eff May 25, 2018.

SECTION 102. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 102 was titled **INTERPRETATIONS**. See, now R 61-16 § 201, R 61-16 § 202, R 61-16 § 203.

SECTION 103. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 103 was titled **CLASSIFICATION OF LICENSES**.

SECTION 104. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 104 was titled **CERTIFICATION TO PERFORM ABORTIONS**. See, now R 61-16 § 201.

SECTION 105. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 105 was titled **PENALTIES**. See, now R 61-16 § 402.

SECTION 200
LICENSE REQUIREMENTS AND FEES

SECTION 201. License Requirements.

A. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise or market) as a hospital or institutional general infirmary in South Carolina without first obtaining a license from the Department. Admission of patients or the provision of care, treatment, and/or services to patients prior to the effective date of licensure is a violation of S.C. Code Ann. Section 44-7-260(A) (1976, as amended). (I)

B. A license shall be effective for a period of time specified by the Department.

C. A new facility, or one that has not been continuously licensed under these or prior standards, shall not admit patients until permission is granted by the Department.

D. Hospitals that provide services to patients requiring skilled nursing care must maintain a separate license for the areas where the services are provided.

E. Upon receipt of a written request from the hospital authorities to the Department requesting such certification, any general hospital having a current license to operate may be certified as a suitable

facility for the performance of abortions. A hospital shall comply with Chapter 41 of Title 44 of the S.C. Code of Laws. (1)

F. Applicants for a license shall file application under oath on a form and frequency specified by the Department. An application shall be signed/authenticated by the owner, if an individual or partnership; or in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction over it. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in case his address is different from that of the facility; the names of persons in control thereof and such additional information as the Department may require, including affirmative evidence of ability to comply with reasonable standards, rules and regulations as may be lawfully prescribed. No proposed hospital shall be named nor may an existing hospital have its name changed to the same or similar name as a hospital licensed in the State.

G. Licensing Fees. The initial and annual license fee shall be ten dollars (\$10.00) per licensed bed. Annual license fees must also include any outstanding inspection fees. Such fees shall be made payable by check or credit card to the Department.

H. A facility shall request issue of an amended license, by application to the Department prior to any of the following circumstances:

1. Change of ownership by purchase or lease;
2. Change of facility's name;
3. Addition or replacement of beds (an inspection will be required prior to issuance of license);
4. Deletion of beds; or
5. Reallocation of types of beds as shown on license.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; SCSR 42-5 Doc. No. 4740, eff May 25, 2018.

Editor's Note

Former R. 61-16 § 201 was titled **GENERAL**. See, now R 61-16 § 501.

Former R. 61-16 §§ 102, 104 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 202. Exceptions to Licensing Standards.

The Department reserves the right to make exceptions to these standards where it is determined that the health and welfare of the community requires the services of the facility. When an "exception" applies to an existing facility, it will continue to meet the standards in effect at the time it was licensed.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014. Renumbered from 61-16.203 and amended by SCSR 42-5 Doc. No. 4740, eff May 25, 2018.

Editor's Note

Former R. 61-16 § 202 was titled **Licensing Fees**, and had the following history: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; deleted by SCSR42-5 Doc. No. 4740, eff May 25, 2018.

Former R. 61-16 § 203 was titled **CHIEF ADMINISTRATIVE OFFICER**. See, now R 61-16 § 503.

Former R. 61-16 § 102 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 203. Transferred

Former R. 61-16 § 203 was titled Exceptions to Licensing Standards and had the following history: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014. Transferred by SCSR 42-5 Doc. No. 4740, eff May 25, 2018. See, now S.C. CODE REGS. 16-16 § 202.

SECTION 204. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 204 was titled **EMPLOYEES**. See, now R 61-16 § 602.

SECTION 205. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 205 was titled **VOLUNTARY WORKERS**. See, now R 61-16 § 604.

SECTION 206. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 206 was titled **REPORTS**. See, now R 61-16 § 701.

SECTION 207. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 207 was titled **DISASTER PREPAREDNESS**. See, now R 61-16 § 901.

SECTION 208. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 208 was titled **EMERGENCY CALL DATA**. See, now R 61-16 § 904.

SECTION 209. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 209 was titled **CLIENT-PATIENT PROTECTION ACT**.

SECTION 210. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 210 was titled **CONTINUITY OF ESSENTIAL SERVICES**.

*SECTION 300
ENFORCING REGULATIONS*

SECTION 301. General.

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 301 was titled **APPOINTMENTS**. See, now R 61-16 § 504.

SECTION 302. Inspections and Investigations.

A. An inspection shall be conducted prior to initial licensing. Inspections shall be conducted as deemed appropriate by the Department. (I)

B. All facilities, proposed facilities, or unlicensed facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by South Carolina Code of Laws. (II)

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records. If photocopies are made for the Department inspector, they shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. Physical area of inspections shall be determined by the extent to which there is potential impact or effect upon patients as determined by the inspector. (I)

D. A facility or proposed facility found noncompliant with the standards of this regulation shall submit an acceptable plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar); and
3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the response(s) by the facility or proposed facility, shall be provided to the public upon written request with the redaction of the names of those persons in the report as provided by S.C. Code Ann. Sections 44-7-310 and 44-7-315 (1976, as amended).

F. In accordance with S.C. Code Section 44-7-270, the Department may charge a fee for inspections. The fee for initial and biennial routine inspections shall be four hundred fifty dollars (\$450.00) plus ten dollars (\$10.00) per licensed bed. The fee for initial unit increase or service modification is two hundred fifty dollars (\$250.00) plus ten dollars (\$10.00) per licensed bed. The fee for follow-up inspections shall be two hundred fifty dollars (\$250.00) plus ten dollars (\$10.00) per licensed bed.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; SCSR 42-5 Doc. No. 4740, eff May 25, 2018.

Editor's Note

Former R. 61-16 § 302 was titled **ELIGIBILITY**. See, now R 61-16 § 504.

SECTION 303. Compliance.

A. A license shall not be issued until the licensee has demonstrated to the Department that the proposed facility is in compliance with the licensing standards. In the event a licensee who already has a facility or activity licensed by the Department makes application for another facility or activity or increase in licensed capacity, the currently licensed facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or activity or an amended license to the existing facility. Facilities shall comply with applicable State, Federal, and local laws, codes, and regulations. (II)

B. The license is considered property of the Department and may not be duplicated in such a manner that it cannot be distinguished from the original. (II)

C. Any additions or renovations to an existing facility shall be approved by the Department prior to occupancy.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 303 was titled **MEETINGS**. See, now R 61-16 § 504.

SECTION 304. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 304 was titled **TYPES OF STAFFS**. See, now R 61-16 § 504.

SECTION 305. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 305 was titled **DEPARTMENTALIZATION**. See, now R 61-16 § 504.

SECTION 306. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 306 was titled **INTERNS AND RESIDENTS**. See, now R 61-16 § 504.

SECTION 307. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 307 was titled **SUPERVISION OF PATIENT CARE**. See, now R 61-16 § 504.

SECTION 308. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 308 was titled **AVAILABILITY FOR EMERGENCIES**. See, now R 61-16 § 504.

SECTION 309. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 309 was titled **DENIAL OF EMERGENCY CARE**. See, now R 61-16 § 1214.

SECTION 400
ENFORCEMENT ACTIONS

SECTION 401. General.

A. When the Department determines that a licensee, proposed licensee, or an unlicensed facility owner is in violation of statutory provisions, rules, or regulations relating to the operation of a facility, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, revoke, or refuse to issue or renew a license.

B. Food service permits may be revoked or suspended for violations in accordance with DHEC Regulation 61-25.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 401 was titled **GENERAL**. See, now R 61-16 § 505.

SECTION 402. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health and safety of the persons in the facility or a substantial probability that death or serious physical harm could result there from. A physical condition or one (1) or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health and safety of persons in the facility. The citation of a Class II violation may specify the time within which the violation is required to be corrected. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

D. Violations of §44-7-320(A)(1)(b) and (A)(1)(d) of the South Carolina Code of Laws of 1976, as amended, are considered Class I violations.

E. The notations, “(I)” or “(II)” placed within sections of this regulation, indicate those standards are considered Class I or II violations, respectively, if they are not met. Standards not so annotated are considered Class III violations.

F. In arriving at a decision to take enforcement action, the Department will consider the following factors: the number and classification of violations, including repeat violations; specific conditions and their impact or potential impact on health and safety of the patients; efforts by the facility to correct cited violations; behavior of the licensee that would reflect negatively on the licensee’s character, such as illegal or illicit activities; overall conditions of the facility; history of compliance; any other pertinent conditions that may be applicable to statutes and regulations.

G. When a decision is made to impose monetary penalties, the Department may invoke S.C. Code Ann. Section 44-7-320(C) (1976, as amended), to determine the dollar amount or may utilize the following schedule as a guide to determine the dollar amount:

Frequency of Violation of Standard within a 24-month period	MONETARY PENALTY RANGES		
	Class I	Class II	Class III
1st	\$ 200–1000	\$100–500	\$ 100
2nd	500–2000	200–1000	100–500
3rd	1000–5000	500–2000	200–1000
4th	5000	1000–5000	500–2000
5th	5000	5000	1000–5000
6th and more	5000	5000	5000

H. In addition to or in lieu of any action taken by the Department affecting the license of any hospital, when it is established that any officer, employee, or member of the hospital medical staff has recklessly violated the provisions of Section 1210.A.5, the Department may require the hospital to pay a civil penalty of up to ten thousand dollars pursuant to 44-7-260(E).

I. Any Department decision involving the issuance, denial, renewal, suspension, or revocation of a license and/or the imposition of monetary penalties where an enforcement action order has been issued may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor’s Note

Former R. 61–16 § 402 was titled **PROFESSIONAL PERSONNEL**. See, now R 61–16 § 505.

Former R. 61–16 § 105 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 403. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor’s Note

Former R. 61–16 § 403 was titled **STAFF MEETINGS**.

SECTION 404. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor’s Note

Former R. 61–16 § 404 was titled **NURSING PROCEDURES**. See, now R 61–16 § 505.

**SECTION 500
STAFF AND TRAINING**

SECTION 501. General.

Every facility shall be organized, equipped, staffed and administered in order that adequate care may be provided for each person admitted.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 501 was titled **MAXIMUM NUMBER OF BEDS**. See, now R 61-16 § 1001.

Former R. 61-16 § 201 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 502. Control.

A. The governing body, or the owner, or the person or persons designated by the owner as the governing authority shall be the supreme authority in the hospital responsible for the management control of the hospital and appointment of the medical staff. The governing body will work with the senior managers and leaders of the organized medical staff to annually evaluate the hospital's performance in relation to its mission, vision, and goals.

B. The governing body is ultimately accountable for the safety of patients and staff and the quality of care, treatment, and services provided.

C. A written set of bylaws for operation of the hospital shall be developed by the governing authority. Committees as determined by the needs and services of the hospital shall be provided. The medical staff shall be accountable to the governing authority for the clinical and scientific work of the hospital.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 502 was titled **LOCATION OF BEDS**. See, now R 61-16 § 1001.

Former R. 61-16 § 202 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 503. Chief Executive Officer.

The Chief Executive Officer shall be the administrator of the facility and be selected by the governing body or owner and shall have charge of and be responsible for the administration of the facility in all its branches and departments and shall see that the bylaws and amendments thereto are complied with. Any change in the position of the Chief Executive Officer shall be reported immediately by the governing body or owner to the Department in writing.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 503 was titled **ROOM EQUIPMENT**.

Former R. 61-16 § 203 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 504. Medical Staff Appointment. (II)

A. The hospital shall have a medical staff organized in accordance with the facility's by-laws and accountable to the governing body including, but not limited to the quality of professional services provided by individuals with clinical privileges. Prior to a physician's initial appointment and periodic reappointment, the governing body shall assure itself that the physician is qualified and competent to practice in his profession. This organized group shall, with the approval of the hospital governing body, adopt bylaws, rules and regulations to govern its operation as an organized medical staff. Hospital bylaws shall contain renewal procedures, authority to limit or terminate staff privileges, and appeal procedures. (II)

B. To be eligible for membership on a staff an applicant must be licensed to practice in his profession in the State of South Carolina competent in his respective field, worthy in character and in matters of professional ethics, and meet the requirements of the hospital's bylaws. Medical staff membership must be limited to doctors of medicine or osteopathy by the State Board of Medical Examiners, dentists licensed to practice dentistry by the State Board of Dentistry and podiatrists licensed to practice podiatry by the State Board of Podiatry Examiners. No individual is automatically entitled to membership on the medical staff or to the exercise of any clinical privilege merely because he is licensed to practice in any state, because he is a member of any professional organization, because he is certified by any clinical examining board, or because he has clinical privileges or staff membership at another hospital without meeting the criteria for membership established by the governing body of the respective hospital.

C. The medical staff, either as a whole or on a department or clinical service basis, shall meet at a frequency as determined by the facilities policies and procedures to review and analyze their clinical experience. Written minutes of such meetings shall be recorded and filed. There shall be mechanisms in place for monitoring and evaluation of the quality of patient care services, for improving services, and for evaluation of the effectiveness of improvement efforts.

D. The governing body may establish categories for membership in the medical staff. These categories for membership shall be identified and defined in the medical staff by-laws, rules, or regulations.

E. In hospitals maintaining organized departments or services, such as medicine, surgery, obstetrics, pediatrics, orthopedics, etc., the medical staff shall elect periodically a chief of staff and staff members to be the responsible heads or chiefs for each department or service, subject to the approval of the governing body. Minutes of all department or service meetings shall be recorded and filed.

F. In compliance with such rules for professional services of resident physicians as the medical staff prescribes, the medical staff shall supervise resident physicians in the diagnosis and treatment of all patients and in the performance of any other professional duties and shall recommend them for approval or disapproval to the governing body and chief executive officer. (II)

G. All persons admitted to any facility covered by these Standards must be under the care of a person duly licensed to practice medicine, dentistry or osteopathy. Patients of podiatrists and dentists who are members of the medical staff of a hospital must be co-admitted by a doctor of medicine or osteopathy who is a member of the medical staff of the hospital who shall be responsible for the general medical care of the patient. Oral surgeons who have successfully completed a postgraduate program in oral surgery accredited by a nationally recognized accredited body approved by the U.S. Department of Education may admit patients without the requirement of co-admission if permitted by the bylaws of the hospital and medical staff. (I)

H. All hospitals shall have a licensed physician available on call at all times. (I)

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 504 was titled **OXYGEN**.

Former R. 61-16 §§ 301, 302, 303, 304, 305, 306, 307, 308 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 505. Nursing Services. (II)

A. Nursing Services shall be organized and staffed at all times to provide safe, appropriate, and individualized care to each patient. The authority, responsibility and function of all patient care providers shall be clearly defined by written hospital policy and position descriptions.

B. The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This service must be a well organized service of the hospital and under the direction of a single registered nurse. A registered professional nurse shall be designated to act in their absence. Nurses must be currently licensed in the state of South Carolina.

C. There shall be a sufficient number of duly licensed registered nurses on duty at all times provide nursing care to meet the needs of the patient population for all areas where nursing care is provided. A registered nurse must be on duty at all times.

D. Other personnel shall be employed to assist the registered nurse in providing nursing care. Licensed practical nurses and all other workers who are employed by a facility in nursing services shall be assigned based on their education, training, and competency.

E. All personnel who render nursing care services in the hospital shall be under the supervision of nursing leadership and shall be subject to all policies and procedures of the facility.

F. All nurses employed in a nursing role in a facility shall be currently licensed to practice in South Carolina.

G. A procedure manual that is in accordance with current accepted practices must be readily available to the nursing personnel.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 505 was titled **INTRAVENOUS FLUIDS**.

Former R. 61-16 §§ 401, 402, 404 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 506. Employees. (II)

A. The Chief Executive Officer shall designate an individual to conduct Human Resources Management within the organization. That individual, and other individuals as needed, shall have responsibility for hiring, personnel management, compensation and benefits, and maintenance of accurate and complete personnel records.

B. The facility shall develop and make available to the employee a written job description for each type of job in the facility. Each job description shall include a written description of the education, experience, license, certification, or other qualifications required for the position.

C. The licensee shall maintain either personnel records or a data base in accordance with all appropriate state and federal laws. The personnel records shall contain, at a minimum, the following:

1. For clinical personnel, information sufficient to verify the employee's qualifications for the job for which that individual is employed. That information includes but is not limited to: employee's education, professional certification or licensure status, other training, experience and indication of clinical competence.

2. For nursing personnel, the information shall also include either a copy of the employee's South Carolina nursing license or a multi-state compact license. Applicants shall be hired only after obtaining verification of their license from the South Carolina Board of Nursing or verification of their multi-state license from the appropriate state Board.

3. For non-clinical personnel, information regarding the employee's education, training, experience and professional competence sufficient to verify the employee's qualifications for the job for which that individual is employed. Such information shall be kept current.

4. Current information relative to periodic work performance and/or competences evaluations.

5. Records of pre-employment health screenings and of subsequent health services rendered to the employees as are necessary to determine that all facility employees are physically able to perform the essential duties of their positions.

D. The facility shall develop, establish and maintain personnel policies and practices which support sound patient care. The policies shall be in writing and made available to all employees. The policies shall be reviewed periodically but no less than annually and the date of the most recent review shall be indicated on the written policies. A procedure shall be established for notifying employees of changes in the established personnel policies.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 506 was titled **CUBICLE CURTAINS**. See, now R 61-16 § 1905.

SECTION 507. Job Orientation and In-Service Training.

A. Orientation of all new personnel shall be structured to educate them about the organization and environment of the facility, the employees' specific duties and responsibilities, and patients' needs. Each employee shall be familiar with the facility's emergency disaster plans. The hospital must ensure annual training of employees regarding emergency management, including surge policies and procedures and events that would indicate a need to implement surge policies and procedures. This requirement for job orientation may be accomplished through any combination of in-person or online sessions, completion of modules, videos, or other types of training approaches.

B. In-service training programs shall be planned and provided for all personnel to ensure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individuals attending. This requirement for in-service training may be accomplished through any combination of in-person or online sessions, completion of modules, videos, or other types of training approaches.

C. Either as a component of orientation or in a separate session, all new employees who will have contact with patients or who will handle or potentially handle blood, body fluids or tissue must receive general education regarding infection prevention and control within the hospital.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 507 was titled **MATTRESSES AND PILLOWS**.

SECTION 508. Plans and Training for Fires and Other Internal Emergencies. (II)

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire and other emergencies. All employees shall be made familiar with these plans and instructed as to required actions.

B. Each employee shall receive instructions covering fire protection training.

C. A fire drill shall be conducted for each shift at least quarterly. Records of drills shall be maintained to report the date, time, shift and a description and evaluation of the drill.

D. Drills shall be designed and conducted to:

1. Assure that all personnel are capable of performing assigned tasks or duties;
2. Assure that all personnel know the location, use and how to operate firefighting equipment;
3. Assure that all personnel are thoroughly familiar with the fire plan; and
4. Evaluate the effectiveness of plans and personnel.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 600
EMPLOYEE HEALTH (II)

SECTION 601. Employee Health Program.

A hospital shall provide an employee health program to support a safe, healthy workplace by providing timely and quality health assessments, prevention services and if needed, intervention strategies. In order to minimize the possibility of contamination and transfer of infection, the employee health program shall include the establishment of policies and monitoring procedures to ensure that all employees are free from communicable infections and open skin lesions.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 601 was titled **MEDICAL RECORDS AND REPORTS**. See, now R 61-16 §§ 1101 through 1108.

SECTION 602. New Employees.

A. To ensure that every person accepted for employment is medically capable of performing the required job duties, a new employee shall be required to satisfactorily pass a health assessment conducted prior to direct patient contact by one of the following:

1. Medical Doctor or Doctor of Osteopathy;
2. Physician Assistant;
3. Nurse Practitioner; or
4. Registered nurse, pursuant to standing orders approved by a physician as required by hospital policy by the physician. The standing orders must be reviewed annually, with a copy maintained at the facility.

B. The health assessment must ensure that all potential hospital employees are evaluated for conditions related to infectious diseases that may have an impact on patient care, the employee, or other healthcare workers. Based upon recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP) for immunization of healthcare personnel, as listed in the CDC Guideline for infection control in healthcare personnel (1998) and as amended, this evaluation must include:

1. Medical history, including immunization status and assessment for conditions that may predispose the person to acquiring or transmitting communicable diseases;
 2. Tuberculosis screening, which is performed in a manner prescribed in the CDC and the Department's most current tuberculosis guidelines; and
 3. Serologic screening for vaccine-preventable diseases, as deemed appropriate by the hospital.
- C. The hospital must provide evidence of education of employees about influenza vaccination and must offer the influenza vaccine to these persons.
- D. Employee health programs must provide evidence of ongoing review and monitoring of both CDC and the Department recommendations and updates and methods for revising the programs as needed.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 602 was titled **LABORATORY**. See, now R 61-16 § 1202.

Former R. 61-16 § 204 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 603. Employee Records.

A. All employee health records, including any medical history, shall be retained in a separate and confidential file in Employee Health. Access to these records will be permitted only to those authorized through hospital policy.

B. The hospital shall have policies and procedures for the maintenance and destruction of employee health records after employment has been terminated.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 603 was titled **RADIOLOGY**. See, now R 61-16 § 1203.

SECTION 604. Volunteer Workers. (II)

A. All volunteer workers who handle food or provide patient care shall have a physical examination prior to their initial food handling or patient care activity.

B. For patient care volunteers, the tuberculin testing and treatment program described in Section 602.B also applies.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 604 was titled **PHARMACEUTICAL SERVICES**. See, now R 61-16 §§ 1204 through 1207.

Former R. 61-16 § 205 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 605. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 605 was titled **CENTRAL SUPPLY**. See, now R 61-16 § 1208.

SECTION 606. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 606 was titled **SURGERY**. See, now R 61-16 §§ 1209, 1210, 1211.

SECTION 607. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 607 was titled **ORGANIZATION (II)**. See, now R 61-16 §§ 1305, 1306.

SECTION 608. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 608 was titled **PERSONNEL (I)**. See, now R 61-16 §§ 1307, 1308.

SECTION 609. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 609 was titled **GENERAL FACILITY AND CARE REQUIREMENTS**. See, now R 61-16 §§ 1309 through 1312.

SECTION 610. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 610 was titled **EVALUATION OF PERINATAL CARE (II)**. See, now R 61-16 § 1313.

SECTION 611. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 611 was titled **ANESTHESIA**. See, now R 61-16 § 1212.

SECTION 612. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 612 was titled **OUTPATIENT DEPARTMENT**. See, now R 61-16 § 1213.

SECTION 613. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 613 was titled **EMERGENCY SERVICES**. See, now R 61-16 § 1214.

SECTION 614. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-614 § 102 was titled **DENTAL SURGERY**. See, now R 61-16 § 1216.

SECTION 615. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-615 § 102 was titled **PHYSICAL THERAPY**. See, now R 61-16 § 1217.

SECTION 616. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-616 § 102 was titled **OCCUPATIONAL THERAPY**. See, now R 61-16 § 1218.

SECTION 617. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 617 was titled **PSYCHIATRIC SERVICE**. See, now R 61-16 § 1219.

SECTION 618. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-618 § 102 was titled **CHEMICAL AND SUBSTANCE ABUSE TREATMENT SERVICE**. See, now R 61-16 § 1220.

SECTION 619. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 619 was titled **PEDIATRICS**. See, now R 61-16 § 1221.

SECTION 700
REPORTING (II)

SECTION 701. Fire Report.

The Department shall be notified immediately regarding any fire, regardless of size or damage that occurs in the facility, and followed by a complete written report to include fire department reports, if any, to be submitted within a time period determined by the facility, but not to exceed 7 business days.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 701 was titled **GENERAL**. See, now R 61-16 § 1401.

Former R. 61-16 § 206 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 702. Accident and/or Incident Report.

A. A record of each accident and/or incident occurring in the facility, including serious medication errors and adverse drug reactions, shall be retained. Incidents resulting in death or serious injury shall be reported, in writing, to the Department within 10 days of the occurrence. Information included in a facilities' report that is acquired from a peer review committee shall maintain its privilege pursuant to S.C. Code of Laws Sections 40-71-20, 44-30-60, and 44-7-315. However, the duty of hospitals to report serious accidents and incidents is not affected by any privilege or confidentiality. The following incidents, including but not limited to those stated, shall be reported:

1. Suicides.
2. Wrong site surgery.
3. Medication errors resulting in death or serious injury.
4. Major fractures or head injuries resulting from falls or other events.
5. Patient death or serious injury resulting from being in a restraint.
6. Criminal events and assaults.
7. Transfusion errors.
8. Neonatal injuries.
9. Maternal deaths or injuries.
10. Elopement events.
11. Anesthesia-related events resulting in death or serious injury.
12. Ventilator errors resulting in death or serious injury.
13. Infant abductions.

B. Reports submitted to the Department shall contain at a minimum: facility name, patient age and sex, date of incident, location, witness names, extent and type of injury and how treated, *e.g.*, hospitalization, identified cause of incident, internal investigation results if cause unknown, identity of other agencies notified of incident and the date of the report.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 702 was titled **BIRTH CERTIFICATES**. See, now R 61-16 § 1402.

SECTION 703. Facility Closure.

A. Prior to the permanent closure of a facility, the Department shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the facility shall notify the Department of the provisions for the maintenance of the records, the identification of displaced patients, the relocated site, and the dates and amounts of patient refunds. On the date of closure, the license shall be returned to Department.

B. In instances where a facility temporarily closes, the Department shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the location where the patients have been/will be transferred, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards of the facility prior to its reopening. If the facility is closed for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 703 was titled **DEATH CERTIFICATES**. See, now R 61-16 § 1403.

SECTION 704. Zero Census.

In instances when there have been no patients in a facility for any reason for a period of 90 days or more, the facility shall notify the Department in writing that there have been no admissions, no later than the 100th day following the date of departure of the last active patient. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the facility prior to any new and/or re-admissions to the facility. If the facility has no patients for a period longer than one year, and there is a desire to admit a patient, the facility shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 705. Joint Annual Report.

The Department requires each health care facility to annually complete a questionnaire named "Joint Annual Report" and return this report within the time period as specified in the report's accompanying cover letter.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 706. Hospital Infections Disclosure Act (HIDA) & Reporting Requirements.

(I)

A hospital is required to collect data and submit reports to the Department on hospital acquired infection rates to be in compliance with S.C. Code of Laws Sections 44-7-2410 through 44-7-2460. Hospitals are also required to report methods and adequacy of selected infection control processes. The Department will notify hospitals annually about the current HIDA reporting requirements and the methods for submitting those reports to the Department.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

*SECTION 800
REQUIREMENTS OF THE LEWIS BLACKMAN ACT (I)*

SECTION 801. Compliance.

In order to be in compliance with The Lewis Blackman Hospital Patient Safety Act, hospitals are required to:

A. Identify all clinical staff, clinical trainees, medical students, interns, and resident physicians as such with identification badges that include their names, their departments, and their job or trainee titles.

B. Institute a procedure whereby a patient may request that a nurse call his or her attending physician regarding the patient's personal medical care.

C. If the patient is able to communicate with and desires to call his or her attending physician or designee, upon the patient's request, the nurse must provide the patient with the telephone number and assist the patient in placing the call.

D. Provide a mechanism, available at all times, and the method for accessing it, through which a patient may access prompt assistance for the resolution of the patient's personal medical care concerns.

E. Establish procedures for the implementation of the mechanism providing for initiation of contact with administrative or supervisory clinical staff who shall promptly assess the urgent patient care concern and cause the patient care concern to be addressed.

F. Provide to each patient prior to, or at the time of the patient's admission to the hospital for inpatient care or outpatient surgery, written information describing the general role of clinical trainees, medical students, interns, and resident physicians in patient care.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 801 was titled **APPROVAL**. See, now R 61-16 § 1501.

SECTION 802. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 802 was titled **SERVICES**. See, now R 61-16 § 1502.

SECTION 803. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 803 was titled **SUPERVISION**. See, now R 61-16 § 1503.

SECTION 804. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 804 was titled **PERSONNEL**. See, now R 61-16 § 1504.

SECTION 805. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 805 was titled **DIETS**. See, now R 61-16 § 1505.

SECTION 806. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 806 was titled **PLANNING OF MENUS AND FOOD SUPPLIES**. See, now R 61-16 § 1506.

SECTION 807. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 807 was titled **PREPARATION AND SERVING OF FOOD**. See, now R 61-16 § 1507.

SECTION 808. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 808 was titled **DIETARY AND FOOD SANITATION**. See, now R 61-16 § 1508.

SECTION 809. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 809 was titled **MEAL SERVICE**. See, now R 61-16 § 1509.

SECTION 810. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 810 was titled **REFRIGERATION AND ICE**. See, now R 61-16 § 1510.

SECTION 900
DISASTER MANAGEMENT (II)

SECTION 901. Emergency Evacuation.

A. All facilities shall develop, by contact and consultation with their county emergency preparedness agency, a suitable written plan for actions to be taken in the event of a disaster and/or emergency evacuation. In the event of mass casualties, the facility shall provide resources as available. Additionally, in instances where there are applications for increases in licensed bed capacity, the emergency evacuation plan shall be updated to reflect the proposed new total licensed bed capacity. The plan shall be updated, as appropriate, annually, or as needed.

B. Each facility shall maintain a means of communication with their local emergency management agency that is capable of transmitting information and/or data during periods when normal communication systems are inoperable. The facility shall also maintain a back-up system. Both systems shall be exercised periodically.

C. Each facility shall operate under an incident command system that is in compliance with FEMA's National Incident Management System (NIMS), and the Hospital Incident Command System (HICS).

D. Annually, prior to June 1st of each year, each facility shall validate/provide the Department the information required by the Department's Critical Data Sheet (CDS) Information system. Hospital data provided to the CDS system will assist the Department, during times of disaster and emergencies, determine the appropriateness of evacuation or shelter-in-place. The disaster/emergency evacuation plan shall include, but not be limited to:

1. A sheltering plan to include:

a. Name, address and phone number of the sheltering facility(ies) to which the patients will be relocated during a disaster; and

b. A letter of agreement signed by an authorized representative of each sheltering facility which shall include: the number of relocated patients that can be accommodated; sleeping, feeding, and medication plans for the relocated patients; and provisions for accommodating relocated staff members. The letter shall be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Horry, Jasper, and Georgetown counties, at least one (1) sheltering facility shall be located in a county other than these counties.

2. A transportation plan, to include agreements with entities for relocating patients, which addresses:

a. The relocation needs of the patients and staff contingent upon the type of disaster/emergency confronted;

b. Procedures for providing appropriate medical support, food, water and medications during relocation based on the needs and number of the patients;

- c. Estimated time to accomplish the relocation during normal conditions; and
 - d. Primary and secondary routes to be taken to the sheltering facility.
- 3. A staffing plan for the relocated patients, to include:
 - a. How care will be provided to the relocated patients, including facility staff members that will accompany patients who are relocated;
 - b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility; and
 - c. Co-signed statement by an authorized representative of the sheltering facility if staffing, bedding, or medical supplies are to be provided by the sheltering facility.
- E. Each facility shall validate/provide the Department the information in Section 901.D. no less than annually.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 901 was titled **MAINTENANCE**. See, now R 61-16 § 1600.
Former R. 61-16 § 207 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 902. Internal Medical Surge.

- A. It is the responsibility of the facility to know what areas are within the licensed inpatient building(s). If a hospital needs to set up and utilize beds in an area outside of the licensed inpatient hospital building(s), it must follow Section 903 of this regulation.
- B. A facility desiring to activate internal medical surge and temporarily admit patients in excess of licensed bed capacity due to an emergency should do the following:
 - 1. Request that the Department concur that an emergency situation exists.
 - 2. During the call to the Department, the facility should be prepared to:
 - a. Describe the emergency situation;
 - b. Outline the maximum number of patients to be temporarily admitted;
 - c. Provide an anticipated date for discharge of the temporary patients; and
 - d. Describe how and where the temporary patients will be housed.
 - 3. Patients temporarily admitted during the emergency situation will not be required to undergo tuberculin screening or submit to an admission history and physical examination.
 - 4. The facility must notify the Department when the patient census has returned to, or moves below, normal bed capacity by discharge or transfer to licensed beds.
- C. If the event occurs after normal business hours, the Department must be contacted promptly during the next business day.
- D. Other issues such as staffing for the care of the temporary patients, physicians' orders, additional food for the temporary patients and handling of medications should be resolved ahead of time by memorandum of agreements, internal policies and procedures, and emergency planning documents.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 903. External Medical Surge.

- A. Some emergency situations might overwhelm a hospital's plans for Internal Medical Surge or render the licensed inpatient hospital building(s) unusable. In such situations, a hospital may activate External Medical Surge and operate an Alternate Care Site (ACS) under the authority of its license during an emergency situation such as a mass casualty event or facility evacuation.
- B. If a hospital desires to be approved to operate an ACS, the hospital must contact the Department for current requirements and guidance in planning.
 - 1. In order to facilitate activation of an ACS, hospitals are advised to conduct an assessment of the proposed ACS location utilizing the Department's Alternate Care Site Preliminary Assessment Form. The Department will not authorize activation of an ACS until the hospital has provided

assessment information. Every ACS shall be planned, designed, and equipped to provide adequate accommodations for the care, safety, and treatment of each patient. Buildings selected for ACS should comply with the local building codes and ordinances applicable to the buildings' original intended use. It is the hospital's responsibility to use the assessment process to assure that an ACS building is in compliance with local codes and has the structural soundness and capacity to provide patient treatment contemplated by the hospital.

2. The Social Security Act contains a provision that allows an emergency waiver of the Emergency Medical Treatment and Active Labor Act (EMTALA) requirements that hospitals accept certain patients until stabilized. See 42 U.S.C. Section 1320b-5. In order for South Carolina hospitals with an ACS to qualify for these waiver provisions, hospitals should provide documentation from the DHEC Regional Public Health Preparedness Director that the ACS location can be identified as an alternative location for the direction or relocation of individuals to receive medical screenings under a State emergency and pandemic preparedness plans.

3. Once a location has been identified, the Department will meet with hospital staff to discuss the details of the ACS. When appropriate, the Department will send the requesting hospital a letter confirming that the location has been identified for future use as an ACS. The location will retain its status as an ACS unless modifications are made to the site. Modifications that might affect the use of an ACS include, but are not limited to, renovations, construction, demolition, or change of ownership. Any modifications to the site should be reported in writing to the Department. Because changes to a site could affect its use as an ACS, hospitals are encouraged to construe the term "modifications" broadly.

C. Alternate Care Sites can only be operated during emergency situations and activation must be coordinated with the Department. To activate an ACS, the hospital's census must be projected to surge beyond its Internal Medical Surge capacity or the hospital's main building, or a portion of the building, must be rendered unusable.

D. A facility desiring to activate External Medical Surge and activate an Alternate Care Site due to an emergency situation shall do the following:

1. Request that the Department concur that an emergency situation does exist.
2. As part of the activation process, the hospital shall be prepared to:
 - a. Describe the emergency situation;
 - b. Explain why activating Internal Medical Surge will not address the situation;
 - c. Identify the ACS;
 - d. Outline the maximum number of patients to be treated at the ACS; and
 - e. Provide an anticipated date for discontinuance of the ACS.

E. Immediately following activation with the Department, the hospital shall notify the DHEC Regional Emergency Point of Contact for possible coordination of activities under State emergency, pandemic preparedness, or mass casualty response plans.

F. After the emergency situation is over, the hospital must notify the Department when the ACS is closed.

G. Other issues such as staffing, food service, equipment requirements, medication management, medical records, and physicians' orders should be resolved ahead of time by memorandum of agreements, internal policies and procedures, and emergency planning documents.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 904. Emergency Call Data. (I)

Emergency call information shall be immediately available to personnel in charge on each unit when needed. Emergency call data shall include at least the following information:

- A. Non emergency telephone numbers of fire and police departments;
- B. Name, address, and telephone number of all personnel to be called in case of fire or emergency;
- C. Name, address, and telephone number of physician on call;
- D. Name, address, and telephone number of supervisory personnel when on call; and

E. Address and telephone number of a poison control center.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 208 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 905. Security.

In order to assure the safety and well-being of all patients, staff, and visitors, the administration shall conduct an annual risk assessment to identify potential areas or situations that may cause harm or where an incident may occur. Based upon the findings of that assessment, the administration shall develop and implement a plan to provide for the appropriate level of security necessary.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

*SECTION 1000
ACCOMMODATIONS FOR PATIENTS (II)*

SECTION 1001. Maximum Number of Beds.

A. No facility shall have set up or in use at any time more beds than the number stated on the face of the license except in cases of justified emergencies. The following categories of beds are not chargeable to the licensed number:

1. Labor room;
2. Newborn nursery;
3. Recovery room;
4. Emergency room treatment;
5. Classroom use only.

B. Neonatal special care beds will be shown on the face of the license in addition to the licensed bed capacity.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1001 was titled **LAUNDRY**. See, now R 61-16 § 1805.

Former R. 61-16 § 501 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1002. Location of Beds.

A. In semi-private and multi-bed rooms there shall be curtains or other means of providing privacy that completely shield the patient.

B. Beds shall not be placed in corridors, solaria or other locations not designed as patient room areas except in cases of justified emergencies.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1002 was titled **OPERATED BY HOSPITAL**. See, now R 61-16 § 1805.

Former R. 61-16 § 502 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1003. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1003 was titled **STORAGE**. See, now R 61-16 § 1805.

SECTION 1004. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1004 was titled **CLEAN LINEN**. See, now R 61-16 § 1805.

SECTION 1005. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1005 was titled **SOILED LINEN**. See, now R 61-16 § 1805.

SECTION 1100
MEDICAL RECORDS (II)

SECTION 1101. Physician's Responsibility.

It shall be the responsibility of each physician to complete and authenticate the medical record within a stipulated time after discharge, not to exceed 30 days after discharge.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1101 was titled **HOUSEKEEPING**. See, now R 61-16 § 1701.

Former R. 61-16 § 601 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1102. Organization.

The responsibility for supervision, filing, indexing, maintenance and storage of medical records shall be assigned to a responsible employee of the hospital who has had training in this field.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1102 was titled **REFUSE DISPOSAL**. See, now R 61-16 § 1702.

Former R. 61-16 § 601 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1103. Indexing.

Medical records shall be properly indexed, organized, filed and ready for access by members of the staff.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 601 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1104. Ownership.

Medical records of patients are the property of the organization and must not be released from the hospital's authority or control except by court order.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 601 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1105. Contents.

A. Each entry in the medical records must be legible, dated, timed and signed/authenticated by the clinician or designee that created the entry. A medical record must be created for all patients admitted to the hospital and newborns delivered in the hospital. Initials will be accepted provided such initials can be readily identified within the medical record. A minimum medical record shall include the following information:

1. An admission record must be prepared for each patient and must contain the following information, when obtainable: Name; address, including county; occupation; age; date of birth; sex; marital status; religion; county of birth; father's name; mother's maiden name; husband's or wife's name; dates of military service; health insurance number; provisional diagnosis; case number; days of care; social security number; the name of the person providing information; name, address and telephone number of person or persons to be notified in the event of emergency;

name and address of referring physician; name and address and telephone number of attending physician; date and hour of admission;

2. History and physical within 48 hours after admission;
3. Provisional or working diagnosis;
4. Pre-operative diagnosis;
5. Plan of care;
6. Complete surgical record, if any, including technique of operation and findings, statement of tissue and organs removed and post-operative diagnosis;
7. Report of anesthesia;
8. Nurses' notes;
9. Progress notes;
10. Gross pathological findings and microscopic, if applicable;
11. Vital signs and other measurements appropriate to patient;
12. Medication Administration Record or similar document for recording of medications, treatments and other pertinent data. This record shall be signed/authenticated after each medication administered or treatment is rendered;
13. Final diagnosis and discharge summary;
14. Date and time of discharge summary;
15. In case of death, cause and autopsy findings, if autopsy is performed, unless the death becomes subject to review by the coroner's office, and;
16. Special examinations, if any, e.g., consultations, clinical laboratory, x-ray and other examinations.

B. Contingent upon the availability of pertinent information in the perinatal records of the mother, newborn records should include the following:

1. History of hereditary conditions in mother's and/or father's family;
2. First day of the last menstrual period (L.M.P.) and estimated day of confinement (E.D.C.);
3. Mother's blood group and RH type - evidence of sensitization and/or immunization (such as, administration of anti-D hyperimmune globulin);
4. Serological test including dates performed for syphilis, HIV, Rubella, and Hepatitis B, results of any other tests performed during pregnancy (e.g., Group B Strep, Chlamydia, Gonorrhea, Herpes);
5. Number, duration and outcome of previous pregnancies, with dates;
6. Maternal disease (e.g., diabetes, hypertension, pre-eclampsia, infections);
7. Drugs taken during pregnancy, labor and delivery;
8. Results of measurements of fetal maturity and well-being (e.g., lung maturity and ultrasonography);
9. Duration of ruptured membranes and labor, including length of second stage;
10. Method of delivery, including indications for operative or instrumental interference;
11. Complications of labor and delivery (e.g., hemorrhage or evidence of fetal distress), including a representative strip of the fetal ECG if recorded;
12. Description of placenta at delivery, including number of umbilical vessels;
13. Estimated amount and description of amniotic fluid;
14. Apgar scores at one and five minutes of age. Description of resuscitations, if required, detailed description of abnormalities and problems occurring from birth until transfer to the special nursery or the referral facility;
15. Results and date specimen was collected for neonatal testing to detect inborn metabolic errors and hemoglobinopathies, including PKU, hypothyroidism and various other metabolic disorders.

Exception: Parents may object because of religious grounds only, and in writing using a form promulgated by the Department; and

16. Results and dates of pulse oximetry screening and/or follow up of evaluation for critical congenital heart defects.

Exception: Parents may object only in writing to the screening for reason pertaining to religious beliefs.

C. When restraints are utilized, there must be an order to include length of time to be used and signed/authenticated by the legally authorized healthcare provider approving use of restraint or seclusion either at the time they are applied to a patient, or in case of emergency, within 24 hours after they have been applied. Each procedure manual shall contain information and instructions on the specific types of safety precautions that may or may not be used.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 601 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1106. Orders for Medication and Treatment.

All medical records shall contain the necessary consent forms for the treatment provided, along with orders for medication and treatment, signed/authenticated and dated by the prescriber or his designee. All orders, including verbal orders, shall be properly recorded in the medical record, dated and signed/authenticated by the prescriber within 30 days.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 601 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1107. Storage.

A. Provisions shall be made by the hospital for the storage of medical records in an environment which will prevent unauthorized access and deterioration. The records shall be treated as confidential and shall not be disposed of before 10 years. Records may be destroyed after 10 years provided that:

1. Records of minors must be retained until after the expiration of the period of election following achievement of majority as prescribed by statute; and
2. The hospital retains a register, either electronic or paper based.

B. Facilities that store records in a format other than paper, such as, but not limited to, microfilm, before 10 years have expired must include the entire record.

C. In the event of change of ownership, all medical records shall be transferred to the new owners.

D. Prior to the closing of a hospital for any reason, the facility shall arrange for preservation of records to ensure compliance with these regulations. The facility shall notify the Department, in writing, describing these arrangements.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 601 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1108. Information to be Provided to Other Health Care Providers.

In order to contribute to the continuity of quality of care, procedures must be established and implemented to provide discharge summaries and/or other appropriate information to health care providers to whom patients are discharged, transferred or referred.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 601 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1109. Maintenance and Disposal.

Records shall be maintained and disposed of as specified in Section 1107.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1110. Access to Medical Records.

Only authorized personnel should have access to medical records and a hospital shall have policies and procedures to assure that a patient's protected health information is private. The patient shall have access to his/her clinical records within a reasonable timeframe and a hospital shall have a process in place to facilitate that access if requested.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1200 PATIENT CARE AND SERVICES

SECTION 1201. Medications. (I)

A. Drugs and biologicals must be prepared and administered in accordance with the orders of the legally authorized healthcare provider(s) responsible for the patient's care as specified under the hospital's governing body as it pertains to the care of the patient. All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with approved medical staff policies and procedures.

B. Student nurses may only administer medications under the direct supervision of a registered nurse who is the student's instructor and/or preceptor. The medical record must be signed/authenticated by both parties.

C. Self-administration of medications by patients may be permitted only when specifically ordered by the legally authorized healthcare provider in writing and the medications have been reviewed by a Registered Pharmacist prior to administration.

D. Medication variances and adverse drug reactions shall be reported immediately to the prescriber, supervising nurse and pharmacist, and recorded in the patient's medical record.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1201 was titled **ARRANGEMENTS FOR FIRE DEPARTMENT PROTECTION.**

SECTION 1202. Laboratory. (II)

A. Organization:

1. The hospital must have laboratory services available, either on site or through a contractual agreement with a certified laboratory whose services are provided in accordance with Clinical Laboratory Improvement Amendments (CLIA) requirements and possess a current CLIA certificate.

2. The laboratory shall be under the supervision of a laboratory director with training in clinical laboratory procedures.

3. Laboratory personnel shall be qualified by education, training and experience for the type of services rendered.

B. The laboratory shall:

1. Have appropriate and sufficient equipment, instruments, reagents, materials and supplies for the type and volume of testing performed.

2. Ensure the quality of testing through monitoring of analytical performance, quality control, proficiency testing and quality improvement activities and as defined by CLIA regulations.

3. Include safety procedures, engineering controls and personal protective equipment readily available, maintained, inspected and utilized to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

4. Include records and materials maintained and stored under conditions that ensure proper preservation.

5. Include a procedure manual for the complete collections and handling instructions for all laboratory specimens, and there must be documentation of an annual review.
 6. Perform proficiency testing and have written procedures sufficient for the extent and complexity of testing performed in the laboratory.
 7. Have a clearly defined policy and procedure outlining ongoing monitoring of analytical performance, including:
 - a. Number and frequency of controls,
 - b. Tolerance limits and,
 - c. Corrective actions based on quality control data.
 8. The following clinical laboratory services must be available twenty-four (24) hours a day:
 - a. Chromosome analysis;
 - b. Viral Culture; and
 - c. Emergency laboratory services must be available either on-site or via contractual agreement twenty-four (24) hours per day, seven (7) days a week.
- C. The laboratory must be constructed, arranged and maintained to ensure adequate and safe space, ventilation and utilities necessary for all phases of the testing and to minimize contamination.
- D. The governing body shall approve the pathologist or physician as physician-in-charge or Medical Director of blood bank and transfusion services.
- E. Hospitals which provide procurement, storage and transfusion of blood shall have acceptable facilities, including a refrigerator, for whole blood. The temperature shall be maintained at 2 to 6 degrees C. or 36 to 43 degrees F., and no foods may be kept in this refrigerator. Standards of the American Association of Blood Banks, as outlined in the most current edition of Standards for a Blood Transfusion Service, will be used as a guide for licensing purposes.
- F. Records shall be kept on file indicating the receipt and disposition of all blood handled. Care shall be taken to ascertain that blood administered has not exceeded its expiration date, and meets all criteria for safe administration.
- G. The facility shall make arrangements to secure on short notice all necessary supplies of blood, typed, and crossmatched as required, for emergencies.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1202 was titled **TESTS AND INSPECTIONS**.

Former R. 61-16 § 602 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1203. Radiology. (II)

- A. Imaging services shall be under the supervision of a full-time radiologist, consulting radiologist, or a physician experienced in the particular imaging modality and the physician in charge must have the credentials required by facility policies.
- B. Activities of the imaging service may include radio-therapy.
- C. All imaging equipment shall be operated by personnel trained in the use of imaging equipment and knowledgeable of all applicable safety precautions required by the Department. Copies of additional regulations are available from the Department.
- D. A written, signed/authenticated report on each x-ray or diagnostic image and therapy treatment shall be made a part of the patient's record; copies of the report shall be readily accessible in the imaging department. Each request for x-ray or diagnostic image examination shall include a concise statement of the reason for the examination.
- E. The length of time that an x-ray image shall be kept on file shall be determined by the individual hospital. For its own protection, every hospital should consult with its legal counsel before selling or disposing of film.
- F. Patients and employees shall be provided protection from radiation in accordance with current practices outlined by the Department.

G. Ultrasound and echocardiogram services shall be available within one hour on a twenty-four (24) hour basis.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1203 was titled **SPECIAL HAZARDS**.

Former R. 61-16 § 603 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1204. Pharmacy Services. (I)

A. The pharmaceutical service shall be directed by a registered pharmacist either on a full or part-time basis. The pharmacist directing the pharmaceutical services is responsible to the administration of the hospital for developing, supervising and coordinating all of the activities of the pharmacy department, which should include, but are not limited to, the following:

1. Dispensing medications in such form that will minimize additional preparation before administering to the patient.
2. Monitoring all medication orders to ensure that clinically significant chemical and therapeutic incompatibilities within the patient's drug regimens are reported to the prescribing physician.
3. Providing education programs for the facility's personnel and counseling patients regarding their medications, including their safe use.
4. Providing a method by which medications can be obtained during the absence of a pharmacist in the facility in such a manner that will minimize the potential for medication error and assure control and accountability of any drugs. A pharmacist shall be available on an on-call basis at all times.
5. Assisting in the formulation of professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures relating to drugs in the facility.
6. Monthly review of drugs and drug records in all locations in which drugs are stored, including, but not limited to, nursing stations, emergency rooms, outpatient departments, operating suites, emergency kits, etc.

B. Each institutional pharmacy shall be directed by a pharmacist, herein after referred to as the pharmacist-in-charge, who is licensed to engage in the practice of pharmacy in this state.

C. The pharmacist-in-charge must be assisted by a sufficient number of licensed pharmacists and registered pharmacy technicians as may be required to competently and safely provide pharmacy services.

D. The pharmacist-in-charge shall maintain and file with the Board of Pharmacy on a form provided by the board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 604 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1205. Drug Distribution and Control.

The pharmaceutical service shall have written policies and procedures for control and accountability, drug distribution, and assurance of quality of all drugs and biological products throughout the hospital. The pharmacist-in-charge shall provide the current license for the institutional pharmacy from the SC Board of Pharmacy, the individual's professional license, and the professional licenses of all personnel working within the pharmacy upon request of the Departments inspectors. The pharmacist-in-charge of an institutional pharmacy shall establish written policies and procedures to provide for access to drugs by the medical staff whenever a licensed pharmacist is not physically present in an institutional facility by use of night cabinets and/or by access to the pharmacy. A licensed pharmacist must be on call at all times.

A. A record of the stock and distribution of all controlled substances in Schedule II shall be maintained in such a manner that the disposition of any particular item may be readily traced. All such records shall be maintained in compliance with the requirements of the Federal and State Controlled Substances Acts.

B. Records for investigational drugs shall be maintained in the pharmacy in compliance with the Federal Food and Cosmetic Act Regulations.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1205 was titled **EXIT SIGN ILLUMINATION**.

Former R. 61-16 § 604 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1206. Physical Facilities and Storage.

A. Drug storage on the nursing units shall be reviewed monthly by the pharmacist or a properly trained individual designated by the pharmacist; a record of each review shall be maintained. All floor stocks shall be properly controlled. Medications requiring refrigeration shall be kept in a secured refrigerator used exclusively for medications, or in a secured manner in which medications are separated from other items kept in a refrigerator (e.g. Lock Box). Refrigerators shall be provided with a thermometer accurate to plus or minus 2 degrees F. Documentation of appropriate temperature control is required by manual or electronic means.

B. Pharmacy practice shall be governed by the SC Board of Pharmacy Practice Act as detailed in the S.C. Code of Laws. If services are provided at more than one location, each location must be permitted by the SC Board of Pharmacy.

C. Only personnel approved by the hospital administrator or his/her designees shall have access to the pharmacy.

D. Emergency boxes, kits or (crash) carts shall be sealed and, when not in actual use, stored either in a secured area or under visual control from the nurses' station. The contents of these containers shall be approved by the appropriate committee of the facility. An inventory list of the contents shall be maintained in or on the container.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1206 was titled **HALLWAY AND STAIRWAY ILLUMINATION**.

Former R. 61-16 § 604 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1207. Labeling of Medications. (I)

A. Any medication administered to inpatients shall be identified with its name and strength labeled on the container in which it is provided or on each single unit package. The labeling of medications administered to inpatients shall be in compliance with applicable Federal, State, and local laws and regulations. The labeling information may also be available through electronic means.

B. Labeling of drugs dispensed to outpatients shall be in compliance with applicable federal, state, and local laws and regulations.

C. Outdated or discontinued medications shall be returned to the pharmacy for proper disposition in accordance with good pharmaceutical practice and facility policy. Medications that have been subjected to contamination shall not be redispensed.

D. Unused medications may be turned over to the patient for whom prescribed on discharge only on the written order of the attending physician. Such medications must be returned to the pharmacy to be labeled in accordance with Section 1207.A before release.

E. Medical staff in conjunction with the pharmacist in charge shall establish policy and procedure when certain medications not specifically prescribed as to time or number of doses will be automatically stopped after a time limit set by the medical staff.

F. Multi-dose vials shall be labeled with the date and time when opened.

G. Up-to-date reference materials shall be readily available.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1207 was titled **PLANS AND TRAINING FOR FIRES AND OTHER INTERNAL EMERGENCIES**.

Former R. 61-16 § 604 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1208. Central Supply. (I)

A. The department head shall be qualified for the position by education, training and experience as determined by the hospital policies and procedures. (II)

B. The number of supervisory and other personnel shall be related to the scope of the services provided. (II)

C. There shall be written policies and procedures for the decontamination and sterilization activities performed in central supply and elsewhere in the hospital. These policies and procedures shall relate, but are not limited to the following:

1. The use of sterilization process monitors, including temperature and pressure recordings, and the use and frequency of appropriate chemical indicator and bacteriological spore tests for all sterilizers.

2. Designation of the shelf life for each hospital-wrapped and hospital-sterilized medical item and, to the maximum degree possible, for each commercially prepared item, by a specific expiration date that sets a limit on the number of days an item will be considered safe for use. When possible, load control numbers shall be used to designate the sterilization equipment used for each item, including the sterilization date and cycle.

D. A recognized method of checking sterilizer performance shall be used. A chemical indicator of some type should be included in the largest package of each load. Biological indicators (live bacterial spores) should be included in all steam and hot air sterilizers at least once per week or more often depending upon the degree of sterilizer usage. Gas sterilizers should employ such indicators on at least a weekly basis and preferably on a daily basis. Further, the gas sterilization of implants, prosthetic devices, etc., should be accompanied by a biological monitor in each load. Monthly checks shall be made to ensure the above, and a written report retained.

E. Adequate precautions shall be taken to ensure that sterile supplies and equipment are not mixed with unsterile material. Suitable space shall be provided for keeping equipment and supplies in a clean, convenient and orderly manner.

F. All packaged supplies and containers for solutions, drugs, medicated supplies, etc., shall be labeled so as to remain plainly legible before and after sterilization. Labels shall include at least the expiration date of the contents.

G. Outdated medical supplies, solutions, etc., shall be returned to central supply for resterilization or disposal.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 605 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1209. Surgery. (II)

A. The surgical service shall be under the supervision of a member of the active staff of physicians.

B. The operating rooms must be supervised by a registered nurse or a doctor of medicine or osteopathy.

C. Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

D. Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and

surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse.

E. Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

F. Hospitals providing surgery should have available consulting physicians to address additional patient needs.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 606 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1210. Facilities.

The operating rooms shall be separated from non-sterile areas and shall be located so as not to be used as a passageway between, or subject to contamination from, other parts of the hospital.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 606 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1211. Equipment. (I)

A. Hospitals shall provide surgical equipment and instruments in good repair and free of potentially harmful microorganisms to assure safe and aseptic treatment. Any indication of contamination shall be immediately called to the attention of the nursing supervisor and the physician in charge of the service.

B. Life support and medical gas equipment shall be readily available and functional.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 606 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1212. Anesthesia. (I)

A. Anesthesia shall be administered according to the South Carolina Code of Laws and the South Carolina Code of State Regulations by:

1. A qualified anesthesiologist;
2. A doctor of medicine or osteopathy other than an anesthesiologist;
3. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
4. A certified registered nurse anesthetist (CRNA), as defined in S.C. Code Ann. Section 40-33-20(20), is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or
5. An anesthesiologist's assistant, as defined in S.C. Code Ann. Section 40-47-1210(2), who is under the supervision of an anesthesiologist who is immediately available if needed.

B. The organization of anesthesia services must be appropriate to the scope of the services offered.

C. Operations under a general anesthetic shall not be performed nor a general anesthetic given until the patient has had a physical examination except in emergency situations. The results of these examinations shall be entered in the patient's record. The history and physical must be readily available in the patient medical record.

D. Anesthesia apparatus shall be equipped with a device to measure the oxygen concentration of the gas being inhaled by the patient. The device shall emit an audible and/or visual alarm should the proportion of oxygen fall below a safe level.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 611 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1213. Outpatient Services. (II)

A. If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice. Outpatient services must be appropriately organized and integrated with inpatient services. The hospital must assign one or more individuals to be responsible for outpatient services and have appropriate professional and nonprofessional personnel available.

B. If the hospital provides outpatient services, complete records shall be kept on all outpatients and shall be completed immediately after treatment is rendered. These records shall contain sufficient identification data, a description of what was done and/or prescribed for the patient and must be signed or authenticated by the attending physician. When a patient is admitted as an inpatient, all of his outpatient records shall be made a part of his permanent medical record. Records of patients are the property of the facility and must not be taken from the hospital property except by court order. These records shall be maintained and disposed of as specified in Section 1107.

C. Outpatient Services shall be in a location that is easily accessible for all patients and shall have easy access to all necessary hospital services.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 612 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1214. Emergency Services. (I)

A. No person, regardless of his ability to pay or county of residence, may be denied emergency care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's medical staff determines that the person is in need of emergency care.

1. If a patient presents in labor, she should be delivered in the hospital to which she has come if appropriate delivery facilities exist. If she is a "high risk" patient or an adverse outcome is expected for the baby if delivered there, e.g., less than 34 weeks gestation, she should be transported to a hospital with appropriate capabilities unless delivery is imminent or unless the hospital has such capabilities.

2. Hospitals that do not offer Obstetrical services shall have readily available in the emergency department a precipitous delivery kit, to include at a minimum: bulb suction syringe, cord clamp, scissors, sterile towels, and emergency telephone numbers for the appropriate Regional Perinatal Center.

3. If the care required for any patient is not available at the facility, arrangements must be made for transfer to a more appropriate facility. Prior to the transfer of a patient to another hospital, the receiving hospital shall be notified of the impending transfer.

4. In addition to or in lieu of any action taken by the Department affecting the license of any hospital, when it is established that any officer, employee, or member of the hospital medical staff has negligently violated the provisions of this section, the Department may require the hospital to pay a civil penalty of up to ten thousand dollars pursuant to S.C. Code Ann. Section 44-7-260(E) (1976, as amended).

B. Each hospital shall provide emergency services which include life-saving procedures when life is in jeopardy. Policies and procedures governing the acceptance and care of emergency patients shall be established. An appropriate record shall be maintained on each person who presents for emergency services.

1. Equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer of the critically ill or injured to other hospitals. A minimum capacity shall be established and equipment provided to perform stabilization procedures.

2. Basic services, such as radiology or routine laboratory services shall be maintained and personnel available for call.

3. A licensed physician shall be available and on call at all times. A registered nurse and ancillary personnel trained in emergency procedures shall be on duty within the hospital who are available 24 hours a day subject to call to assist in providing emergency services.

C. A poison control chart shall be readily available in the emergency room with communications access to a Poison Control Center for consultation.

D. The emergency service entrance shall be separated from the main entrance, well marked and illuminated, easily accessible from the street and sufficiently covered or enclosed to protect ambulance patients from the elements during the unloading process.

E. Space for stretchers and wheelchairs should be accessible to the facility and the facility should have the appropriate equipment to transport patients. Stretchers should be sufficiently sturdy to serve as examining tables.

F. In those instances wherein a specific hospital has been designated to provide emergency services for a political or other subdivision through mutual planning efforts of all the hospitals located in this subdivision, or otherwise determined, such designation obviates the necessity for the remaining hospitals to provide general emergency services.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 §§ 309, 613 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1215. Inpatient Dialysis Services. (I)

A. Written policies and procedures shall be developed and maintained by the service provider responsible for the service in consultation with other appropriate health professionals and the administration. Procedures shall be approved by the administration and medical staff where such is appropriate.

B. Renal Dialysis Service Equipment and Supplies

1. Equipment and supplies shall include at least:

a. A dialysis machine or equivalent (with appropriate monitoring equipment) for each bed or station.

b. Dialysis equipment appropriate for pediatric patients, if treated.

2. Water used for dialysis purposes shall be analyzed for bacteriological quality at least monthly and chemical quality at least quarterly and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Water used to prepare a dialysate shall not contain concentrations of elements or organisms in excess of those specified below:

ELEMENTS	LIMIT IN MILLIGRAMS PER LITER
Aluminum	.01
Arsenic	.005
Barium	.100
Cadmium	.001
Calcium	2.0
Chloramines (Tested Daily)	.001
Chlorine (Tested Daily)	.500
Chromium	.014
Copper	.100
Fluorides	.200
Lead	.005
Magnesium	4.0
Mercury	.0002
Nitrates (Nitrogen)	2.0

Potassium	8.0
Selenium	.090
Silver	.005
Sodium	70.0
Sulfates	100.0
Zinc	.100
Bacteria	200 colonies per milliliter

3. A written preventive maintenance program for all equipment used in dialysis and related procedures including, but not limited to, all patient monitoring equipment, isolated electrical systems, conductive flooring, patient ground systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1216. Dental Surgery. (II)

In a hospital providing dental services, the services shall be performed by a qualified practitioner of dentistry who shall be a member of the medical staff.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 614 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1217. Physical Therapy. (II)

If offered as a service of the hospital, physical therapy shall be on orders of a physician and administered by or under supervision of a registered physical therapist. Adequate space and equipment shall be provided.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 615 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1218. Occupational Therapy. (II)

If offered as a service of the hospital, occupational therapy shall be on orders of a physician and administered by or under supervision of an occupational therapist. Adequate space and equipment shall be provided.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 616 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

Republished in 2016 to correct a scrivener's error, substituting "occupational therapy" and "an occupational therapist" for "physical therapy" and "a registered physical therapist".

SECTION 1219. Psychiatric Services. (II)

A. A physician, preferably a board-certified psychiatrist, should be designated as physician-in-charge (or chief) of the psychiatric service. A designated physician who is experienced in the practice of psychiatry should be on call at all times.

B. A registered nurse who has had at least two years training and/or experience in psychiatric nursing shall be responsible for the nursing care of psychiatric patients. At least one registered nurse shall be on duty in each nursing unit at all times.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 617 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1220. Chemical and Substance Abuse Treatment Services. (II)

A. A physician, who is experienced in the treatment of chemical and substance abuse, shall be designated as physician-in-charge of this service. Such a physician shall also be on call at all times.

B. A registered nurse who has had at least two years training and/or experience in chemical and substance abuse care shall be responsible for the nursing care of this service. At least one registered nurse shall be on duty in each nursing unit at all times who has demonstrable training in chemical and substance abuse treatment. Relevant content of this training shall include physical and psychological assessment, psychopharmacology, basic counseling and intervention techniques, and the role of self-help groups in the recovery process. The training may be received through on-the-job training, specialized workshops, or classroom experience.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 618 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1221. Pediatrics. (II)

A. Organization: Pediatric services, if provided, shall be under the supervision of a registered nurse.

B. Facilities: Pediatric services shall have separate facilities for the care of children. Facilities and procedures shall be provided for isolation of children having contagious infections or communicable diseases.

C. Pediatric Nursery: Pediatric nurseries shall provide at least 40 square feet per bassinet or 80 square feet per crib.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 619 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

**SECTION 1300
PERINATAL SERVICES**

SECTION 1301. Newborn Hearing Screening.

A. A facility that averages greater than 100 deliveries a year shall conduct a hearing screening on each newborn prior to discharge. In addition, the facility shall provide educational information about the screening procedure, the importance of the screening and the importance of having a complete audiobiological evaluation after discharge if the need is indicated.

B. If a facility averages fewer than 100 deliveries a year, a hearing screening is not required for each newborn, but the facility shall give the parents of each newborn educational information concerning the hearing screening procedure and the importance of having the screening procedure after discharge.

C. Each facility required to conduct newborn hearing screening shall regularly report the results of the screening to the Department in the required format.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; State Register Volume 39, Issue No. 6, Doc. No. 4461, eff June 26, 2015.

Editor's Note

Former R. 61-16 § 1301 was titled **GENERAL**. See, now R 61-16 § 2200.

SECTION 1302. Shaking infant video & infant CPR information for parents and caregivers of newborn infants and adoptive parents.

A. A facility shall provide to the parents of each newborn baby delivered in the facility a video presentation on the dangers associated with shaking infants and young children. The facility shall also make available information on the importance of parents and caregivers learning infant CPR.

B. The facility shall request that the maternity patient, the father, or the primary caregiver view the video. Those persons whom the facility requests to view the video shall sign a document prescribed by the Department of Health and Environmental Control stating that they have been offered an opportunity to view the video.

C. The facility shall only use a video approved by the Director, or his/her designee, of the Department of Health and Environmental Control.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014. Amended by State Register Volume 39, Issue No. 6, Doc. No. 4461, eff June 26, 2015.

SECTION 1303. Providing a Safe Haven for Abandoned Babies.

Facilities and outpatient facilities shall:

A. Accept temporary physical custody of an infant not more than sixty (60) days old who is voluntarily left by a person who does not express an intent to return for the infant and the circumstances create a reasonable belief that a person does not intend to return for the infant.

B. Be in full compliance with EMTALA rules and regulations and perform any act necessary to protect the physical health or safety of the infant.

C. Offer the person information concerning the legal effect of leaving the infant by delivering to the person the information brochure supplied by the state DSS. Ask the person to identify any parent other than the person leaving the infant. Attempt to obtain from the person information concerning the infant's background and medical history as specified in the forms provided by DSS and appropriate forms available from facility files.

D. Using the DSS form, an attempt must be made to get information concerning use of controlled substances by the infant's mother and other pertinent health information which might determine medical care required by the infant.

E. If the person does not wish to provide or is unable to provide the information to the facility, the person must be offered the DSS form with a prepaid envelope supplied to the facility by DSS.

F. No later than the close of the first business day, after the date on which the facility takes possession of the infant, the facility must notify DSS that it has taken temporary physical custody of the infant. DSS will have legal custody of the infant upon receipt of this notice and DSS will assume physical custody no later than 24 hours after receiving notice that the infant is ready for discharge.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014. Amended by State Register Volume 39, Issue No. 6, Doc. No. 4461, eff June 26, 2015; SCSR 42-5 Doc. No. 4740, eff May 25, 2018.

SECTION 1304. Paternity - In-Hospital Voluntary Paternity Acknowledgement Program.

A. In accordance with 45 CFR 303, a hospital that provides obstetrical services at a minimum must provide to both the mother and alleged father:

1. Written materials about paternity establishment.
2. Forms as provided by the Department necessary to voluntarily acknowledge.
3. Notice, both orally and in writing of the alternatives to the legal consequences of, and the rights and responsibilities of acknowledging paternity, and
4. The opportunity to speak with staff, either by telephone or in person, who are trained to clarify information and answer questions about paternity establishment.

B. Hospital must forward completed voluntary acknowledgement forms, or copies to the Department Division of Vital Records.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1305. Perinatal Organization.

A. Each hospital providing perinatal services shall request designation as a Level I, II, III, or IV perinatal hospital, or regional perinatal center (RPC) by letter to the Department. Initially, a hospital shall demonstrate capability to comply with requirements of a particular designation by submitting to

the Department documentation pertaining to the request for desired designation. For licensure renewals, along with maintaining compliance with the requirements of Section 1306, the hospital shall have birth weight-specific neonatal mortality data readily available for Department review relative to hospitals in the state of the same designation.

B. Each Level I, II, III, and IV hospital shall maintain and document a relationship with its designated RPC for consultation, transport and continuing education. All patients shall be transferred to the appropriate RPC when medically appropriate, if beds are available. This agreement/relationship shall include the ability to share data, as appropriate, related to these functions.

C. Labor and delivery shall occur in a hospital capable of meeting the expected needs of both the mother and the neonate. Ongoing risk assessment shall occur to determine the appropriate level of care.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; State Register Volume 39, Issue No. 6, Doc. No. 4461, eff June 26, 2015.

Editor's Note

Former R. 61-16 § 607 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1306. Designation of Inpatient Perinatal Care Services.

A. Basic Perinatal Center with Well Newborn Nursery (Level I). Level I hospitals shall provide services for normal uncomplicated pregnancies. Level I hospitals shall identify maternity patients requiring transfer to a facility providing the appropriate level of care for the fetus, consult with the RPC on such matters, and offer a basic level of newborn care to infants at low risk. Level I hospitals shall have personnel who provide care for physiologically stable infants born at or beyond 35 weeks of gestation and stabilize ill newborn infants born at less than 35 weeks of gestation until they can be transferred to a facility where the appropriate level of neonatal care is provided. Level I hospitals shall have personnel and equipment available to provide neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care for healthy term newborn infants. Level I hospitals shall have the capability to begin an emergency cesarean delivery within an interval based on timing that best incorporates maternal and fetal risks and benefits. When it is anticipated or determined that these criteria will not be or have not been met, consultation and a plan of care shall be initiated and mutually agreed upon with the RPC and documented in the medical record, immediately after the patient is stabilized. Level I hospitals shall provide care of postpartum conditions and make provisions of accommodations and policies that allow families, including their other children, to be together in the hospital following birth. Appropriate anesthesia, radiology, and laboratory and blood bank services shall be available on a twenty-four (24) hour basis. Management shall include emergency resuscitation and/or stabilization for both maternal and neonatal patients in preparation for transfer/transport for more specialized services. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

B. Specialty Perinatal Center with Special Care Nursery (Level II). In addition to complying with all requirements of Section 1306.A, Level II hospitals shall provide services for both normal and selected high-risk obstetrical and neonatal patients. Level II hospital care shall include management of neonates who are at least 32 weeks of gestation with an anticipated birth weight of at least 1500 grams and problems expected to resolve rapidly (neonates not in need of sub-specialty services on an urgent basis). Level II hospitals shall provide care for infants convalescing after intensive care. Level II hospital shall stabilize infants born before 32 weeks of gestation and weigh less than 1500 grams until transfer to a neonatal intensive care facility. Level II hospitals shall have experienced personnel capable of providing continuous positive pressure airway pressure or mechanical ventilation for a brief period (less than 24 hours) or both until the infant's condition improves or the infant can be transferred to a higher-level facility. Level II hospitals shall have equipment (e.g. portable x-ray equipment, blood gas laboratory) and personnel (e.g. physicians, specialized nurses, respiratory therapists, radiology technicians, and laboratory technicians) available at all times to provide ongoing care and address emergencies. Referral to a higher level of care should occur for all infants when needed, for medical or subspecialty intervention. Support personnel shall include respiratory therapists, radiology technicians, laboratory technicians, and a lactation consultant. A board-certified or board-eligible pediatrician shall be in the hospital or on site within 30 minutes, 24 hours a day. There

shall be no limit on the duration of Nasopharyngeal Continuous Positive Airway Pressure (NCPAP) or Nasal Prong Continuous Positive Airway Pressure (NPCPAP) when cared for by a neonatologist. The provision of CPAP or mechanical ventilation beyond the immediate stabilization period requires the immediate availability of respiratory therapists with neonatal training (including intubation of premature infants), nursing support with training to identify and respond to complications of ventilation, and the immediate availability of personnel and equipment to evacuate a pneumothorax. Level II hospitals with a board certified or board eligible neonatologist having responsibilities limited to a single center and in house or within 30 minutes of the unit at all times may provide care for patients requiring mechanical ventilation for up to 24 hours. For shared neonatology coverage, a certified Neonatal Nurse Practitioner having responsibilities limited to a single center and in house may provide coverage for that center. Neonates requiring the initiation of mechanical ventilator support beyond 24 hours of age shall be referred to the RPC. Neonates shall not require high-frequency ventilation support. These hospitals shall manage no less than an average of 500 deliveries annually, calculated over the previous three years based on the individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. A Level II hospital shall not admit outborn neonates into its nursery without prior concurrence with the RPC. Level II units shall not transport neonates between hospitals. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

C. Subspecialty Perinatal Center with Neonatal Intensive Care Unit (Level III). In addition to complying with all requirements of Sections 1306.A through 1306.B, Level III hospitals shall provide all aspects of perinatal care, including intensive care and a range of continuously available subspecialty consultation as recommended in the most recent edition of the *Guidelines for Perinatal Care* (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. Level III hospitals shall provide care for mothers and infants at less than 32 weeks gestation, estimated fetal weight less than 1500 grams, and anticipated complex medical or surgical conditions for mother or infant that may require sub-specialty services. Level III hospitals shall also provide care for infants born at less than 32 weeks of gestation and weigh less than 1500 grams at birth or have actual or anticipated complex medical or surgical conditions regardless of gestational age. Level III hospital care shall include expertise in neonatology and maternal-fetal medicine. Level III neonatal intensive care units (NICUs) shall include continuously available personnel (neonatologists, neonatal nurses, and respiratory therapists) and equipment available to provide life support as long as needed. Level III facilities shall provide ongoing assisted ventilation for periods longer than 24 hours, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. Level III hospitals shall provide services and care for women and fetuses at high risk, both admitted and transferred to the facility. Level III hospitals shall have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care. Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity shall also be readily available in Level III hospitals. Level III hospitals shall have the capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography. Level III hospitals shall also have the capability to perform major surgery on site or at a closely related institution. A board-certified or board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day. A board-certified maternal-fetal medicine specialist (perinatologist) shall be available for supervision and consultation, 24 hours a day. Perinatal consultation requirements may be met via telemedicine arrangements with a RPC. In addition to the Level II capabilities, Level III hospitals shall have the staffing and technical capability to manage high-risk obstetric and complex neonatal patients, including neonates requiring prolonged ventilatory support, surgical intervention, or 24-hour availability of multispecialty management. Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, and at least an average of 100 neonate admissions who weigh less than 1500 grams each, require ventilatory support for over twenty-four (24) hours, or require surgery based on individual hospital statistics. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. The NICU budget shall include support for outcomes measurement, including data collection and membership in a multi-institutional collaborative quality improvement data base. Level III hospitals shall collect data to assess outcomes within their facility and to compare with other hospitals within their level. Hospitals at this level shall not provide additional

care or services designated only for RPC's, or perform neonatal transport, except under unforeseen, emergent circumstances. In this situation, the Department shall be notified within 24 hours.

D. Regional Perinatal Center with Neonatal Intensive Care Units (Level III) (RPC). In addition to complying with all requirements of Sections 1306.A through 1306.C, the RPC shall provide consultative, outreach, and support services to Level I, II, and III hospitals in the region. The RPC shall manage no less than an average of 2000 deliveries annually, calculated over the previous three years. Personnel qualified to manage obstetric or neonatal emergencies shall be in-house. A board-certified maternal-fetal medicine specialist (perinatologist) shall be in the hospital or on site within 30 minutes for supervision and consultation, 24 hours a day. The RPC shall participate in residency programs for obstetrics, pediatrics, and/or family practice. Physician-to-physician consultation shall be available 24 hours a day for Level I, II, and III hospitals. Regional Perinatal Centers shall coordinate the development and implementation of professional continuing education to maintain competency and provide education to other facilities within the region, facilitate transport from the perinatal centers to the regional perinatal center and back transport when possible, and collect data on long-term outcomes to evaluate the effectiveness of delivery of perinatal care services and the efficacy of new therapies. The RPC shall provide a perinatal transport system that operates 24 hours a day, seven days a week, and return transports neonates to lower level perinatal hospitals when the neonates' condition and care requirements are within the capability of those hospitals.

E. Complex Neonatal Intensive Care Unit (Level IV). In addition to complying with all requirements of Sections 1306.A through 1306.C, Level IV hospitals shall include additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and have pediatric medical and surgical specialty consultants available 24 hours a day. Level IV hospitals shall have capability to perform surgical repair of complex congenital or acquired conditions (e.g. Congenital malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation). Level IV hospitals shall maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the facility. Not all Level IV hospitals need to act as regional centers. Regional organization of perinatal health care services requires that there be coordination in the development of specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and return transport, and collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. Level IV hospitals shall collect data to assess outcomes within their facility, and to compare with other hospitals within their level, if applicable.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; State Register Volume 39, Issue No. 6, Doc. No. 4461, eff June 26, 2015.

Editor's Note

Former R. 61-16 § 607 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1307. Personnel.

A. Detailed components of support services and medical, nursing and ancillary staffing for each level shall meet the recommendations outlined in the most recent edition of the *Guidelines for Perinatal Care*.

B. The following medical specialists and subspecialists shall have medical staff credentials and/or written consultative agreements as follows:

1. Level I shall include:

a. Membership: Physician designated as physician-in-charge of obstetric services, physician designated for supervision of newborn care, anesthesia personnel with credentials to administer obstetric anesthesia available within 30 minutes, 24-hours a day, one person capable of initiating neonatal resuscitation available at every delivery.

b. Consultation: Obstetrician, pediatrician, general surgeon.

2. Level II, in addition to Level I requirements, shall include:

a. Membership: General surgeon, pathologist, radiologist, obstetrician, pediatrician, and anesthesiologist;

b. Consultation: Maternal-fetal medicine specialist, neonatologist, and pediatric surgeon.

3. Level III and RPC, in addition to Level II requirements, shall include:

a. Membership: Maternal-fetal medicine specialist or effective consultation with Maternal-Fetal medicine specialist, (available 24 hours a day, 7 days a week) via telemedicine, obstetrician or radiologist with special interest and competence in maternal disease and its complications, pediatric radiologist, anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease, and pediatric surgeon.

b. Urgent Consultation: Pediatric subspecialists including cardiology, neurology, hematology, genetics, endocrinology, nephrology, gastroenterology-nutrition, infectious diseases, pulmonology, immunology, pathology, metabolism and pharmacology. Pediatric surgical subspecialists, to include cardiovascular, neurosurgery, orthopedics, ophthalmology, urology and otolaryngology.

c. For Level III hospitals: Pediatric medical subspecialists, pediatric anesthesiologists, pediatric surgeons, and pediatric ophthalmologists may be at the site or at a closely related institution by prearranged consultative agreement. Prearranged consultative agreements can be performed using, for example, telemedicine technology, or telephone consultation, or both from a distant location.

4. Level IV, in addition to Level III requirements, shall include: Membership and on-site: Maternal-fetal medicine specialist, obstetrician or radiologist with special interest and competence in maternal disease and its complications, pediatric radiologist, anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease, and pediatric surgeon.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; State Register Volume 39, Issue No. 6, Doc. No. 4461, eff June 26, 2015.

Editor's Note

Former R. 61-16 § 608 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1308. Neonatal Intensive Care Nurse Staffing.

Neonatal intensive care nurse staffing is required if any of the following conditions exist:

- A. Any advanced support therapy, e.g., extracorporeal membrane oxygenation, nitric oxide, high frequency ventilation, peritoneal dialysis;
- B. Acute pre- or post-operative surgical conditions, except for minor surgical procedures such as inguinal hernia repair;
- C. Ventilator support (with the exception of do-not-resuscitate situations and chronic ventilator-dependent conditions);
- D. Less than 32 weeks of gestation and less than 1500 grams on the first day of life;
- E. Chest tubes required;
- F. Cardio-pulmonary resuscitation required in the previous 24 hours;
- G. Vital signs required every hour or more frequently;
- H. Umbilical artery or vein catheterization or three or more intravenous sites required;
- I. Pressor agent (excluding initial stabilization) or inotropic support required, e.g., dopamine (doses for renal perfusion maintenance excluded);
- J. Complex diagnostic/assessment support required; or
- K. Evidence of seizure activity/unstable neurologic status.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 608 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1309. General Facility and Care Requirements.

- A. Environment, equipment, supplies, and procedures utilized in the care of perinatal patients shall meet the recommendations outlined in the most recent edition of the *Guidelines for Perinatal Care*. The

environmental temperature in newborn care areas should be independently adjustable, as to maintain per the GPC.

B. Obstetrical Care: In each hospital providing obstetrical services, written policies and procedures shall be established and implemented through cooperative efforts of the medical and nursing staffs. These policies and procedures shall outline the process, providers, and methods of providing risk-appropriate care to the obstetrical patient, and shall include, but not be limited to:

1. Admission criteria and documentation;
2. Preterm labor;
3. Maternal transfer to another hospital;
4. Induction and augmentation;
5. Analgesia and anesthesia;
6. Labor process;
7. Capability to perform cesarean delivery within 30 minutes of the decision to do so;
8. Immediate neonatal care/resuscitation;
9. Recovery room care; and
10. Postpartum care.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 609 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1310. Neonatal Care.

Specific policies and procedures for the care of the neonate shall follow the recommendations outlined in the most recent edition of the GPC.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 609 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1311. Neonatal Resuscitation.

A. Personnel, equipment, supplies, and medications as recommended by the most recent edition of the American Heart Association and AAP *Textbook of Neonatal Resuscitation* shall be readily available in every hospital providing perinatal services.

B. In order to meet the potential need for resuscitation of every neonate, at least one person who has a current provider-designation, as defined by completion of the AAP Neonatal Resuscitation Program, shall be on site.

C. Personnel trained and qualified to perform neonatal resuscitation must be immediately available and not responding from an area removed from the delivery or nursery area.

D. Equipment, supplies, and medications for neonatal resuscitation must be immediately available to the delivery and nursery areas at all times.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 609 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1312. Inter-hospital Care of the Perinatal Patient (Transport).

A. Each hospital providing perinatal services shall establish and implement a written plan which outlines the process, providers, and methods of providing risk-appropriate stabilization and transport of any high-risk perinatal patient requiring specialized services. This plan shall be updated in conjunction with the designated RPC on an annual basis, and shall include, but not be limited to, procedures outlining:

1. Communication between referring hospitals and the RPC, transport teams and medical control, and perinatal providers and families;
2. Indications for both acute phase and return transport between perinatal hospitals, to include essential contact persons and telephone numbers for referral and transport; and
3. A list of all medical record copies and additional materials to accompany each patient in transport.

B. Equipment, supplies, and procedures used in preparation and support of transport of maternal patients shall be based upon the most recent edition of the GPC. Equipment, supplies, and procedures used in the transport of a neonate shall be based upon the most recent edition of the AAP *Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients*.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 609 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1313. Evaluation of Perinatal Care.

A. Review of maternal and neonate mortality and morbidity shall be conducted at least every three months by the medical staff or designated committee, regardless of the size or designation of the perinatal service. A perinatal mortality and morbidity review committee composed of representatives from the pediatric, obstetrical, and nursing staffs, with additional participation from other professionals, depending upon the cases to be reviewed, shall be established at all perinatal centers.

B. In all perinatal centers, selected case reviews shall include, but not be limited to:

1. Analysis of total perinatal mortality with identification of deaths attributable to various categories of complication;
2. Analysis of perinatal morbidity and related factors.

C. Level I and II hospitals shall review all live births or fetal/neonatal deaths in which the neonate weighed at least 350 grams and less than 1500 grams, utilizing the Department's *Very Low Birthweight Self-monitoring Tool*. Each completed self-monitoring DHEC form shall be retained by the facility and a copy made available to the Department as specified in the self-monitoring tool.

D. Each event shall be evaluated for potential opportunities for intervention with the intervention and follow-up described, if applicable. Written minutes of committee meetings shall be maintained and made available to the Department for review.

E. Each Level I, II, and III perinatal center shall annually review and document the findings from these case reviews with its designated RPC. Minutes of these meetings shall be maintained and made available to the Department for review.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; State Register Volume 39, Issue No. 6, Doc. No. 4461, eff June 26, 2015.

Editor's Note

Former R. 61-16 § 610 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1400

VITAL STATISTICS

SECTION 1401. General.

Hospitals must comply fully with the Regulations of the Department relating to vital statistics.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 701 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1402. Birth Certificates.

A. For inpatient newborns a licensee shall be responsible for filing a birth certificate for all live births occurring in the licensed facility (see DHEC Regulation 61-19 for definition of live birth). The record should be filed as prescribed within five (5) days of delivery per DHEC Regulation 61-19.

B. A licensee shall be responsible for filing a birth certificate for outpatient newborns brought to the emergency room when a live birth was delivered either at home or en route to the hospital. If the live birth is delivered by a licensed midwife or other practitioner, the licensee shall not be responsible for filing a birth certificate.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 702 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1403. Death Certificates.

Filing of a death certificate shall be in accordance with DHEC Regulation 61-19 and the S.C. Code of Laws.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 703 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1500

FOOD AND NUTRITION SERVICE (II)

SECTION 1501. Approval.

All facilities that prepare food on-site shall be approved by the Department, and shall be regulated, inspected, and graded pursuant to DHEC Regulation 61-25.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 801 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1502. Services.

All facilities shall provide food and nutrition services to meet the daily nutritional and dietary needs of patients in accordance with written policies and procedures.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 802 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1503. Management.

The nutrition services shall be under the direction of a dietitian or qualified food and nutrition manager/director who has a written agreement for consultation services by a dietitian. These services shall be organized with established lines of accountability and clearly defined job assignments. A qualified food and nutrition manager/director shall be a person who:

A. Is a graduate of a dietetic technician training program approved by the American Dietetic Association; or

B. Is a graduate of a course of study meeting the requirements of the American Dietetic Association and approved by the Department; or

C. Is certified by the Certifying Board for Dietary Managers of the Dietary Managers Association and maintains that credential; or

D. Has at least three (3) years of training and experience in meal service supervision and management in military service equivalent in content to the programs described in paragraph A, B, or C above.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 803 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1504. Personnel.

A. Dietary services shall be organized with established lines of accountability and clearly defined job assignments for those engaged in food preparation and serving. There shall be trained staff members/volunteers to supervise the preparation and serving of the proper diet to the patients including having sufficient knowledge of food values in order to make appropriate substitutions when necessary.

B. The qualified food and nutrition manager/director shall be responsible for supervising food and nutrition service personnel, the preparation and serving of the food, and the maintenance of proper records. When the qualified food and nutrition service manager/director is not on duty, a responsible person shall be assigned to assume their job responsibilities.

C. Work assignments and duty schedules shall be posted and kept current.

D. No person, infected with or a carrier of a communicable disease, or while having boils, open or infected skin lesions, or an acute respiratory infection, shall work in any area of food preparation and service.

E. Employees shall wear clean garments, maintain a high degree of cleanliness, and conform to hygienic practices while on duty. Individuals engaged in the preparation and service of food shall wear clean hair restraints, e.g., hair nets, hair wraps, hats, that will properly restrain all hair of the face and head and prevent contamination of food and food contact surfaces. They shall wash their hands thoroughly in an approved hand washing lavatory before starting work, after visiting the bathroom and as often as may be necessary to remove soil and contamination.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 804 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1505. Diets.

Diets shall be prepared in conformance with orders of a physician or, if permitted by the facility's policies, a dietitian. A current diet manual shall be readily available to attending physicians, food and nutrition service personnel, nursing personnel, and dietitians.

A. Diets shall be prescribed, dated and signed or authenticated by the physician or dietitian.

B. Facilities with patients in need of special or therapeutic diets shall provide for such diets.

C. Notations shall be made in the medical record of diet served, counseling or instructions given, as identified by patient and/or nutritional assessment and patient's tolerance of the diet.

D. Diets shall be planned, written, prepared and served with consultation from a dietitian.

E. Persons responsible for diets shall have sufficient knowledge of food values in order to make substitutions when necessary. All substitutions made on the master menu shall be documented.

F. Nothing in this regulation shall be read or interpreted to prohibit a facility's policies from allowing a dietitian to:

1. Order or prescribe patient diets, including therapeutic diets;
2. Order laboratory tests to monitor the effectiveness of dietary plans and orders; and/or
3. Make subsequent modifications to patient diets based on the results of laboratory tests.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; SCSR 42-5 Doc. No. 4740, eff May 25, 2018.

Editor's Note

Former R. 61-16 § 805 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1506. Planning of Menus and Food Supplies.

A. Menus shall be planned and written at least two weeks in advance and dated as served. The current week's menus, including routine and special diets and any substitutions or changes made, shall be posted in one or more conspicuous places in the Food and Nutrition Services area.

B. Records of menus as served shall be filed and maintained for at least 30 days.

C. Food supplies shall be adequate to meet menu and emergency plan requirements.

D. Records of food and supplies purchased shall be kept on file.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 806 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1507. Preparation and Serving of Food.

A. Food shall be prepared by methods that conserve the nutritive value, flavor and appearance. The food shall be palatable, properly prepared, and sufficient in quantity and quality to meet the nutritional needs of the patients.

B. A file of tested recipes, adjusted to appropriate yield, shall correspond to items on the posted menus.

C. Food shall be served with special attention given to preparation and prompt serving in order to maintain correct food temperatures in accordance with DHEC Regulation 61-25 and to meet individual needs.

D. Food and Nutrition service personnel will have the responsibility of accompanying the food cart to the patient care area when necessary to complete tray assembly. Facilities with automated food distribution systems in operation are not required to have dietary personnel accompanying the cart. Each facility shall designate who will be responsible for distribution of trays, feeding of patients, and collection of soiled trays.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 807 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1508. Dietary and Food Sanitation.

A. Sanitary conditions shall be maintained in all aspects of the storage, preparation and distribution of food.

B. The facility shall be in compliance with local health codes and DHEC Regulation 61-25.

C. Written procedures for cleaning, disinfecting and sanitizing all equipment and work areas shall be developed and followed.

D. Written reports of inspections by state and local health authorities shall be kept on file in the facility with notations made of actions taken by the facility to comply with recommendations.

E. Drugs shall not be stored in the food and nutrition services area or any refrigerator or storage area utilized by the food and nutrition services area.

F. All walk-in refrigerators and freezers must be equipped with opening devices which will permit opening of the door from the inside at all times.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 808 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1509. Meal Service.

A minimum of three nutritionally balanced meals in each 24-hour period shall be offered for each patient unless otherwise directed by the patient's physician. Not more than 14 hours shall elapse between the serving of the evening meal and breakfast. As an exception, there may be up to 16 hours

between the scheduled serving of the evening meal and breakfast the following day if approved by the patient's attending physician and the patient, and if a nourishing snack is provided after the evening meal.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 809 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1510. Ice and Drinking Water.

Ice and water that meets the approval of the Department shall be available and precautions shall be taken to prevent contamination. Ice delivered to patient areas in bulk shall be in nonporous, easily cleanable covered containers. The ice scoop shall be stored in a sanitary manner with the handle at no time coming in contact with the ice. Clean, sanitary drinking water shall be available and accessible in adequate amounts at all times.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 810 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1600. MAINTENANCE. (II)

An institutional structure, its component parts, facilities, and all equipment shall be kept in good repair and operating condition.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 901 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1700

HOUSEKEEPING AND REFUSE DISPOSAL (II)

SECTION 1701. Housekeeping.

A. A facility shall be kept neat and clean. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, windows and premises. There must be an effective rodent and insect control program for the facility to prevent infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. Dry dusting and dry sweeping are prohibited.

B. Upon discharge or transfer of a patient, all bedside equipment shall be cleansed and disinfected. Bed linen shall be removed and mattresses turned; if damaged, replaced. Beds shall be made with fresh linens to maintain them in a clean and sanitary condition for each patient.

C. Employee locker rooms shall be maintained in a clean and sanitary condition.

D. Janitor closets, floors, walls, sinks, mops, mop buckets, and all equipment shall be cleaned daily or more often as needed. A supervisory hospital employee shall make frequent inspections to assure compliance.

E. All storage spaces shall be kept clean, orderly and free of trash, papers, old cloths and empty boxes. In areas provided with a sprinkler system, a minimum vertical distance of 18 inches shall be maintained between the top of stored items and the sprinkler heads.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1101 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1702. Refuse Disposal.

A. All garbage and refuse storage shall be in accordance with DHEC Regulation 61-25.

B. All contaminated dressings, pathological, and/or similar waste shall be properly disposed of in accordance with DHEC Regulation 61–105.

C. All radioactive waste shall be disposed of by a method in accordance with DHEC Regulation 61–63.

D. All outside areas, grounds and/or adjacent buildings on the premises shall be maintained neat and clean.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61–16 § 1102 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1800

INFECTION CONTROL (I)

SECTION 1801. General.

A. The hospital shall provide a safe and healthy environment that minimizes infection exposure and risk to patients, employees, health care workers, volunteers and visitors. The hospital shall implement and maintain a written, effective, organized, active, hospital-wide program for the surveillance, prevention, control, and investigation of infections, infectious agents and communicable diseases, with the goal of implementing best practices and continuously reducing infections. The infection prevention and control program must be implemented in a manner that minimizes the risk of health care associated infections. The hospital must designate a qualified employee as the hospital's Infection Practitioner, whose function is to administer the infection prevention and control program. The Infection Practitioner must be provided with the resources and assistance necessary to carry out the activities of the infection prevention and control program. Each hospital must assess the time requirement needed for surveillance and infection prevention activities at each of its locations and provide sufficient staffing to meet the organization's assessed needs.

B. Hospital policies and procedures for infection prevention and control shall comply with Federal and State laws and regulations and shall reference guidelines, including but not limited to, the following:

1. Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; 29 CFR 1910 Occupational Safety and Health Standards with emphasis on compliance with 29 CFR 1910–1030 (Bloodborne Pathogens);
2. The Center for Disease Control and Prevention's (CDC) Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPIC);
3. CDC's Guideline for Hand Hygiene in Health-Care Settings;
4. CDC's Guidelines for Environmental Infection Control in Health-Care Facilities;
5. CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities;
6. CDC's Guidelines for the Management of Multidrug-Resistant Organisms In Healthcare Settings;
7. DHEC Regulation 61–105;
8. CDC's Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings; and
9. CDC's Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005.

C. The hospital must comply with and demonstrate compliance with this regulation as well as their own policies and procedures.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1802. Infection Control Training.

A. The hospital shall require annual education regarding infection prevention and control for all employees, students, and volunteers who have contact with patients or who handle or potentially

handle blood, body fluids, or tissue. If any of these persons work or perform tasks at more than one hospital, the hospital may accept infection prevention and control education received at another hospital or at an in-person or online seminar to meet this requirement, but only if the education is reported to and documented by the hospital.

B. Infection prevention and control education requirements may be met through in-person or online training, or completion of modules, videos or other training materials designed to convey such education.

C. In addition to general infection prevention education provided during initial orientation, each employee, student, and volunteer who has contact with patients or who handles or potentially handles blood, body fluids or tissue, shall receive infection prevention and control education specific to his/her job classification and work activities to inform him/her about the infection prevention and control policies and procedures of his/her position. Infection prevention and control training should be targeted to the functions of different categories of employees.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1803. Patient/Public Education and Disclosure.

Prior to or upon admission to the hospital as an inpatient or for outpatient surgery, the hospital must provide to patients materials designed to educate the patient and his/her responsible party about the prevention of healthcare associated infections and the public availability of healthcare associated infection reports through the Hospital Infections Disclosure Act, S.C. Code Ann. Section 44-7-2410, et. seq. The hospital must document provision of this information to the patient or responsible party. The hospital is not required to provide the information to the patient or responsible party if he or she is unable or unwilling to receive the information or if there is no responsible party.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1804. Live Animals.

Service animals, therapy animals, and personal pets may be permitted for strictly limited visitation pursuant to strict hospital policies; however, no non-human primates may be allowed in the hospital. Each hospital must have appropriate policies which require at a minimum that the animal is free of fleas, ticks, and intestinal parasites, has been screened by a veterinarian within the past twelve (12) months prior to entering the facility, has received all required inoculations, is clean and well-groomed, and presents no apparent threat to the health and safety of patients, visitors, employees or others. All animals must be supervised by persons who know the animal and its behavior and can control the animal.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1805. Laundry and Linens.

A. Linen includes surgical clothing. An adequate supply of clean, sanitary linen shall be available at all times.

B. The hospital shall have a clean linen storage area and a separate soiled linen storage area. These storage areas shall be used solely for their intended purposes. The soiled linen storage area shall have mechanical ventilation to the outside.

C. In order to prevent contamination of clean linen by dust or other airborne particles or organisms, linen shall be stored and transported in a sanitary manner, i.e., enclosed and covered. Clean linen shall be stored in a dedicated cart, closet, or cabinet which is covered and dedicated only for the use of clean linen. Non-linen items shall not be stored in the same cart as clean linen. Clean non-linen items may be stored in the same closet or cabinet as clean linen, but shall not be stored on the same shelf.

D. The hospital shall have policies addressing the storage, handling, distribution, collection, and reprocessing of linen for the hospital. If the hospital uses an off-site laundry, the hospital must ensure through contract that the linen is handled and cleaned properly to institutional standards. The hospital will assure that laundry services whether operated by the hospital or contracted will exercise necessary precautions to render all linen to be safe for reuse.

E. The hospital shall have policies for collecting, transporting, and storing all soiled linen. Soiled linen shall be kept in closed or covered containers while being collected, transported or stored and shall be stored separately from clean linen and patient areas. These containers shall be cleaned and disinfected weekly at a minimum and immediately if visibly soiled. Hospitals operating laundries within the buildings accommodating patients shall provide proper insulation to prevent transmission of noises to patient areas. The laundry shall be well ventilated and the general air movement shall be from the cleanest areas to the most contaminated areas.

F. All used linen must be handled as if it is infectious. Used linen shall be placed in durable bags which, by color or terminology, identify the contents as contaminated and must be transported in these closed bags to the soiled linen holding area or laundry. All linen from patients with infectious or communicable diseases shall be placed in durable bags identified "contaminated" and transported in these closed bags to the soiled linen holding area or laundry.

G. Soiled linen shall be neither sorted nor rinsed in patient rooms.

H. Laundry operations shall not be carried out in patient rooms or where food is prepared, served, or stored.

I. Soiled linen area floors shall be cleaned daily. The area shall be cleaned and disinfected weekly at a minimum and more frequently if necessary to control odors and bacteria.

J. If linen chutes are used, the linen shall be enclosed in durable bags, identified, by color or terminology, as contaminated, before placing in the chute. Chutes shall be cleaned monthly.

K. Personnel must wear appropriate protective attire in accordance with the hospitals policies and procedures. Personnel must wash their hands thoroughly after handling soiled linen.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 §§ 1001, 1002, 1003, 1004, 1005 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1806. Waste Management.

A. The hospital shall be able to demonstrate that it has a comprehensive waste management program for identification, collection, handling, and management, of all medical waste, including nonhazardous and hazardous pharmaceutical waste.

B. The hospital shall provide for a regular review of its policies and procedures to assure compliance of its waste management practices in comparison with federal EPA and state regulatory requirements.

C. Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in compliance with the following standards: Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; related regulations at 29 CFR 1910; the Department's *Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*; DHEC Regulation 61-105, and other applicable federal, state and local laws and regulations.

D. The hospital shall inform personnel involved in the handling and disposal of potentially infectious waste of health and safety hazards, and ensure that they are trained in appropriate handling and disposal methods.

E. The hospital shall have policies for the use and disposal of sharps. The hospital shall use sharps containers capable of maintaining their impermeability after waste treatment to avoid subsequent physical injuries during final disposal. Disposable syringes with needles, including sterile sharps that are being discarded, scalpel blades, and other sharp items must be placed into puncture-resistant containers located as close as practical to the point of use.

F. Regulated medical wastes awaiting treatment shall be stored in a properly ventilated area inaccessible to vermin. Waste containers that prevent development of noxious odors must be used. If treatment options are not available at the site where the medical waste is generated, the hospital must ensure transport of the regulated medical wastes in closed, impervious containers to the on-site treatment location or to another facility for treatment as appropriate. Regulated medical wastes must

be treated by using a method (e.g., steam sterilization, incineration, interment, or an alternative treatment technology) in accordance with local, state and federal laws and regulations.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1807. Water Requirements.

A. The hospital shall establish written policies and procedures to prevent waterborne microbial contamination within the water distribution system.

B. The hospital shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions (e.g. gloves) in accordance with established guidelines.

C. The hospital shall eliminate contaminated water or fluid from environmental reservoirs (e.g. in equipment or solutions) wherever possible.

D. The hospital shall not place decorative fountains and fish tanks in patient-care areas. If decorative fountains are used in separate public areas, the hospital shall ensure that they are disinfected in accordance with manufacturer's instructions and safely maintained.

E. The hospital plumbing fixtures which require hot water and which are accessible to patients shall be supplied with water which thermostatically controlled to a temperature of at least 100 degrees F. (37.8 degrees C) and not exceeding 125 degrees F. (51.7 degrees C.) at the fixture.

F. The hospital shall have a written plan to respond to disruptions in water supply. The plan must include a contingency plan to estimate water demands for the entire facility in advance of significant water disruptions (i.e., those expected to result in extensive and heavy microbial or chemical contamination of the potable water), sewage intrusion, or flooding.

G. When a significant water disruption or an emergency occurs, the hospital shall:

1. Adhere to any advisory to boil water issued by the municipal water utility;
2. Alert patients, families, employees, volunteers, students and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water, while the advisory is in effect, unless the water has been disinfected;
3. After the advisory is lifted, run faucets and drinking fountains at full flow for greater than 5 minutes, or use high-temperature water flushing or chlorination;
4. All ice and drinks that may have been contaminated must be disposed and storage containers cleaned; and
5. Decontaminate the hot water system as necessary after a disruption in service or a cross-connection with sewer lines has occurred.

H. The hospital shall adhere to Association for the Advancement of Medical Instrumentation (AAMI) standards for quality assurance performance of devices and equipment used to treat, store and distribute water in hemodialysis units and for the preparation of concentrates and dialysate.

I. The hospital shall follow appropriate recommendations to prevent cross connection and other sources of contamination of ice for human consumption, and to prevent contamination of hydrotherapy equipment and medical equipment connected to water systems (e.g. automated endoscope reproprocessors).

J. The hospital shall maintain and implement policies and procedures addressing the management of failure of waste water systems.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1900

DESIGN AND CONSTRUCTION

SECTION 1901. General.

Every facility shall be planned, designed and equipped to provide adequate facilities for the care, safety, and treatment of each patient.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1902. Codes and Standards.

The design and construction specifications for hospitals shall conform to the most current nationally accepted standards for hospital design set forth in the International Building Code (IBC); International Fire Codes (IFC); International Plumbing Codes (IPC); International Mechanical Codes (IMC); National Fire Protection Association (NFPA) codes - NFPA 10 - Standard for Portable Fire Extinguishers, NFPA 11 - Standard for Low-, Medium-, and High-Expansion Foam, NFPA 12 - Standard on Carbon Dioxide Extinguishing Systems, NFPA 12A - Standard on Halon 1301 Fire Extinguishing Systems, NFPA 13 - Standard for the Installation of Sprinkler Systems, NFPA 13R - Standard for the Installation of Sprinkler Systems in Low-Rise Residential Occupancies, NFPA 14 - Standard for the Installation of Standpipe and Hose Systems, NFPA 15 - Standard for Water Spray Fixed Systems for Fire Protection, NFPA 16 - Standard for the Installation of Foam-Water Sprinkler and Foam-Water Spray Systems, NFPA 17 - Standard for Dry Chemical Extinguishing Systems, NFPA 17A - Standard for Wet Chemical Extinguishing Systems, NFPA 18 - Standard on Wetting Agents, NFPA 20 - Standard for the Installation of Stationary Pumps for Fire Protection, NFPA 22 - Standard for Water Tanks for Private Fire Protection, NFPA 24 - Standard for the Installation of Private Fire Service Mains and Their Appurtenances, NFPA 25 - Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, NFPA 30 - Flammable and Combustible Liquids Code, NFPA 30A - Code for Motor Fuel Dispensing Facilities and Repair Garages, NFPA 52 - Vehicular Gaseous Fuel Systems Code, NFPA 54 - National Fuel Gas Code, NFPA 58 - Liquefied Petroleum Gas Code, NFPA 59 - Utility LP-Gas Plant Code, NFPA 70 - National Electrical Code®, NFPA 72 - National Fire Alarm and Signaling Code, NFPA 96 - Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations, NFPA 99 - Health Care Facilities Code, NFPA 101 - Life Safety Code®, and NFPA 110 - Standard for Emergency and Standby Power Systems; International Code Council (ICC) American National Standards I (ANSI) A117.1 - Accessibility Codes; the *Guidelines for Design and Construction of Health Care Facilities* as published by the Facility Guidelines Institute (FGI); and International Existing Building Code (IEBC).

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1903. Submission of Plans.

A. When construction is contemplated either for new buildings, additions or major alterations or replacement to existing buildings, buildings being licensed for the first time, buildings changing license type, or facilities increasing occupant load/licensed capacity, plans and specifications shall be submitted to the Department for review. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. These submissions shall be made in at least three stages: schematic, design development, and final. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for supervision and inspections. The Department shall conduct periodic inspections throughout each project.

B. When alterations are contemplated that are new construction, or projects with changes to the physical plant of a licensed facility which has an effect on: the function, use or accessibility of an area; structural integrity; active and passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under the said hood); door, wall and ceiling system assemblies; exit corridors; Increase the occupant load/licensed capacity; and projects pertaining to any life safety systems, require preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department. Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications, kept on file at the facility and made available to the Department.

C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. The licensee shall pay the following inspection fees during the construction phase of the project. The plan inspection fee is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	Fee
< \$10,001.00	\$750
\$10,001 - \$100,000	\$1,500
\$100,001 - \$500,000	\$2,000
> \$500,000	\$2,500 plus \$100 for each additional \$100,000 in project cost
Site Inspection	
50% Inspection	\$500
80% Inspection	\$500
100% Inspection	\$500

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014; SCSR 42-5 Doc. No. 4740, eff May 25, 2018.

Editor's Note

Former R. 61-16 § 2003 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1904. Construction Inspections.

Construction work which violates codes or standards will be required to be brought into compliance. All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1905. Patient Rooms.

A. Cubicle curtains with built-in curtain tracks shall be provided in all multiple bed rooms which will shield each patient completely. Curtains will be flameproof.

B. Beds must be placed at least three feet apart.

C. At least one private room shall be provided in each nursing unit for purposes of medical isolation, incompatibility, personality conflicts, etc.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 506 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 1906. Signal System.

A signal system shall be provided for each patient. The system shall consist of a call button for each bed, bath, toilet and treatment/examination room; a light at or over each patient room door visible from the corridor; a control panel in utility rooms, treatment/examination rooms, medication rooms, nurses' lounges and floor kitchens. Indicators and control panels shall employ both an audible and visual signal.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1907. Nurses Station.

A nurses' station shall serve not more than 44 beds, unless additional services and facilities are provided. In order for a nurses' station to be permitted to serve more than 44 beds, justification must

be furnished showing how the additional beds served will not adversely affect the health care provided to each patient.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1908. Utility Rooms.

A. Soiled Utility Room: At least one soiled utility room per nurses' station shall be provided which contains a clinical sink, work counter, waste receptacle and soiled linen receptacle.

B. Clean Utility Room At least one clean utility room per nurses' station shall be provided which contains a counter with handwashing sink and space for the storage and assembly of supplies for nursing procedures.

Exception: Item B above does not apply to facilities licensed prior to May 1968.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 1909. Temperature and Humidity. (II)

A. Minimum design temperature of 75 degrees F. (23.9 degrees C.) at winter design conditions and 81 degrees F. maximum summer design conditions shall be provided for all occupied areas not listed below. The systems shall be designed to provide the following temperatures and humidities in the areas noted:

Area Designation	Temperature		Relative Humidity	
	F	C	Minimum	Maximum
Operating Room	68-75	20.0-24.0	20	60
Recovery Rooms	75	23.9	30	60
Intensive Care Units	75-80	23.9-26.7	30	60

B. Perinatal design temperature and humidity shall follow the current edition of *Guidelines for Perinatal Care*.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 2000

FIRE PROTECTION, PREVENTION AND LIFE SAFETY (I)

SECTION 2001. Alarms.

A. A partial, manual, automatic, supervised fire alarm system shall be provided. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. There must be a fire alarm pull station in or near each nurses station.

C. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former 61-16 § 2001 was titled **GENERAL** and was deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430.

Former 61-16 § 2801 revised to this section by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

SECTION 2002. Emergency Generator Service.

A. Facilities shall provide certification that construction and installation of emergency generator service complies with requirements of all adopted State, Federal, or local codes, ordinances, and regulations.

B. An emergency generator shall be provided to deliver emergency electrical service during interruption of the normal electrical service and shall be provided to the distribution system as follows:

1. Exit lights and exit directional signs;
2. Exit access corridor lighting;
3. Lighting of means of egress and staff work areas;
4. Fire detection and alarm systems;
5. In patient care areas;
6. Signal system;
7. Equipment necessary for maintaining telephone service;
8. Elevator service that will reach every patient floor when rooms are located on other than the ground floor;
9. Fire pump;
10. Equipment for heating patient rooms;
11. Public restrooms;
12. Essential mechanical equipment rooms;
13. Battery-operated lighting and a receptacle in the vicinity of the emergency generator;
14. Alarm systems, water flow alarm devices, and alarms required for medical gas systems;
15. Patient records when solely electronically based.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former 61-16 § 2002 was titled **LOCAL AND STATE CODES AND STANDARDS** and was deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430.

SECTION 2003. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2003 was titled **SUBMISSION OF PLANS AND SPECIFICATIONS**. See, now R 61-16 § 1903.

SECTION 2004. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2004 was titled **LOCATION**.

SECTION 2100. PREVENTIVE MAINTENANCE OF LIFE SUPPORT EQUIPMENT.

A written preventive maintenance program for all life support equipment including, but not limited to, all patient monitoring equipment, isolated electrical systems, conductive flooring, patient grounding systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to insure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of life support equipment to indicate its history of testing and maintenance.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2100 was titled **HEIGHT AND AREA LIMITATIONS**.

Former R. 61-16 § 2801 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 2101. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2101 was titled **HEIGHT AND AREA LIMITATIONS**.

SECTION 2102. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2102 was titled **FIRE RESISTIVE RATING**.

SECTION 2103. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2103 was titled **VERTICAL OPENINGS**.

SECTION 2104. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2104 was titled **WALL AND PARTITION OPENINGS**.

SECTION 2105. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2105 was titled **CEILING OPENINGS**.

SECTION 2106. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2106 was titled **FIRE WALLS**.

SECTION 2107. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2107 was titled **STORAGE AREAS**.

SECTION 2108. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2108 was titled **ALTERATIONS AND REPAIRS**.

SECTION 2109. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2109 was titled **FLOOR CONSTRUCTION**.

SECTION 2110. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2110 was titled **CARPETING**.

SECTION 2200. GENERAL.

Conditions which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 1301 revised to this section by State Register Volume 38, Issue No. 6, Document No. 4430.

SECTION 2201. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2201 was titled **FURNACES AND BOILERS**.

SECTION 2202. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2202 was titled **DAMPERS**.

SECTION 2203. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2203 was titled **INCINERATORS**.

SECTION 2204. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2204 was titled **GASES**.

SECTION 2205. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2205 was titled **FLAMMABLE LIQUIDS**.

SECTION 2301. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2301 was titled **SCREENS**.

SECTION 2401. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2401 was titled **FIRE FIGHTING EQUIPMENT**.

SECTION 2402. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2402 was titled **ALARMS**.

SECTION 2403. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2403 was titled **DETECTION SYSTEM**.

SECTION 2501. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2501 was titled **NUMBER AND LOCATIONS**.

SECTION 2502. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2502 was titled **CORRIDORS**.

SECTION 2503. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2503 was titled **DOORS**.

SECTION 2504. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2504 was titled **STAIRS**.

SECTION 2505. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2505 was titled **RAMPS**.

SECTION 2506. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2506 was titled **SMOKE BARRIERS**.

SECTION 2601. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2601 was titled **WATER SUPPLY/HYGIENE**.

SECTION 2602. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2602 was titled **WASTEWATER**.

SECTION 2603. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2603 was titled **ELECTRICAL REQUIREMENTS**.

SECTION 2604. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2604 was titled **MECHANICAL SYSTEMS**.

SECTION 2701. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2701 was titled **PATIENT ROOMS**.

SECTION 2702. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2702 was titled **NURSES' STATION**.

SECTION 2703. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2703 was titled **PHYSICAL AND OCCUPATIONAL THERAPY AREAS**.

SECTION 2704. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2704 was titled **UTILITY ROOMS**.

SECTION 2705. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2705 was titled **STORAGE**.

SECTION 2706. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2706 was titled **FOOD SERVICE**.

SECTION 2707. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2707 was titled **LAUNDRY**.

SECTION 2708. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2708 was titled **JANITOR'S CLOSET**.

SECTION 2709. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2709 was titled **ELEVATORS**.

SECTION 2801. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 2801 was titled **GENERAL**. See, now R. 61-16 § 2100.

SECTION 3001. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former R. 61-16 § 3001 was titled **General** and had the following history: Added by State Register Volume 16, Issue No. 4, eff April 24, 1992.

Appendix A. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former Appendix A was titled **Prerequisites for Initial Licensure**.

Appendix B. Deleted by State Register Volume 38, Issue No. 6, Doc. No. 4430, eff June 27, 2014.

Editor's Note

Former APPENDIX B had the following history: Amended by State Register Volume 16, Issue No. 4, eff April 24, 1992.

61-17. Standards For Licensing Nursing Homes.

(Statutory Authority: 1976 Code Section 44-7-260)

SECTION 100—DEFINITIONS AND REFERENCES

101. Definitions
102. References

SECTION 200—LICENSE REQUIREMENTS AND FEES

201. License Requirements
202. License Fees
203. Exceptions to Licensing Standards

SECTION 300—ENFORCING REGULATIONS

301. General
302. Inspections and Investigations
303. Consultations

SECTION 400—ENFORCEMENT ACTIONS

401. General
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101. Definitions

For the purpose of this regulation, the following definitions shall apply:

A. Abuse. Physical abuse or psychological abuse.

1. Physical Abuse. The act of intentionally inflicting or allowing to be inflicted physical injury on a resident by an act or failure to act. Physical abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, burning, actual or attempted sexual battery, use of medication outside the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that a therapeutic procedure prescribed by a physician or other legally authorized healthcare professional or that is part of a written ICP by a physician or other legally authorized healthcare professional is not considered physical abuse. Physical abuse does not include altercations or acts of assault between residents.

2. Psychological Abuse. The deliberate use of any oral, written, or gestured language or depiction that includes disparaging or derogatory terms to a resident or within the resident's hearing distance, regardless of the resident's age, ability to comprehend, or disability, including threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

B. Activities of Daily Living (ADL). Those personal functions performed by an individual in the course of a day that include, but are not limited to, walking; bathing; shaving; brushing teeth; combing hair; dressing; eating; getting in or getting out of bed; toileting; ambulating and other similar activities.

C. Administering Medication. The direct application of a single dose of a medication to the body of a resident by injection, ingestion, or any other means. It includes the acts of preparing and giving medications in accordance with the orders of a physician or other legally authorized healthcare provider as to medication, dosage, route and frequency; observing, recording, and reporting desired effects, adverse reactions, and side effects of medication therapy; intervening when emergency care is required as a result of medication therapy; appropriately instructing the resident regarding his or her medication; recognizing accepted prescribing limits and reporting deviations to the prescriber.

D. Administrator. The individual designated by the licensee who has the authority and responsibility to manage the facility, who is in charge of all functions and activities of the facility, and who is appropriately licensed as a nursing home Administrator by the South Carolina State Board of Long-Term Health Care Administrators.

E. Adult. A person eighteen (18) years of age or older.

F. Advance Directive. Any document recognized under state law indicating a resident's choice with regard to a specific service, treatment, medication or medical procedure option that may be implemented in the future, such as power of attorney, healthcare directive, limited or restricted treatment cardio-pulmonary resuscitation (CPR), do not resuscitate (DNR), and organ tissue donation.

G. Airborne Infection Isolation (AII). A room designed to maintain Airborne Infection Isolation, formerly called a negative pressure isolation room. An Airborne Infection Isolation room is a single-occupancy resident-care room used to isolate persons with suspected or confirmed infectious tuberculosis (TB) disease. Environmental factors are controlled in Airborne Infection Isolation rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. Airborne Infection Isolation rooms may provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of six to twelve (6–12) air changes per hour (ACH), and direct exhaust of air from the room to the outside of the building or recirculation of air through a high efficiency particulate air (HEPA) filter.

H. Annual (Annually). A time period that requires an activity to be performed at least every twelve to thirteen (12 to 13) months.

I. Application. A completed application form and any supplemental documentation and information required by this regulation, for example, fee, emergency evacuation plan.

J. Assessment. A procedure for determining the nature and extent of the problem(s) and needs of a resident and/or a potential resident to ascertain if the facility can adequately address those problems, meet those needs, and to secure information for use in the development of the ICP. Included in the process is an evaluation of the physical, emotional, behavioral, social, spiritual, nutritional, recreational, and, when appropriate, pain management, vocational, educational, legal status or needs of a resident and/or a potential resident. Consideration of each resident's needs, strengths, and weaknesses shall be included in the assessment.

K. Blood Assay for *Mycobacterium tuberculosis* (BAMT). A general term to refer to *in vitro* diagnostic tests that assess for the presence of tuberculosis (TB) infection with *M. tuberculosis*. This term includes, but is not limited to, IFN-gamma release assays (IGRA).

L. Certified Nurse Aide (CNA). A person whose duties are assigned by a licensed nurse and who has successfully completed a state-approved training program or course with a curriculum prescribed by the South Carolina Department of Health and Human Services, holds a certificate of training from that program or course and is listed on the South Carolina Registry of Certified Nurse Aides.

M. Consultation. A visit by Department representatives who will provide information to the licensee in order to facilitate compliance with these regulations.

N. Contact Investigation. Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify Latent TB Infection (LTBI) or TB disease, and treatment of these persons, as indicated.

O. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the South Carolina Controlled Substances Act.

P. Controlling Interest. In the case of a corporation, controlling interest means more than fifty percent (50%) of the total combined voting power of all classes of stock of the corporation entitled to vote or more than fifty percent (50%) of the capital, profits or beneficial interest in the voting stock of the corporation. In the case of a partnership, association, trust or other entity, controlling interest means more than fifty percent (50%) of the capital, profits or beneficial interest in the partnership, association, trust or other entity.

Q. Department. The South Carolina Department of Health and Environmental Control (DHEC).

R. Designee. A staff member designated by the Administrator to act on his or her behalf.

S. Direct Care Staff Member and Direct Care Volunteer. A licensed nurse, or nurse aide; any other licensed professional who provides to residents 'hands on' direct care or services and includes, but is not limited to, a physical, speech, occupational, or respiratory care therapist; a person who is not licensed but provides 'hands on' physical assistance or care to a resident. It does not include a family member, a faculty member or student enrolled in an educational program, including clinical study in a nursing home.

T. Discharge. The termination of resident or outpatient status in a facility by which the facility no longer maintains active responsibility for the care of the resident or outpatient.

U. Dispensing Medication. The transfer of possession of one (1) or more doses of a medication or device by a licensed pharmacist or individual as permitted by law, to the ultimate consumer or his or her agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by a resident.

V. Do Not Resuscitate (DNR) Order. An order entered by the resident's attending physician in the resident's record that states that in the event the resident suffers cardiac or respiratory arrest, cardio-pulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardio-pulmonary resuscitation to the exclusion of other types of cardio-pulmonary resuscitation.

W. Electronic Signature. An electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by an individual with the legal authority to sign the record.

X. Exploitation. 1) Causing or requiring a resident to engage in an activity or labor that is improper, unlawful, or against the reasonable and rational wishes of a resident. Exploitation does not include requiring a resident to participate in an activity or labor that is a part of a written ICP or that is prescribed or authorized by the resident's attending physician; 2) an improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a resident by an individual for the profit or advantage of that individual or another individual; 3) or causing a resident to purchase goods or services for the profit or advantage of the seller or another individual through undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the resident through cunning arts or devices that delude the resident and cause him or her to lose money or other property.

Y. Facility. A nursing home licensed by the Department.

Z. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, other legally authorized healthcare provider, or registered nurse, pursuant to written standing orders and/or protocol approved by a physician's signature.

AA. Incident. An unusual unexpected adverse event, including harm, injury, or death of staff or residents, accidents, for example, medication errors, adverse medication reactions, elopement of a resident.

BB. Individual Care Plan (ICP). A documented regimen of appropriate care, treatment, services or written action plan prepared by the facility for each resident, based on assessment data, for example, social services, which is to be implemented for the benefit of the resident.

CC. Inspection. A visit by a Department representative(s) for the purpose of determining compliance with this regulation.

DD. Institutional Nursing Home. A nursing home (established within the jurisdiction of a larger nonmedical institution) that maintains and operates organized facilities and services to accommodate only students, residents or inmates of the institution.

EE. Interdisciplinary Team. A group designated by the facility to provide or supervise care, treatment, and services provided by the facility. The group normally includes the following persons: a registered nurse, dietary, social services, direct care staff members, nurse aides, and activity professionals.

FF. Investigation. An official inquiry by an authorized individual(s) to a licensed or unlicensed facility for the purpose of determining the validity of allegations received by the Department relating to this regulation.

GG. Isolation. The separation of individuals known or suspected (via signs, symptoms, or laboratory criteria) to be infected with a contagious disease to prevent them from transmitting disease to others.

HH. Latent TB Infection (LTBI). Infection with *M. tuberculosis*. Persons with Latent TB Infection carry the organism that causes TB but do not have TB disease, are asymptomatic, and are noninfectious. Such persons usually have a positive reaction to the tuberculin skin test and/or positive BAMT.

II. Legally Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina to provide specific medical treatments, care, or services to staff members and/or residents, for example, advanced practice registered nurses, physician assistants.

JJ. Legend Drug.

1. A medication required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:

- a. "Caution: Federal law prohibits dispensing without prescription";
- b. "Rx only";

2. A medication required by federal or state law to be dispensed pursuant to a prescription medication order or restricted to use by practitioners only;

3. Any medication products designated by the South Carolina Board of Pharmacy to be a public health threat; or

4. Any prescribed compounded prescription within the meaning of the South Carolina Pharmacy Practice Act.

KK. License. A printed certificate issued by the Department to the licensee that authorizes the operation of a nursing home.

LL. Licensed Nurse. A person licensed by the South Carolina Board of Nursing as a registered nurse or licensed practical nurse or a person licensed as a registered nurse or licensed practical nurse who resides in another state that has been granted multi-state licensing privileges by the South Carolina Board of Nursing. This person may practice nursing in any facility or activity licensed by the Department subject to the provisions and conditions as indicated in the Nurse Licensure Compact Act.

MM. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care, treatment, and services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

NN. Medication. A substance that has therapeutic effects, including, but not limited to, legend drugs, nonlegend and herbal products, vitamins, and nutritional supplements.

OO. Monthly. A time period that requires an activity to be completed at least twelve (12) times a year within intervals ranging from twenty-five to thirty-five (25 to 35) days.

PP. Neglect. The failure or omission of a direct care staff member or direct care volunteer to provide the care, goods, or services necessary to maintain the health or safety of a resident including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services. Neglect may be repeated conduct or a single incident that has produced or could result in physical or psychological harm or substantial risk of death. Noncompliance with regulatory standards alone does not constitute neglect.

QQ. Nonlegend Medication. A medication that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws of this state and the federal government.

RR. Nursing Home. A facility with an organized nursing staff to maintain and operate organized facilities and services to accommodate two (2) or more unrelated individuals over a period exceeding twenty-four (24) hours which is operated either in connection with a hospital or as a freestanding facility for the express or implied purpose of providing intermediate or skilled care for persons who are not in need of hospital care.

SS. Occupational Therapist. A person currently licensed as such by the South Carolina Board of Occupational Therapy Examiners.

TT. Pharmacist. A person currently registered as such by the South Carolina Board of Pharmacy.

UU. Physical Examination. An examination of a resident that addresses those issues identified in Section 1200 of this regulation.

VV. Physical Therapist. A person currently licensed as such by the South Carolina Board of Physical Therapy Examiners.

WW. Physician. A person currently licensed as such by the South Carolina Board of Medical Examiners.

XX. Physician Order. A physician's written authorization or prescription for the provision of services.

YY. Physician Assistant. A person currently licensed as such by the South Carolina Board of Medical Examiners.

ZZ. Quality Improvement Program. The process used by a facility to examine its methods and practices of providing care, treatment, and services, identify the ways to improve its performance, and take actions that result in higher quality of care and services for the facility's residents.

AAA. Quarterly. A time period that requires an activity to be performed at least four (4) times a year within intervals ranging from eighty-one to ninety-nine (81 to 99) days.

BBB. Repeat Violation. The recurrence of any violation cited under the same section of the regulation within a thirty-six-month (36-month) period. The time period determinant of repeat violation status is not interrupted by licensee changes.

CCC. Resident. Any person, other than a staff member or volunteer, who resides in a facility and occupies a licensed bed.

DDD. Resident Council. A group of residents having the right to meet as a group to address resident issues and to make recommendations and suggest ways to improve resident care and services.

EEE. Resident Room. An area enclosed by four (4) ceiling high walls (or as determined by the Department) that can house one (1) or more residents of the facility.

FFF. Respite Care. Short-term care (a period of six (6) weeks or less) provided to an individual to relieve the family members or other individuals caring for the individual, but for not less than twenty-four (24) hours.

GGG. Responsible Party. A person who is authorized by the resident or by law to make decisions on behalf of a resident, to include, but not be limited to, a court-appointed guardian (or legal guardian as referred to in the Bill of Rights for Residents of Long-Term Care Facilities) or conservator, or individual with a healthcare power of attorney or other durable power of attorney.

HHH. Restraint. Any means by which movement of a resident is inhibited, for example, physical, mechanical, chemical. In addition, devices shall be considered restraints if a resident is unable to easily release from the device. Wrist bands or devices that trigger electronic alarms to warn staff that a resident is leaving a chair, bed, or room that do not restrict freedom of movement are not considered restraints.

III. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding a facility's authority to operate.

JJJ. Risk Assessment. A periodic comprehensive process of gathering, organizing, and analyzing tuberculosis data by a qualified individual or group of individuals, for example, epidemiologists, infectious disease specialists, pulmonary disease specialists, infection-control practitioners, health-care Administrator, occupational health personnel, or local public health personnel, to establish the probability of adverse health impacts and to determine the current risk for transmission of tuberculosis in all areas of the facility.

KKK. Self-Administration. A procedure in which any medication is taken orally, injected, inserted, or topically or otherwise administered by a resident to himself or herself without prompting. The procedure is performed without staff assistance and includes removing an individual dose from a previously dispensed and labeled container (including a unit dose container), verifying it with the directions on the label, taking it orally, injecting, inserting, or applying topically or otherwise administering the medication.

LLL. Shifts. Shift one (1) is a work period that occurs primarily during the daytime hours including, but not limited to, seven a.m. to three p.m. (7:00 a.m. to 3:00 p.m.); Shift two (2) is a work period that generally includes both daytime and evening hours including, but not limited to, three p.m. to eleven p.m. (3:00 p.m. to 11:00 p.m.); Shift three (3) is a work period that occurs primarily during the nighttime hours including, but not limited to, eleven p.m. to seven a.m. (11:00 p.m. to 7:00 a.m.) In those facilities utilizing two (2) twelve-hour (12-hour) shifts, shift one (1) is the twelve-hour (12-hour) shift occurring primarily during the day, and the next shift is the twelve-hour (12-hour) shift occurring primarily during the night (See Section 605.C).

MMM. Signal System. A system that visibly and audibly registers nurse calls electronically from the resident's bed, toilet, or bathing area to the staff work area.

NNN. Signature. At least the first initial and full surname and title, for example, R.N., L.P.N., D.D.S., M.D., or D.O., of a person, written with his or her own hand. A controlled electronic representation of the signature or an approved rubber stamp signature may be used as legally appropriate.

OOO. Staff Member. A person who is a compensated employee of the facility on either a full or part-time basis.

PPP. Suspension of License. An action by the Department terminating the licensee's authority to admit new residents or readmit former residents for a period of time until the Department rescinds that restriction. It may also require the transfer or relocation of residents or the discontinuance of the services, treatment or care provided to residents. Suspension of license also includes instances when the Department determines that an immediate threat to the residents exists and residents are appropriately transferred, per S.C. Code Section 44-7-320(A).

QQQ. Tuberculin Skin Test (TST). A diagnostic aid for detecting *M. tuberculosis* infection. A small dose (0.1 mil) of purified protein derivative (PPD) tuberculin is injected just beneath the surface of the skin (by the Mantoux method), and the area is examined for induration (hard, dense, raised area at the site of TST administration) by palpation forty-eight to seventy-two (48-72) hours after the injection (but positive reactions can still be measurable up to a week after TST administration). The size of the indurated area is measured with a millimeter ruler after identifying the margins transverse (perpendicular) to the long axis of the forearm. The reading is recorded in millimeters, including zero (0) mm to represent no induration. Redness or erythema is insignificant and is not measured or recorded.

RRR. Two-Step Testing. Procedure used for the baseline skin testing of persons who may periodically receive TST to reduce the likelihood of mistaking a boosted reaction for a new infection. If the initial TST result is interpreted as negative, a second test is repeated one to three (1-3) weeks after the initial test. If the initial TST result is interpreted as positive, then the reaction shall be documented and followed up as positive; this reaction will serve as the baseline and no further skin testing is indicated. If the second test is given and its result is interpreted as positive, then the reaction shall be documented and followed up as positive; this reaction will serve as the baseline reading and no further skin testing is indicated. In general, the result of the second TST of the two-step procedure shall be used as the baseline reading.

SSS. Unit Dose. The ordered amount of a drug in a prepackaged dosage form ready for administration to a particular individual by the prescribed route at the prescribed time in accordance with all applicable laws and regulations governing these practices.

TTT. Unrelated (As in kinship). All degrees of kinship that are not included "within the third degree of consanguinity," for example, a spouse, son, daughter, sister, brother, parent, aunt, uncle, niece, nephew, grandparent, great-grandparent, grandchild, or great-grandchild.

UUU. Volunteer. An individual who performs tasks at the facility at the direction of facility staff without compensation.

VVV. Weekly. A time period that requires an activity to be completed at least fifty-two (52) times a year within intervals ranging from six to eight (6 - 8) days.

WWW. Written. Any worded or numbered expression, that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

102. References

- A. The following Departmental standards and/or publications are referenced in these regulations:
 1. Regulation 61-4, Controlled Substances;
 2. Regulation 61-19, Vital Statistics;
 3. Regulation 61-20, Communicable Diseases;
 4. Regulation 61-25, Retail Food Establishments;
 5. Regulation 61-58, State Primary Drinking Water Regulations;
 6. Regulation 61-105, Infectious Waste Management.
- B. Non-Departmental standards, publications, or organizations:
 1. Alzheimer's Special Care Disclosure Act;

2. American Association of Blood Banks (AABB) (Blood Products Advisory Committee, March 14, 2002);
3. Bill of Rights for Residents of Long-Term Care Facilities;
4. Bloodborne Pathogens Standards, Occupational Safety and Health Act of 1970 (OSHA 29 CFR 1910.1030, April 3, 2006);
5. Centers for Disease Control and Prevention (CDC) (CDC Personnel Health Guideline, June, 1998);
6. Centers for Medicare and Medicaid Services (CMS);
7. Civil Rights Act of 1964;
8. Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences;
9. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005;
10. Occupational Safety and Health Act of 1970 (OSHA);
11. Omnibus Adult Protection Act;
12. South Carolina State Fire Marshal Regulations.

C. The Department shall, at its discretion, enforce new laws that may amend the above-noted references.

SECTION 200—LICENSE REQUIREMENTS AND FEES

201. License Requirements

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise or market) as a nursing home in South Carolina without first obtaining a license from the Department. (I)

1. When it has been determined by the Department that nursing care is being provided at a location to accommodate two (2) or more unrelated persons over a period exceeding twenty-four (24) hours, and the owner has not been issued a license from the Department to provide such care, treatment, and/or services, the owner shall cease operation immediately and assure the health and safety of the residents. (I)

2. A facility shall provide only the care, treatment, and/or services of which it is capable and equipped to provide, and has been authorized by the Department to provide. (I)

3. Current or previous violations of the South Carolina Code of Laws and/or Department regulations may jeopardize the issuance of a license for the facility or the licensing of any other facility or activity or addition to an existing facility that is owned or operated by the licensee. (I)

4. No license may be issued, reissued, or renewed until all monetary penalties finally assessed against a facility have been paid and/or other enforcement actions resolved.

B. Compliance. An initial license shall not be issued to an owner and/or operator until the owner and/or operator has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing standards. In the event a licensee who already has a facility or activity licensed by the Department makes application for another facility or activity or increase in licensed capacity, the currently licensed facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or activity or an amended license to the existing facility. Facilities shall comply with applicable state, federal, and local laws, codes, and regulations. (II)

1. A copy of the licensing regulation for nursing homes in South Carolina and a current copy of R.61-25 shall be maintained in the facility by the licensee.

2. The license is considered property of the Department and may not be duplicated in such a manner that it cannot be distinguished from the original. (II)

C. Compliance with Building Standards. Licensed facilities shall be allowed to continue utilizing the previously-licensed structure without building modification and shall comply with the remainder of the standards within this regulation. Proposed facilities for which the licensee has received written approval from the Department's Division of Health Facilities Construction prior to the effective date of this regulation shall be allowed to comply with the previously-approved building standards and shall

comply with the remainder of the standards within this regulation. Existing facilities are not required to modify square footage of resident rooms, sitting areas, and maximum number of beds in resident rooms. (II)

D. Licensed Bed Capacity. No facility that has been licensed for a set number of licensed beds, as identified on the face of the license, shall exceed the licensed bed capacity. No facility shall establish new care or services or occupy additional beds or renovated space without first obtaining authorization from the Department. Beds for use of staff members and volunteers are not included in the licensed bed capacity number, provided such beds and locations are so identified and used exclusively by staff members and volunteers. (I)

E. Persons Received in Excess of Licensed Bed Capacity. No facility shall receive for care, treatment, or services persons in excess of the licensed bed capacity. As an exception, in the event that the facility temporarily provides shelter for evacuees who have been displaced due to a justified emergency, such as a disaster, then for the duration of that emergency, provided the health and safety of all residents are reasonably accommodated, it is permissible to temporarily exceed the licensed capacity for the facility in order to accommodate these persons (See Section 1503). (I)

F. Issuance and Terms of License. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility. (II)

1. The issuance of a license does not guarantee adequacy of individual care, treatment and/or services, personal safety, and fire safety of any resident or occupant of a facility. (II)

2. A license is not assignable or transferable and is subject to suspension or revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this state. (II)

3. A license shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status. (II)

4. Multiple nursing homes owned by the same entity but not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, for example, interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property. Separate licenses are not required for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

5. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

6. A facility may furnish respite care if it complies compliance with the standards of this regulation.

G. Facility Name. No proposed facility shall be named nor shall any existing facility have its name changed to the same or similar name as any other facility licensed in South Carolina. The Department shall determine if names are similar. If an entity owns multiple facilities and elects to use a common name for two (2) or more of the facilities, the geographic area in which the facilities is located may be part of the name.

H. Application. Applicants for a license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes both the applicant's oath assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; in the case of a corporation, by two (2) of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in the event his or her address is different from that of the facility, the names of the persons in control of the facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with this regulation. Corporations or partnerships shall be registered with the South Carolina Office of the Secretary of State. Other required application information includes:

1. A copy of the business license, as applicable;
2. A copy of the facility's emergency evacuation plan (See Section 1502);
3. A copy of the Nursing Home Administrator's license;

4. Articles of Incorporation or Partnership documents, as applicable;
 5. A licensing fee (See Section 202);
 6. A written agreement with a public fire department arranging for emergency response in case of fire, if applicable (See Section 1601.B);
 7. A state and federal fingerprint-based criminal records check on the person(s) required to sign the application for licensure pursuant to S.C. Code Section 44-7-264.
- I. License Renewal. For a license to be renewed, applicants shall file an application with the Department, pay a licensing fee, and shall not be under consideration for or undergoing enforcement actions by the Department. (II)
- J. Change of License. A licensee shall request issuance of a new or amended license by application to the Department prior to any of the following circumstances: (II)
1. Change of licensee; where any of the following occurs:
 - a. A change in the controlling interest even if, in the case of a corporation or partnership, the legal entity retains its identity and name.
 - b. A change of the legal entity, for example, sole proprietorship to or from a corporation, partnership to or from a corporation, even if the controlling interest does not change.
 - c. In a new or change in management agreement, if the ultimate authority for the operation of the facility is surrendered and transferred from the licensee to a new manager, then a change of licensee has occurred.
 2. Change of licensed bed capacity; or
 3. Change of facility location from one geographic site to another.
- K. Change of Facility Name or Address. Changes in facility name or address (as notified by the post office) shall be accomplished by application from the licensee. (II)
- L. Facilities Owned and Operated by the Federal Government. A nursing home license shall not be required for, nor shall such a license be issued to facilities owned and operated by the federal government or facilities providing room, board, and personal care which do not require the technical skill, services or supervision of a licensed nurse.

202. License Fees

- A. Licensing Fees. A nonrefundable initial and annual licensing fee of twenty dollars (\$20.00) per licensed bed, or four hundred dollars (\$400.00), whichever is greater, shall be submitted to the Department. Such fee shall be made payable by credit card, check or money order to the Department.
- B. Late Fee. Failure to submit a license renewal application or fee to the Department by the license expiration date may result in a late fee of seventy-five dollars (\$75.00) or twenty-five percent (25%) of the licensing fee amount, whichever is greater, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time period specified by the Department may result in enforcement actions. (II)

203. Exceptions to Licensing Standards

The Department may make exception(s) to these standards, providing an option for compliance, when it is determined that the health and safety of residents are not compromised and provided the standard(s) is not specifically required by statute. In the event of a licensee change, exceptions are not transferable to the new licensee unless approved by the Department.

SECTION 300—ENFORCING REGULATIONS

301. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

302. Inspections and Investigations

- A. An inspection shall be conducted prior to initial licensing. Inspections shall be conducted as deemed appropriate by the Department. (I)
- B. All facilities, proposed facilities, or unlicensed facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by South Carolina Code of Laws. (II)

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records. If photocopies are made for the Department inspector, they shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. Physical area of inspections shall be determined by the extent to which there is potential impact or effect upon residents as determined by the inspector. (I)

D. A facility or proposed facility found noncompliant with the standards of this regulation shall submit an acceptable written plan of correction to the Department that shall be signed by the Administrator and returned by the date specified by the Department. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar);
3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the response(s) by the facility or proposed facility, shall be provided to the public upon written request with the redaction of the names of those persons in the report as provided by S.C. Code Sections 44-7-310 and 44-7-315.

F. The Department may charge a fee for plan reviews, construction inspections, and licensing inspections.

303. Consultations

Consultations may be provided by the Department as requested by the facility or as deemed appropriate by the Department.

SECTION 400—ENFORCEMENT ACTIONS

401. General

A. When the Department determines that a licensee, proposed licensee, or an unlicensed facility owner is in violation of statutory provisions, rules, or regulations relating to the operation of a facility, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, revoke, or refuse to issue or renew a license.

B. Food service permits may be revoked or suspended for violations in accordance with R.61-25.

402. Violation Classifications

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health and safety of the persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one (1) or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health and safety of persons in the facility. The citation of a Class II violation may specify the time within which the violation is required to be corrected. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. When a specific time is designated for correction, each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

D. The notations, “(I)” or “(II)” placed within sections of this regulation, indicate those standards are considered Class I or II violations, respectively, if they are not met. Standards not so annotated are considered Class III violations.

E. In arriving at a decision to take enforcement action, the Department will consider the following factors: the number and classification of violations, including repeat violations; specific conditions and their impact or potential impact on health and safety of the residents; efforts by the facility to correct cited violations; behavior of the licensee that would reflect negatively on the licensee's character, such as illegal or illicit activities; overall conditions of the facility; history of compliance; any other pertinent conditions that may be applicable to statutes and regulations.

F. When a decision is made to impose monetary penalties, the Department may invoke S.C. Code Section 44-7-320(C), to determine the dollar amount or may utilize the following schedule as a guide to determine the dollar amount:

Frequency of violation of standard within a thirty-six (36) month period:

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	\$500 - 1,500	\$300 - 800	\$100 - 300
2nd	1,000 - 3,000	500 - 1,500	300 - 800
3rd	2,000 - 5,000	1,000 - 3,000	500 - 1,500
4th	5,000	2,000 - 5,000	1,000 - 3,000
5th	5,000	5,000	2,000 - 5,000
6th and more	5,000	5,000	5,000

SECTION 500—POLICIES AND PROCEDURES (II)

A. There shall be written policies and procedures addressing the manner in which the requirements of this regulation shall be met. The written policies and procedures shall accurately reflect actual facility practice regarding care, treatment, procedures, services, record keeping and reporting, admission and transfer, physician services, nursing services, social services, resident rights and assurances, medication management, pharmaceutical services, meal service operations, emergency procedures, fire prevention, maintenance, housekeeping and infection control, the operation of the facility, and other special care and procedures as identified in this section. The policies and procedures shall address the provision of any special care offered by the facility that would include how the facility shall meet the specialized needs of the affected residents such as Alzheimer's disease and/or related dementia, physically or developmentally disabled, in accordance with any laws that pertain to that service offered, for example, Alzheimer's Special Care Disclosure Act.

B. Specifically, there shall be written policies and procedures to:

1. Assure that residents do not develop pressure-related wounds unless the resident's clinical condition demonstrates that they were unavoidable and to address treatment of existing pressure-related wounds;
2. Address resident exit-seeking and elopement, including prevention and actions to be taken in the event of occurrence;
3. Implement advance directives in accordance with S.C. Code Sections 44-77-10, *et seq.*, including provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical treatment and, at the individual's option, formulate an advance directive. The policies shall not condition treatment or admission upon whether the individual has executed or waived an advance directive;
4. Control the use and application of physical restraints and all facility practices that meet the definition of a restraint, such as bed rails used to keep a resident from getting out of bed;

C. All policies and procedures shall:

1. Establish a time period for review of policies and procedures in writing and such reviews shall be documented;
2. Be revised as appropriate in order to reflect actual facility practice; and
3. Be accessible to staff, printed or electronically, at all times.

D. If the facility permits any portion of a resident's record to be generated by electronic or optical means, there shall be policies and procedures to prohibit the use or authentication by unauthorized users.

SECTION 600—STAFF AND TRAINING

601. General (II)

A. Direct care staff members shall undergo a criminal background check prior to being employed or contracting with a licensed nursing home facility pursuant to S.C. Code Section 44-7-2910. Staff members of the facility shall not have a prior conviction or pled no contest (nolo contendere) for child or adult abuse, neglect, or mistreatment, or pursuant to S.C. Code Section 16-1-10(A), any Class A, B, C, or D felony or Class E or F felony involving criminal sexual conduct, physical or sexual abuse of children, elderly or infirm, or crimes where the victim is a patient or resident of a health care facility. The facility shall coordinate with appropriate abuse-related registries prior to the employment of staff. (I)

B. Direct care staff members, in addition to meal service staff, shall have at least the following qualifications: (I)

1. Ability to render care and services to residents in an understanding and gentle manner;
2. Sufficient education to be able to perform their duties;
3. A working knowledge of regulations applicable to their scope of work;
4. Be an adult, or, if not an adult, the facility shall assure that there is compliance with state, federal, and local laws pertaining to the employment of children.

C. There shall be accurate current information maintained regarding all staff members of the facility that shall include:

1. Name, address and telephone number;
2. Date of hire;
3. Past employment, experience, and education;
4. Professional licensure or registration number or certificate or letter of completion;
5. Position in the facility and job description;
6. Documentation of orientation to the facility, including residents' rights, regulation compliance, policies and procedures, job duties, in-service training and on-going education;
7. Health status, health assessment, and tuberculin testing results;
8. Evidence that a criminal record check has been completed;
9. For former staff members, the date of separation;
10. Date of initial resident contact may be maintained by the facility.

D. Time schedules shall be maintained indicating the numbers and classification of all staff, including relief staff, who work on each shift of duty. The time schedules shall reflect all changes so as to indicate who actually worked.

E. Staff members shall not have an active dependency on a psychoactive substance(s) that would impair his or her ability to perform assigned duties.

F. Staff members shall display identification in accordance with facility policies and procedures that is visible at all times while on duty.

G. When a facility engages a source other than the facility to provide services normally provided by the facility, for example, staffing, training, recreation, meal service, social services, professional consultant, maintenance, transportation, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and the requirement that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to resident care, treatment, services, and rights.

602. Administrator

A. Each facility shall have a full-time licensed Administrator. (II)

B. The facility Administrator shall be licensed as a nursing home Administrator in accordance with S.C. Code Section 40-35-30. In addition, all other applicable provisions of S.C. Code Title 40, Chapter 35, shall be followed. (II)

C. The Administrator shall exercise judgment that reflects that he or she is in compliance with these regulations and shall demonstrate adequate knowledge of these regulations. (II)

D. A staff member shall be designated, by name or position, in writing, to act in the absence of the Administrator, for example, a listing of the lines of authority by position title, including the names of the individuals filling these positions. (II)

E. The Administrator shall have sufficient freedom from other responsibilities and duties to carry out the functions associated with the position.

F. No individual may be the Administrator of more than one (1) nursing home. (II)

603. Direct Care Staff (II)

A. There shall be direct care staff adequate in number and skill in the facility at all times to provide nursing and related care and services to attain or maintain the highest practicable physical, mental, and psychosocial health and safety of each resident, as determined by resident assessments and ICPs. Direct care staff shall be assigned only duties for which they are trained.

B. Licensed nurse staff members shall be currently and continuously licensed to practice nursing in South Carolina during the period they are staff members. Only individuals appropriately licensed may perform duties requiring a registered or licensed practical nurse. (I)

C. Persons working in the facility as nurse aides shall be certified in South Carolina. As an exception, facility nonlicensed staff who are enrolled in a nurse aide training and competency evaluation program approved by the S.C. Department of Health and Human Services and who have been working in the facility four (4) months or less are exempt from Section 603.C. Licensed nurses or applicants for such licensure who have been granted a permit to practice nursing in accordance with rules adopted by the South Carolina Board of Nursing are exempt from Section 603.C. (I)

604. Medical Staff (I)

The facility shall have a medical director who is a physician who shall be responsible for implementation of policies and procedures that pertain to the care and treatment of the residents and the coordination of medical care in the facility.

605. Staff (I)

A. Licensed Nursing Staff. An adequate number of licensed nurses shall be on duty to meet the total nursing needs of residents. Licensed nursing staff shall be assigned to duties consistent with their scope of practice as determined through their licensure and educational preparation.

1. The facility shall designate a registered nurse as a full-time Director of Nursing. Another registered nurse, who is employed by the licensee, shall be designated in writing to act in his or her absence. In facilities with a licensed bed capacity of twenty-two (22) or fewer beds, the Director of Nursing may be included in the requirements of Section 605.A.2.

2. There shall be at least one (1) licensed nurse per shift for each staff work area. If there are more than forty-four (44) residents per staff work area, there shall be two (2) licensed nurses on first shift and at least one (1) licensed nurse on second and third shift.

3. At least one (1) registered nurse shall be on duty in the facility, or on call, whenever residents are present in the facility.

4. An Administrator who is a registered nurse or licensed practical nurse shall not be included in meeting the staffing requirements of this section.

B. Nonlicensed Nursing Staff. The required number of nurse aides and other nonlicensed nursing staff shall be determined by the number of residents assigned to beds at the facility. Additional staff members shall be provided if the minimum staff requirements are inadequate to provide appropriate care and services to the residents of a facility.

1. Nonlicensed nursing staff shall be provided to meet at least the following resident-to-staff ratio schedule:

- a. Nine to one (9 to 1) for shift one (1);
- b. Thirteen to one (13 to 1) for shift two (2);
- c. Twenty-two to one (22 to 1) for shift three (3).

2. When nonstaff members are utilized as sitters or attendants, they shall comply with facility policies and procedures.

C. In those facilities utilizing two (2) twelve-hour (12-hour) shifts, both the licensed and nonlicensed staffing ratios for shift one (1) apply to the twelve-hour (12-hour) shift occurring primarily during the day, and both the licensed and nonlicensed staffing ratios for shift three (3) apply to the twelve-hour (12-hour) shift occurring primarily during the night.

D. In settings and on a nonroutine basis where there is more than one (1) type of level of care, for example, community residential care, independent living, staff members from the nursing home may temporarily provide assistance in special situations to one (1) or more of the other areas, but at no time may staffing levels in any area of the nursing home fall below minimum licensing standards or diminish the care and services provided.

606. Inservice Training (II)

A. Staff members shall be provided the necessary training to perform the duties for which they are responsible.

B. Before performing any duties, all newly-hired staff members shall be oriented to the facility organization and physical plant, specific duties and responsibilities of staff members, and residents' needs. All staff members shall be instructed in the provisions of S.C. Code Section 43-35-5 *et seq.*, "Omnibus Adult Protection Act" and S.C. Code Section 44-81-10 *et seq.*, "Bill of Rights for Residents of Long-Term Care Facilities" as well as other rights and assurances as required in this regulation.

C. All staff shall be provided inservice training programs that identify training needs related to problems, needs, care of residents and infection control and are sufficient to assure staff's continuing competency. Training for the tasks each staff member performs shall be conducted in order to provide the care, treatment, procedures, and/or services delineated in Section 1000.

D. All licensed nurses shall possess a valid Healthcare Provider cardio-pulmonary resuscitation (CPR) certificate within six (6) months of their first day on the job in the facility. (I)

E. Those staff members who operate motor vehicles that transport residents shall have a valid driver's license.

F. Training shall be provided to staff members by appropriate resources, for example, licensed or registered individuals, video tapes, books, in context with their job duties and responsibilities, prior to their date of initial resident contact (unless otherwise as noted below) and at a frequency determined by the facility, but at least annually. (I)

1. All staff members:

a. Emergency procedures and disaster preparedness to address various types of potential disasters such as evacuation, bomb threat, earthquake, flood, hurricane, tornado and others within forty-eight (48) hours of their first day on the job in the facility (See Section 1500);

b. Fire response training (See Section 1603);

c. Confidentiality of resident information and records and the protection of resident rights (review of "Bill of Rights for Residents of Long-Term Care Facilities").

2. Direct care staff members, all of the training listed in Section 606.F.1, and:

a. Management and care of individuals with contagious and/or communicable disease, for example, hepatitis, tuberculosis, HIV infection;

b. Use of restraints that promote resident safety, including alternatives to physical and chemical restraints, in accordance with the provisions of Section 1012 (for designated staff members only);

c. Prevention of pressure-related wounds;

d. Aseptic techniques, such as handwashing and scrubbing practices, proper gowning and masking, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of equipment and supplies.

607. Health Status (II)

A. All staff members who have contact with residents shall have a health assessment (in accordance with Section 101.Z) within twelve (12) months prior to date of hire or initial resident contact.

B. The health assessment shall include tuberculosis screening in the manner designated by guidelines established by the Department.

C. If a staff member is working at multiple facilities operated by the same licensee, copies of his or her record for tuberculin testing results and the pre-employment health assessment shall be acceptable at each facility.

608. Volunteers

A. If the facility has a volunteer program, a facility staff person shall direct the program. Community groups such as Boy and Girl Scouts, church groups, civic organizations or individuals that may occasionally present programs, activities, or entertainment in the facility shall not be considered volunteers. Volunteers shall be subject to the same standards regarding resident confidentiality and practice as the facility staff. Volunteers shall consult with licensed staff prior to any changes in resident care or treatment. The facility may elect to prohibit volunteers to work in the facility.

B. The licensee is responsible for all the activities that take place in the facility including the coordination of volunteer activities. (II)

1. Volunteers shall receive the orientation, training, and supervision necessary to assure resident health and safety before performing any duties. The orientation program shall include, but not be limited to:

- a. Resident rights;
- b. Confidentiality;
- c. Disaster preparedness;
- d. Emergency response procedures;
- e. Safety procedures and precautions; and
- f. Infection control.

2. There shall be accurate current information maintained regarding all volunteers that shall include:

- a. Name, address and telephone number;
- b. Documentation of orientation to the facility, including residents' rights, regulation compliance, policies and procedures, training, and duties;
- c. Date of initial resident contact may be maintained by the facility, if applicable.

3. Facilities shall require that volunteers sign in and out with staff of the facility upon entering or leaving the facility. Volunteers shall wear legible name and title badges that are visible at all times while on duty.

4. Volunteers and paid feeding assistants (as defined in the federal regulations on paid feeding assistants) shall not be included in the minimum staffing requirements of Section 605.

C. Documentation maintained for direct care volunteers shall include: (II)

1. A health assessment (in accordance with Section 607) within twelve (12) months prior to initial date of volunteering or initial resident contact;

2. Familiarization with the disaster plan (See Section 1502) and documented instructions as to any required actions;

3. Fire response training (See Section 1603) within twenty-four (24) hours of his or her first day as a direct care volunteer and at least annually thereafter;

4. A criminal record check (See Section 601.A) completed prior to working as a direct care volunteer;

5. Determination of TB status (See Section 1703) prior to initial resident contact or his or her first day working as a direct care volunteer;

6. Annual influenza vaccination and hepatitis B vaccination series (See Section 1706) unless the vaccine is medically contraindicated or the person is offered the vaccination and declined. In either case, the decision shall be documented.

609. Private Sitters

A. If a resident or responsible party has not agreed in writing with the facility to not have a private sitter and chooses to employ a private sitter for use in the facility, the facility may establish a formalized private sitter program that shall be directed by a facility staff member.

1. The facility shall assure that private sitters have been chosen in accordance with the Bill of Rights for Residents of Long-Term Care Facilities.

2. The facility shall establish written policies and procedures for the private sitter program, to include duties.

3. There shall be accurate current information maintained regarding private sitters including:

a. Name, address and telephone number;

b. Date of initial resident contact may be maintained by the facility, if applicable.

c. Prior to resident contact, the private sitter shall have documented orientation to the organization and environment of the facility. Orientation to the facility shall consist, at least, of the following:

1. Residents' rights;

2. Confidentiality;

3. Disaster preparedness;

4. Emergency response procedures;

5. Fire response training (See Section 1603) within twenty-four (24) hours of his or her first day as a private sitter and at least annually thereafter;

6. Safety procedures and precautions;

7. Infection control; and

8. Private Sitter Policies and Procedures.

B. The facility shall maintain the following documentation regarding private sitters:

1. A health assessment (in accordance with Section 607) within twelve (12) months prior to initial resident contact or his or her first day working as a private sitter;

2. A criminal record check (See Section 601.A) completed prior to working as a private sitter;

3. Determination of TB status (See Section 1703) prior to initial resident contact or his or her first day working as a private sitter;

4. Annual influenza vaccination and hepatitis B vaccination series (See Section 1706).

C. Private sitters shall not be included in the minimum staffing requirements of Section 605.

D. Private sitters shall sign in and sign out with facility staff upon entering or leaving the facility. Private sitters shall display identification in accordance with facility policies and procedures that is visible at all times while on duty.

SECTION 700—REPORTING

701. Accidents and Incidents

A. A facility shall maintain a record of each accident and incident, including each serious accident and incident as defined in Section 701.B, involving residents or staff members or volunteers, occurring in the facility or on the facility grounds. A facility's record of each accident and incident shall be reviewed, investigated if necessary, evaluated in accordance with facility policies and procedures, and retained by the facility for six (6) years after the resident stops receiving services.

B. A facility shall report every serious accident and incident that results in resident's death or significant loss of function or damage to a body structure, not related to the natural course of a resident's illness or underlying condition or normal course of treatment, and resulting from an accident or incident occurring to resident within the facility or on the facility grounds. Serious accidents and incidents requiring reporting include, but are not limited to:

1. Crime(s) against resident;

2. Confirmed or suspected cases of abuse, neglect, or exploitation;

3. Medication error with adverse reaction;

4. Hospitalization as a result of the accident or incident;

5. Severe hematoma, laceration, or burn requiring medical attention or hospitalization;

6. Bone fracture or joint fracture;

7. Severe injury involving use of restraints;
8. Attempted suicide; or
9. Fire.

C. A facility shall immediately report every serious accident and incident to the attending physician, next-of-kin or responsible party, and the Department via telephone, email, or facsimile within twenty-four (24) hours of the serious accident or incident.

D. A facility shall submit a written report of its investigation of every serious accident and incident to the Department within five (5) days of the serious accident or incident. A facility's written report to the Department shall provide at a minimum:

1. Facility name;
2. License number;
3. Type of accident or incident;
4. Date accident or incident occurred;
5. Number of residents directly injured or affected;
6. Resident record number or last four (4) digits of Social Security Number;
7. Resident age and sex;
8. Number of staff directly injured or affected;
9. Number of visitors directly injured or affected;
10. Name(s) of witness(es);
11. Identified cause of accident or incident;
12. Internal investigation results if cause unknown; and
13. Brief description of the accident or incident including the location of occurrence and treatment of injuries.

E. A facility shall retain a copy of every serious accident and incident with all of the information provided to the Department and the names, injuries, and treatments associated with each resident, staff, and/or visitor involved. A facility shall retain all serious accident and incident records for six (6) years after the resident stops receiving services.

F. The Administrator or his or her designee shall report every accident and incident involving a resident that leaves the premises for more than twenty-four (24) hours without notice to staff members of intent to leave to local law enforcement, the resident's responsible party, and the Department. The Administrator or his or her designee shall immediately notify local law enforcement and the responsible party by telephone when a cognitively impaired resident leaves the premises for any amount of time without notice to staff members.

G. The Administrator or his or her designee shall report changes in the resident's condition, to the extent that serious health concerns and/or injuries, such as, fracture, behavior changes or heart attack, are evident, to the attending physician and the responsible party immediately, not to exceed twenty-four (24) hours, consistent with the severity or urgency of the change in accordance with facility policies and procedures. (I)

H. The Administrator or his or her designee shall report abuse and suspected abuse, neglect, or exploitation of residents the South Carolina Long-Term Care Ombudsman Program in accordance with S.C. Code Section 43-35-25.

702. Fire and Disasters (III)

A. The Department shall be notified immediately via telephone, email, or fax regarding any fire, regardless of size or damage that occurs in the facility, and followed by a complete written report to include fire department reports, if any, to be submitted within a time period determined by the facility, but not to exceed five (5) days.

B. Any natural disaster in the facility which requires displacement of the residents, or jeopardizes or potentially jeopardizes the safety of the residents, shall be reported to the Department via telephone, email, or fax immediately, with a complete written report that includes the fire department

report from the local fire department, if appropriate, submitted within a time period as determined by the facility, but not to exceed five (5) days.

703. Communicable Diseases and Animal Bites (I)

All cases of reportable diseases, animal bites, any occurrences such as epidemic outbreaks or poisonings, or other unusual occurrences that threaten the health and safety of residents or staff shall be reported in accordance with R.61-20.

704. Administrator Change

The Department shall be notified in writing by the licensee within ten (10) days of any change in Administrator. The notice shall include at a minimum the name of the newly-appointed individual, the effective date of the appointment, and a copy of the Administrator's license.

705. Joint Annual Report

Facilities shall complete and return a "Joint Annual Report" to the Revenue and Fiscal Affairs Office (RFA) within the time period specified by the Department or RFA.

706. Facility Closure

A. Prior to the permanent closure of a facility, the licensee shall notify the Department in writing of the intent to close and the effective closure date. Within ten (10) days of the closure, the facility shall notify the Department of the provisions for the maintenance of the facility records as required by regulation. On the date of closure, the current original license shall be returned to the Department.

B. In instances where a facility temporarily closes, the licensee shall notify the Department in writing within fifteen (15) days prior to temporary closure. In the event of temporary closure due to an emergency, the facility shall notify the Department in writing within twenty-four (24) hours of the closure. At a minimum this notification shall include, but not be limited to, the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards to the facility prior to its reopening. If the facility is closed for a period longer than one (1) year, and there is a desire to reopen, the facility shall reapply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

707. Zero Census

In instances when there have been no residents in a facility for any reason, for a period of ninety (90) days or more, the facility shall notify, in writing, the Department no later than the one-hundredth (100th) day following the date of discharge or transfer of the last active resident. If the facility has no residents for a period longer than one (1) year, and there is a desire to re-open, the facility shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application, including Certificate of Need review and construction-related requirements for a new facility. Instances of zero census do not relieve the facility of the requirement to pay licensing fees that may be due during that time.

SECTION 800—RESIDENT RECORDS

801. Content (II)

A. All entries in the resident record shall be legible and complete, and shall be separately authenticated and dated promptly by the individual, identified by name and discipline, who is responsible for ordering, providing or evaluating the service or care furnished. Authentication may include written signatures or computerized or electronic entries. If an entry is signed on a date other than the date it was made, the date of the signature shall also be entered. Although use of initials in lieu of signatures is not encouraged, initials will be accepted provided such initials can be readily identified within the resident record.

B. Contents of the resident record may be stored in separate files, in separate areas within the facility, and the record shall include the following information:

1. Medical history and physical examination;
2. Consent form for treatment signed by the resident or his or her legal representative;
3. Care and services agreement;

4. Healthcare directives and special information, for example, advance directive information, do-not-resuscitate (DNR) orders, allergies;
5. Accidents and/or Incidents involving the resident; (I)
6. Medical treatment;
7. Orders, including telephone and standing orders, for all medication, care, services, therapy, procedures, and diet from physicians or other legally authorized healthcare providers, which shall be completed prior to, or at the time of admission, and subsequently, as warranted;
8. Individual Care Plan; (I)
9. Provisions for routine and emergency medical care, to include the name and telephone number of the resident's physician;
10. Assessments and progress notes, for example, dietary, activity, therapy;
11. Record of administration of each dose of medication; (I)
12. Record of the use of restraints, if applicable, including time, type, reason and authority for applying; (I)
13. Treatment, procedure, wound care report (dictated or written into the record after treatment, procedure, or wound care) to include at least: (I)
 - a. Description of findings;
 - b. Techniques utilized to perform treatments and procedures;
 - c. Specimens removed, if applicable;
 - d. Name of provider;
14. Progress notes generated by physicians and healthcare professionals;
15. Notes of observation, including temperature, pulse, respiration, blood pressure and weight when indicated by physician's orders or by a change in the resident's condition; (I)
16. Special procedures and preventive measures performed, for example, isolation for symptoms, diagnosis, and/or treatment of infectious conditions including but not limited to tuberculosis, influenza, pneumonia, therapies;
17. Reports of all laboratory, radiological, and diagnostic procedures along with tests performed and the results appropriately authenticated; (I)
18. Consultations by physicians or other healthcare professionals;
19. Photograph of resident, if the resident or his or her responsible party approves;
20. Date and hour of discharge or transfer, as applicable;
21. Discharge and/or transfer summary, including care and condition at discharge or transfer, date and time of discharge or transfer, instructions for self-care, instructions for obtaining post-treatment or procedure emergency care, and signature of physician authorizing discharge or transfer;
22. Date and circumstances of death, as applicable.

C. Except as required by law, records may contain written and interpretative findings and reports of diagnostic studies, tests, and procedures, for example, interpretations of imaging technology and video tapes without the medium itself.

D. Unauthorized alterations of information in the record are prohibited. Corrections to entry errors shall include the date the correction was made and the signature of the individual making the correction.

E. Records shall be maintained on all outpatients and shall be completed immediately after treatment is rendered. These records shall contain sufficient identification data, a description of what was done and/or prescribed for the outpatient and shall be signed by the attending physician. When an outpatient is admitted as a resident of the facility, all of the outpatient records shall be made a part of his or her permanent resident record.

802. Physician Orders (II)

A. Physician Orders. The resident's physician shall sign and date all treatment, care, and medication orders, including standing orders.

1. The use of a rubber stamp signature or electronic representation is acceptable under the following conditions:

a. The physician whose signature the rubber stamp or electronic representation denotes is the only one who has possession of the stamp or electronic representation and is the only one who uses it; and

b. The physician places in the administrative offices of the facility a signed statement to the effect that he or she is the only one who has the stamp or electronic representation and is the only one who will use it.

2. The use of rubber stamp signatures is not permissible on orders for "controlled substances."

3. Consultative reports and diagnostic procedures requested by a physician, for example, radiological, laboratory reports, shall be acknowledged by the physician signature. (I)

B. Verbal Orders. (I)

1. All orders for medication, treatment, care and diet shall be signed and dated by the individual receiving the orders.

2. Verbal orders received shall include the date of the order, description of the order, and identification of the physician or other legally authorized healthcare provider and the individual receiving the order.

3. Verbal orders in other specialized departments or services, as authorized in facility policy and procedures, may be received by those departments or services, for example, orders pertaining to physical therapy may be received by a physical therapist.

4. A committee (to include representation by physicians treating residents at the facility, a pharmacist, and the Director of Nursing) shall identify and list categories of diagnostic or therapeutic verbal orders (associated with any potential hazard to the resident) that shall be authenticated by the prescriber within a limited time period (within two (2) days after the order is given). A copy of this list shall be maintained at each staff work area.

a. Verbal orders designated by the committee as requiring authentication within a limited time period shall be authenticated and countersigned and dated by the prescriber or designee within a time period defined in facility policies and procedures, but in no case more than two (2) days after the order was given.

b. All other verbal orders shall be countersigned and dated by the prescriber or his or her designee within sixty (60) days.

c. Verbal orders for restraints shall be authenticated in the manner prescribed in Section 1012.B.

C. Standing Orders. (I)

1. Physician's standing orders, except for restraints, are permissible but shall take into consideration specific circumstances such as medication allergies, gender-specific orders, and the pertinent physical condition of the resident, when appropriate.

2. Over-the-counter medications may be utilized on a physician's standing orders. Controlled or legend medications shall be an individual order reduced to writing on the physician's order sheet as either a routine or *pro re nata* (prn) order and shall not be utilized on a physician's standing order unless the medications have been identified by the facility as those commonly used in routine situations. Each standing order shall include on the order sheet the following, as appropriate:

a. Name of the medication;

b. Strength of the medication;

c. Specific dose (or dose range) of the medication;

d. Mode of administration;

e. Reason for administration;

f. Time interval between doses for administering the medication; and

g. Maximum dosage or number of times to be administered in a specific time period.

3. Standing orders shall be signed and dated by the prescribing physician initially and reviewed at least annually thereafter.

D. Standing orders regarding restraints are prohibited.

803. Individual Care Plan (ICP) (II)

A. The facility shall develop an ICP with participation by, and as evidenced by the signatures of the resident or responsible party, or documentation that the facility attempted to obtain the signatures, and an interdisciplinary team of qualified individuals, within twenty-one (21) days of admission. The ICP shall be reviewed and/or revised as changes in resident needs occur, but not less than quarterly by the interdisciplinary team.

B. The ICP shall describe:

1. The needs of the resident, including the services that are to be furnished, for example, what assistance, how much, who will provide the assistance, how often, and when;

2. Advance directives and healthcare power-of-attorney, as applicable;

3. Recreational and social activities that are suitable, desirable, and important to the resident;

4. Dietary needs and preferences of resident as approved by a physician;

5. Discharge planning, to include assessing continuing care needs and developing a plan designed to assure the resident's needs will be met after discharge or transfer.

804. Record Maintenance

A. Organization.

1. The Administrator shall designate a staff member the responsibility for the maintenance of resident and outpatient records.

2. Resident and outpatient records shall be properly indexed and filed for ready access by staff members.

B. Accommodations.

1. The licensee shall provide space, supplies, and equipment adequate for the maintenance, protection and storage of resident and outpatient records.

2. The facility shall maintain records pertaining to resident personal funds accounts, as applicable, financial matters, statements of resident rights and responsibilities, and resident possessions (provided that the facility has been notified by the resident or responsible party that items have been added or removed).

3. The licensee shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by staff, as needed.

4. Records of residents and outpatients shall be maintained for at least six (6) years following discharge or death. Facilities that microfilm (or use other processes that accurately reproduce or form a durable medium) inactive records before six (6) years have expired shall process the entire record. Records may be destroyed after six (6) years provided that:

a. Records of minors must be retained until after the expiration of the period of election following achievement of majority as prescribed by statute; and

b. The facility retains an index, register, or summary cards providing such basic information as dates of admission and discharge, and name of responsible physician for all records so destroyed.

5. Records of residents and outpatients are the property of the facility and shall not be removed without court order.

EXCEPTION: When a resident moves from one licensed facility to another within the same provider network (same licensee), the original record may follow the resident; the sending facility shall maintain documentation of the resident's transfer and discharge date and identification information. In the event of change of licensee, all resident records or copies of resident records shall be transferred to the new licensee.

6. When a resident is transferred from one facility to another, a transfer summary, to include copies of relevant documents, shall accompany the resident to the receiving facility at the time of

transfer or be forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the resident record.

7. Upon discharge or death of a resident, the record shall be completed and filed in an inactive file within a time period as determined by the facility, but no later than thirty (30) days after discharge or death.

8. Facilities shall comply with R.61-19 with regard to vital statistics.

C. Access.

1. The resident and outpatient record is confidential. Records containing protected or confidential health information shall be made available only to individuals granted access to that information, in accordance with state, federal, and local laws.

2. A facility may charge a fee for the search and duplication of a resident record in accordance with S.C. Code Section 44-7-325.

D. Copies of the criminal record check results of direct care staff shall be provided to the Department upon request within a reasonable amount of time after receiving the request. A copy of the criminal record check results shall be retained at the facility.

E. Regulation-required documents other than resident records, such as fire drills, medication destruction records, activity schedules, firefighting equipment inspections, monthly pharmacist reviews, controlled medication count sheets, emergency generator logs, shall be maintained for a minimum of twelve (12) months or until the next inspection by the Department, whichever is longer. Records of menus as served shall be maintained for at least thirty (30) days and available for inspection.

805. Electronic Resident Records

A. Electronic records are subject to all of the standards of this regulation.

B. A facility that maintains electronic records shall:

1. Retain the hard copy originals of any materials that cannot be electronically stored;

2. Employ an off-site backup storage system as protection in the event that the on-site system is damaged or destroyed;

3. Use an imaging mechanism that is able to copy documents with signatures;

4. Assure that records, once put in electronic form, are unalterable.

C. Electronic signatures may be used any place in the resident or outpatient record that requires a signature, provided signature identification can be verified and an electronic signature may be legally used. Electronic authorization shall be limited to a unique identifier (confidential code) used only by the individual making the entry to preclude the improper or unauthorized use of any electronic signature.

SECTION 900—ADMISSION AND RETENTION

A. Individuals seeking admission shall be identified as appropriate for the level of care, services, or assistance offered. The facility shall establish admission criteria that are consistently applied and comply with state, federal, and local laws and regulations. (I)

B. The facility shall admit and retain only those individuals whose needs can be met by the accommodations and services for which the facility is licensed. (I)

C. Residents and/or outpatients shall be admitted to the facility only on physician orders and all care rendered under his or her direction. In the institutional nursing home setting, individuals living on that campus, but outside the nursing home may be admitted by the Administrator, provided that the admission is authorized by physician order within two (2) business days of admission. (I)

D. A medical history and physical examination shall be completed in the manner prescribed in Section 1200. (II)

E. Respite care may be furnished provided there is compliance with this regulation. If the resident is regularly re-admitted in a respite status only, then a physical examination for admission is required only once every six (6) months. (I)

F. Individuals not eligible for admission or retention are:

1. Anyone who is destructive of property, self-destructive, suicidal, disturbing or abusive to other residents as determined by a physician or other legally authorized healthcare provider, unless the facility has and uses sufficient resources to appropriately manage and care for the person;
2. Anyone under eighteen (18) years of age, unless placed in a private room and written certification is obtained from the attending physician stating that proper care of the resident can be given;
3. Anyone who has need for medical care for acute illness or injury that is beyond the scope of the facility to provide, and where hospitalization is consistent with the individual's condition, prognosis, and choice; and
4. Anyone not meeting facility requirements for admission; the facility may determine who is eligible for admission and retention in its policies, provided compliance with state, federal, and local laws and regulations is accomplished.

SECTION 1000—RESIDENT CARE AND SERVICES

1001. General

A. There shall be a written care and services agreement between the resident, and/or his or her responsible party, and the facility. The agreement shall be signed and completed before or at the time of admission and include and/or address at least the following:

1. An explanation of the specific care, treatment, services, or equipment provided by the facility, for example, degree of nursing care, administration of medication, provision of special diet as necessary, assistance with bathing, toileting, feeding, dressing, and mobility;
2. Disclosure of fees for all care, treatment, services, or equipment provided;
3. Advance notice requirements to change fees;
4. Refund provisions to include when monies are to be forwarded to resident upon discharge, transfer, or relocation;
5. Transportation provisions in accordance with facility policies and procedures;
6. Discharge and transfer provisions to include the conditions under which the resident may be discharged and the agreement terminated, and the disposition of personal belongings;
7. Documentation of the explanation of the Bill of Rights for Residents of Long-Term Care Facilities and grievance procedures;
8. Arrangements for, or the provision at a specified written cost for the laundering of resident personal clothes.

B. Residents shall receive care and treatment, services, such as, routine and emergency medical care, podiatry care, dental care, counseling and medications, as ordered by a physician or other legally authorized healthcare provider. Such care shall be provided and coordinated among those responsible during the process of providing such care and modified based upon any changing needs, or, when appropriate, requests of the resident. (II)

C. Treatment and services shall be rendered effectively and safely in accordance with orders from physicians or other legally authorized healthcare providers. (I)

D. Staff shall respond to a signal system call from a resident to provide care or assistance in a prompt manner.

E. Each resident shall be encouraged and assisted in self care and activities of daily living, and be given care that promotes skin integrity, proper body alignment and joint movement. (I)

F. Residents shall be neat, clean, appropriately and comfortably dressed in clean clothes, and shall be encouraged and assisted to achieve and maintain the highest level of self care and independence. Neatness and cleanliness shall include personal hygiene, skin care, shampooing and grooming of hair, shaving and trimming of facial hair, nail trimming, and being free of offensive body odors. (II)

G. The provision of care, treatment, and services shall be resident-centered and resident-directed to the fullest extent possible. Such care, treatment, and services to residents shall be guided by the recognition of and respect for cultural differences and personal preferences to assure reasonable accommodations shall be made for residents with regard to differences, such as, but not limited to, religious practices and dietary preferences.

H. Opportunities for participation in religious services shall be available. Assistance in obtaining pastoral counseling shall be provided upon request by the resident.

I. Facilities shall take an interdisciplinary approach to decrease the risk of pressure-related wounds, and institute measures to prevent and treat wounds that are consistent with each resident's clinical condition, risk factors, and goals. Such actions shall include but not be limited to: (I)

1. Body position of bed or chair bound residents changed in accordance with the ICP;

2. Proper skin care provided for bony prominences and weight bearing parts to prevent discomfort and the development of pressure areas, unless contraindicated by physician's orders.

J. Soiled or wet bed linen shall be replaced promptly with clean, dry linen and clothing after being soiled. (I)

K. Necessary actions shall be taken to prevent resident elopement. (I)

L. A facility shall have the equipment and supplies required to administer cardio-pulmonary resuscitation (CPR) to any resident when necessary and in accordance with the resident's advance directives. Equipment and supplies required to administer CPR include, but are not limited to: (I)

1. Adult-sized Pocket Mask;

2. Adult-sized Bag-Valve-Mask Ventilation Unit (BVM); and

3. Large and Medium Adult-sized Oropharyngeal airway (OPA).

M. In the event of closure of a facility for any reason, the facility shall assure continuity of care, treatment, and services by promptly notifying the resident's attending physician or other legally authorized healthcare provider and arranging for referral to other facilities.

1002. Fiscal Management (II)

A. Provisions shall be made for safeguarding money and valuables for those residents who request this assistance.

B. Residents shall manage their own money whenever possible.

C. Only residents may endorse checks made payable to them, unless a legally constituted authority has been authorized to endorse their checks.

D. Upon written request of the resident or his or her responsible party, the facility may maintain the personal monies for the resident.

E. There shall be an accurate accounting of resident's personal monies and written evidence of purchases by the facility on behalf of the residents to include a record of items or services purchased, written authorization from residents of each item or service purchased, and an accounting of all monies paid to the facility for care and services. Personal monies include all monies, including family donations. No personal monies shall be given to anyone, including family members, without written consent of the resident or his or her responsible party. If a resident's money is given to anyone by the facility, a receipt shall be obtained.

F. A written report of the balance of resident finances shall be physically provided to each resident by the facility on a quarterly basis in accordance with the Bill of Rights for Residents of Long-Term Care Facilities, regardless of the balance amount, for example, zero balance.

G. Within sixty (60) days of a resident's death or discharge, a final written account of remaining resident monies shall be made to the individual administering the resident's estate, or to the resident or the resident's responsible party upon discharge. Any personal monies due shall be refunded within thirty (30) days.

H. In the event of a licensee change, the existing licensee shall provide written verification to the new licensee that all resident monies have been transferred to the new licensee.

1003. Recreation

A. The facility shall offer a regular and ongoing program of varied, meaningful activities designed to suit the interests and physical and cognitive capabilities of the residents who choose to participate. The facility shall provide recreational activities that provide stimulation (intellectual, physical); promote or enhance physical, mental, and/or emotional health; are age-appropriate; and are based on input from the residents and/or responsible party, as well as information obtained in the initial assessment.

These activities shall include appropriate group activities and also activities for individuals with particular interests and needs.

B. Variety in planning may include some outdoor activities in suitable weather. Plans for activity involvement both on an individual and a group basis shall be developed for all residents. The planned activities may include community intergenerational programs, if applicable.

C. A staff member shall be designated as director of the resident activities program who shall be responsible for the development of the recreational program, to include responsibility for obtaining and maintaining recreational supplies. This staff member shall have sufficient time to provide and coordinate the activities program so that it fully meets the needs of the residents. Staff members responsible for providing and coordinating recreational activities for the residents shall have expertise or training and/or experience in individual and group activities. The director of resident activities shall hold at least one (1) of the following four (4) qualifications:

1. A baccalaureate degree from an accredited college or university with a major area of concentration in recreation, creative arts therapy, therapeutic recreation, art, art education, psychology, sociology, or occupational therapy;

2. A high school diploma and three (3) years of experience in resident activities in a health care facility;

3. Served as the facility director of resident activities on the effective date of promulgation of this regulation, and has continuously served as activities director since that time; or

4. Holds current certification from the National Certification Council for Activity Professionals, or the National Council for Therapeutic Recreation Certification.

D. The recreational supplies shall be adequate and shall be sufficient to accomplish the activities planned. Space, needed supplies, and equipment, for example, books, magazines, newspapers, games, arts and crafts, computers, radio and television, shall be provided for all pertinent activities.

E. At least one (1) current month's resident activity schedule shall be conspicuously posted in order for residents to be made aware of activities offered. This schedule shall include activities, dates, times, and locations. Residents may choose activities and schedules consistent with their interests and physical, mental, and psychosocial health. If a resident is unable to choose for him or herself, staff members shall encourage participation and assist when necessary.

F. Residents shall retain autonomous control over a wide range of activities and shall not be compelled to participate in any activity. Activities provided shall be in accordance with the ICP.

G. There shall be adequate staff to provide activity and recreational programs each day to achieve a meaningful experience for the residents. Opportunities for spontaneous activities shall be available to residents at any time. Community resources and volunteers may be utilized under the direction of the activities director to the fullest possible extent.

H. Religious services shall be considered resident activities. Every resident shall have the freedom to attend the church service of his or her choice.

I. Bedridden residents and those otherwise unable or unwilling to participate in group activities shall be provided activity to stimulate and promote their physical, spiritual, social, emotional, and intellectual health in accordance with the ICP.

J. Visiting by relatives and friends shall be encouraged, with minimum restrictions. Visiting hours shall be posted in accordance with facility policies and procedures. Reasonable exceptions to these hours shall be granted.

1004. Physician Services (II)

A. Each resident or responsible party shall designate a physician licensed to practice in South Carolina for the supervision of the care and treatment of the resident.

1. Residents shall be seen by the attending physician at least once every sixty (60) days, unless more frequent visits are indicated.

EXCEPTION: Another legally authorized healthcare provider who is authorized by the attending physician in writing, may make the sixty (60) day visits and the resident or the resident's responsible party shall be notified in writing of the person who will be making the visits in lieu of the attending physician.

2. A facility shall not restrict a resident's or responsible party's choice in attending physician coverage, provided that the physician agrees to, and demonstrates that he or she will provide care in accordance with facility policies and procedures.

B. Residents who have an attending physician licensed in a state other than South Carolina shall have thirty (30) days from admission to establish an attending physician licensed in South Carolina. (I)

C. Each resident shall be informed of the name, specialty, and a way of contacting the physician responsible for his or her care.

D. At least one (1) physician shall be available on call at all times.

1005. Social Services

A. Social services for residents shall be provided by the facility. When a facility provides social services directly, there shall be a staff member designated in writing who is responsible for the program and provides the leadership and direction of the program, including the maintenance of any required records.

B. Social service history shall be obtained and documented for each resident. This history shall include social and emotional factors related to the resident's condition, information concerning home situation, financial resources and relationships with other people. The social history shall be obtained within seven (7) business days of admission. The social service history shall be utilized in the preparation of the ICP and maintained current in terms of changes in financial resources, physical condition, mental state or family situation.

C. Services shall be provided to assist all residents in addressing social, emotional and related problems or through effective arrangements with a social service agency.

D. The social services staff shall participate in discharge planning to assist residents to access inpatient, outpatient, extended care, and home health services in the community.

1006. Dental Services

A. Within one (1) week of admission, an oral assessment by a physician, dentist or registered nurse shall be conducted to determine the consistency of diet which the resident can best manage and the condition of gums and teeth.

B. Residents shall be assisted as necessary with daily dental care. (II)

C. Each facility shall maintain names of dentists who can render emergency and other dental treatments. Residents shall be encouraged to utilize dental services of choice.

1007. Oxygen Therapy (II)

A. The facility shall provide oxygen for the treatment of residents when ordered by a physician or other legally authorized healthcare provider.

B. The facility shall post "No Smoking" signs conspicuously when oxygen is dispensed, administered, or stored. The facility shall appropriately secure all cylinders.

EXCEPTION: "Smoke-Free" facilities where smoking is prohibited, and where the facility nonsmoking policy is strictly enforced, and where "Smoke-Free" signs are strategically placed at all major entrances, secondary "No Smoking" signs shall not be required in and in the vicinity of resident rooms where oxygen is being administered. "No Smoking" signs shall be required in and in the vicinity of resident rooms and all other areas of the facility where oxygen is being stored. (I)

1008. Laboratory Services

A. Laboratory services required in connection with the care or treatment to be performed shall be provided or arrangements made to obtain such services.

B. Laboratories that examine materials derived from the human body for diagnosis, prevention, or treatment purposes shall be certified by the Centers for Medicare and Medicaid Services (CMS). Some laboratory tests, for example, blood sugar levels or hemoglobin, may not require the certification; however a Clinical Laboratories Improvement Amendments (CLIA) "Certificate of Waiver" shall be obtained from the Department's CLIA Program if those tests are performed.

C. Expired laboratory supplies shall be disposed of in accordance with facility policies and procedures.

1009. Outpatient Services

A. When the facility provides outpatient services such as those described in Section 1010, a physician shall be in charge of the service.

B. Outpatient services shall be in a location that is easily accessible for all outpatients and to all necessary outpatient equipment and supplies. Adequate toilet facilities, waiting, dressing, examining, treatment, and therapy rooms shall be provided.

1010. Other Services to Residents

Other services, such as physical therapy, occupational therapy, and speech therapy, if offered as a service of the facility, shall be on orders of a physician or other legally authorized healthcare provider and administered and/or furnished by legally authorized healthcare providers. If offered, space and equipment shall be provided to accommodate the service(s).

1011. Transportation (I)

The facility shall arrange for appropriate transportation of residents to other healthcare services provided outside the facility, for example, hospital, medical clinic, dentist, and in accordance with the physician's orders. If a physician's services are not immediately available and the resident's condition requires immediate medical attention, the facility shall provide or secure transportation for the resident to the appropriate healthcare providers, such as, but not limited to, physicians, dentists, physical therapists, or for treatment at renal dialysis facilities.

1012. Restraints (II)

A. A facility shall maintain written instructions on how to apply specific restraints.

B. A facility shall have a written order signed by the physician who approved of the use of restraints either at the time the restraints are applied to a resident or, in case of emergency, within twenty-four (24) hours after the restraints are applied.

C. During emergency restraint, residents shall be monitored, their condition recorded at least every fifteen (15) minutes, and they shall be provided with an opportunity for motion and exercise at least every thirty (30) minutes. Prescribed medications and treatments shall be administered as ordered, and residents shall be offered nourishment and fluids and given restroom privileges. (I)

D. Only those devices specifically designed as restraints may be used. Makeshift restraints shall not be used under any circumstance. (I)

1013. Discharge and Transfer

A. Residents shall be transferred or discharged only upon physician orders and only as appropriate in accordance with the Bill of Rights for Residents of Long-Term Care Facilities. Immediate transfer is permissible in cases of medical emergencies or where the health and safety of other residents would be endangered, in accordance with the Bill of Rights for Residents of Long-Term Care Facilities.

B. Notification of resident discharge and transfer shall be in accordance with the Bill of Rights for Residents of Long-Term Care Facilities. In cases of transfer due to medical emergencies or instances where other residents may be endangered, the family member, if any, shall be notified within a time period that is practicable under the circumstances, but not later than twenty-four (24) hours following the transfer.

C. Other than residents transferred back to their home, residents requiring care and/or supervision shall be transferred or discharged to a location that is licensed to provide that care and is appropriate to the resident's needs and abilities. (II)

D. Upon transfer or discharge, the facility shall assure that resident information, medications, as appropriate, personal possessions and personal monies are released to the resident and/or the receiving facility in a manner that assures continuity of treatment, care, and services. (II)

E. A discharge summary shall accompany each resident discharged or transferred to another licensed healthcare facility, or shall be forwarded to the receiving facility in a manner that assures continuity of care and services.

F. The facility shall have a written transfer agreement with one (1) or more hospitals that provides reasonable assurance that transfer of residents will be made between the hospital and the facility whenever such transfer is deemed medically appropriate by the attending physician; or, the facility shall have on file documented evidence that it has attempted in good faith to effect a transfer agreement. The transfer agreement shall be dated and signed by authorized officials who are a party to

the agreement. The agreement shall provide reasonable assurance of mutual exchange of information necessary or useful in the care and treatment of individuals transferred between the facilities. The agreement may be updated following a change of Administrator; the agreement shall be updated following changes in licensee or at any other time as deemed advisable to maintain or further improve continuity of care.

SECTION 1100—RIGHTS AND ASSURANCES

1101. General (II)

A. The facility shall comply with all current state, federal, and local laws and regulations concerning resident care, treatment, procedures, and/or services, resident rights and protections, and privacy and disclosure requirements, such as, S.C. Code Section 44–81–10, Bill of Rights for Residents of Long-Term Care Facilities, Alzheimer’s Special Care Disclosure Act, and the Omnibus Adult Protection Act notice, S.C. Code Section 43–35–5, *et seq.*

B. Posted notices as required in the Bill of Rights for Residents of Long-Term Care Facilities, the Omnibus Adult Protection Act, and other notices as required by law, shall be prominently displayed in the facility.

C. The facility shall comply with all relevant state, federal, and local laws and regulations concerning discrimination, such as, Title VII, Section 601 of the Civil Rights Act of 1964.

D. Achievement of the highest level of self-care, independence and choice by residents shall be reflected in the manner in which the facility provides and promotes resident care and how the facility honors reasonable requests.

E. Residents shall be given the opportunity to provide input concerning changes in facility operational policies, procedures, services, for example, resident councils.

F. Other than the limitations of resident movement in special instances, for example, Alzheimer’s unit, residents shall be assured freedom of movement. Residents shall not be locked in or out of their rooms.

G. There shall be a grievance and complaint procedure to be exercised on behalf of the residents to enforce the Bill of Rights for Residents of Long-Term Care Facilities that includes the address and telephone number of the Department and a provision prohibiting retaliation should the grievance right be exercised. Residents shall be made aware of this procedure and it shall be posted adjacent to the Bill of Rights for Residents of Long-Term Care Facilities.

H. Care, services, treatments, items provided by the facility, the charges, and those services that are the responsibilities of the resident shall be delineated in writing. Residents shall be made aware of such charges and services and changes to charges and services.

I. Residents shall not be requested or required to perform any type of care, treatment, or service in the facility that would normally be the duty of a staff member.

J. Information regarding advance directives shall be provided to each resident at admission.

K. The facility shall furnish itemized billing for all charges to the resident or the individual paying the bill upon request by the resident or individual.

1. Items that remain unpaid are not required to be itemized again.

2. This provision shall not apply to the contracted amount of a state or federal agency. Any amount above such contract shall be itemized as provided.

L. Residents shall be permitted to use the telephone and shall be allowed privacy when making telephone calls.

M. A quiet environment shall be provided that is the least intrusive to residents.

N. The facility shall inform residents of the resident councils (See Section 1102).

1102. Resident and Family Councils (II)

A. The facility shall allow residents to form and participate in resident councils to discuss and resolve concerns.

B. Adequate notification shall be provided to family members or to the responsible party of the resident concerning pertinent information pertaining to the operation or interest of the family council in accordance with facility policies and procedures.

C. Should there be a council, the facility Administrator shall designate a staff coordinator and provide suitable private accommodations within the facility for these council(s). The staff coordinator shall assist the council(s) in scheduling regular meetings and preparing written reports of meetings for dissemination to residents of the facility.

SECTION 1200—RESIDENT PHYSICAL EXAMINATION AND TUBERCULOSIS SCREENING (I)

A. The admission physical examination shall be conducted by the attending physician or legally authorized healthcare provider within five (5) days prior to admission or within seven (7) business days after admission and shall address the physical condition and diagnosis of the resident.

EXCEPTION: Physical examinations conducted by physicians licensed in states other than South Carolina are permitted for new admissions under the condition that residents obtain an attending physician licensed in South Carolina within thirty (30) days of admission to the facility. The physical examination information shall be updated to include new medical information if the resident's condition has changed since the last physical examination was completed.

B. The admission physical examination shall include tuberculosis screening (See Section 1704), as determined by the facility risk assessment (See Section 101.JJJ) in the manner designated by guidelines established by the Department.

C. In the event that a resident transfers from a healthcare facility licensed by the Department, as defined in S.C. Code Section 44-7-130(10), to a nursing home, an additional admission physical examination shall not be required, provided the resident transferring has had a physical examination conducted not earlier than three (3) months prior to the admission of the resident to the nursing home that addresses the physical condition and diagnosis of the resident, and meets the requirements specified in Section 1200.B unless the receiving facility has an indication that the health status of the resident has changed significantly. A discharge summary from a healthcare facility, which includes a physical examination, may be acceptable as the admission physical examination, provided the summary addresses the physical condition and diagnosis of the resident, meets the requirements specified in Section 1200.B, and the resident's physician attests to its accuracy by countersigning it. The receiving nursing home shall acquire a copy of the physical examination and tuberculosis screening, if applicable, from the licensed facility transferring the resident with the attending physician updating by signature and date.

SECTION 1300—MEDICATION MANAGEMENT

1301. General

A. Medications, including controlled substances, medical supplies, and those items necessary for the rendering of first aid shall be properly managed in accordance with state, federal, and local laws and regulations. Such management shall address the securing, storing, and administering of medications, medical supplies, first aid supplies, and biologicals, their disposal when discontinued or expired, and their disposition at discharge, transfer, or death of a resident. (I)

B. Applicable medication-related reference materials such as Physicians' Desk Reference and information on the use of medications shall be readily available at each staff work area in order to provide staff members with adequate information concerning medications. At least one (1) such reference in the facility shall have been published within the previous year and none shall be older than three (3) years.

1302. Medication and Treatment Orders (II)

A. Medication and treatment, to include oxygen, shall be administered to residents only upon orders (to include standing orders) of a physician or other legally authorized healthcare provider. (I)

B. All orders (including verbal) shall be received only by licensed nurses or other legally authorized healthcare providers, and shall be authenticated and dated by a physician or other legally authorized healthcare provider pursuant to the facility's policies and procedures. This restriction shall not be construed to prohibit the issuance and acceptance of verbal orders in other specialized departments or services in accordance with facility policies and procedures, for example, orders pertaining to respiratory therapy modalities; medications administered therewith may be given to respiratory therapy personnel and physical therapy orders to physical therapists. (I)

C. Physician's orders for medication, treatment, care and diet shall be reviewed and reordered no less frequently than every two (2) months. (I)

D. All medication orders that do not specifically indicate the number of doses to be administered or the length of time the medication is to be administered shall automatically be stopped in accordance with facility policies and procedures.

1303. Administering Medication (II)

A. Medications shall be administered in accordance with orders of the attending physician, dentist or other individual legally authorized to prescribe medications or biologicals for human consumption. (I)

B. Medications and medical supplies ordered for a specific resident shall not be provided to or administered to any other resident.

C. Medications shall be administered in accordance with state practice acts. The administration of medication shall include, but not be limited to:

1. Removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container);
2. Verifying the dosage with the physician's orders;
3. Giving the individual dose to the proper resident;
4. Monitoring the ingestion or application of the dose; and
5. Promptly recording on the MAR, as it is administered, the date, time, dose given, mode of administration, and identification of the individual who administered the medication.

D. Doses of medication shall be administered by the same licensed nurse or other legally authorized healthcare provider who prepared them for administration. Preparation of doses for more than one (1) scheduled administration shall not be permitted. (I)

E. Self-administration of medications by residents is permitted only on the specific written orders of the resident's attending physician or other legally authorized healthcare provider, verified by direct contact with the resident by a licensed nurse, and recorded on the MAR by that same person. Verification and documentation shall occur at the same frequency as the medication is taken. Facilities may elect to prohibit self-administration. The facility shall not allow residents to self-administer controlled substances. (I)

F. When residents who are unable to self-administer medications leave the facility for an extended period of time, the proper amount of medications, along with dosage, mode, date, and time of administration, shall be given to a responsible individual who will be in charge of the resident during his or her absence from the facility; these details shall be properly documented in the MAR. (I)

G. At each shift change, there shall be a documented review of all scheduled controlled substances, such as, Schedules II, III, IV, and V, by outgoing licensed nurses with incoming licensed nurses who shall include verification by outgoing licensed nurses that the count was correct, and if incorrect, an explanation of the discrepancy and any corrective actions taken. The review shall include controlled substances in an unsealed emergency medication kit or cart. (I)

1304. Pharmacy Services

A. There shall be a written agreement with a consulting pharmacist to direct, supervise and be responsible for pharmacy services in the facility in accordance with accepted professional principles and appropriate state, federal, and local laws and regulations. (II)

B. At least monthly the pharmacist shall: (II)

1. Review the medication profile for each resident for potential adverse reactions, allergies, interactions and laboratory test modifications. The attending physician shall be advised of recommended changes in the medication regimen, medication therapy duplication, incompatibilities or contraindications;
2. Review medication storage areas and emergency medication kits;
3. Review all medications in the facility for expiration dates and assure the removal of discontinued or expired medications from use as indicated;
4. Verify proper storage of medications and biologicals in the facility and make recommendations concerning the handling, storing and labeling of medications;

5. Examine the controlled substances records and affirm to the Administrator that this inventory is correct;

6. Assess the facility pharmaceutical services to assure the services have been properly implemented and maintained and submit to the Administrator a written report of each pharmaceutical assessment including recommendations.

C. In addition to the services enumerated in Section 1304.B, the pharmacist shall participate in the formulation of pharmacy service policies and procedures and coordinate pharmacy services. (II)

D. Facilities that maintain stocks of legend medications and biologicals for resident use within the facility shall obtain and maintain from the South Carolina Board of Pharmacy a valid, current, nondispensing drug outlet permit, displayed in a conspicuous location in the facility.

1305. Medication Containers (II)

A. The labeling of medications and biologicals shall be based on currently accepted professional principles. Labels shall identify, at a minimum, the name of the medication or biological, strength and lot number. As appropriate, labels shall include resident name and any identifying number. The prescribing physician's name and directions for use shall be on the label if it is not documented in another effective manner. (I)

B. Medication containers that have been damaged, compromised, or without labels, or that have damaged, incomplete or makeshift labels are considered to be misbranded and are prohibited and shall be destroyed in accordance with Section 1309.

C. Medications for each resident shall be maintained in the original container(s) including unit dose systems. Opening blister packs to remove medications for destruction or adding new medications for administration, except under the direction of a pharmacist, is prohibited. (I)

D. When a physician or other legally authorized healthcare provider changes the dosage of a medication, such information shall be documented in the medication administration record and a label that does not obscure the original label shall be attached to the container that states, "Directions changed; refer to MAR and physician or other legally authorized healthcare provider orders for current administration instructions." The new directions shall be communicated to the pharmacist upon receipt of the order. (I)

1306. Medication Storage

A. Medications shall be stored and safeguarded in a locked medicine preparation room or locked cabinet at or near the staff work area to prevent access by unauthorized individuals. If medication carts are utilized for storage, they shall be locked when not in use. Expired or discontinued medications shall not be stored with current medications. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life. (I)

B. Medications requiring refrigeration or freezing shall be stored in a refrigerator or freezer as appropriate at the temperature range established by the manufacturer used exclusively for that purpose in the medicine preparation room, or in a locked refrigerator used exclusively for medications, or in a separate locked box within a multi-use refrigerator at or near the staff work area. Food and drinks shall not be stored in the same refrigerator or freezer in which medications and biologicals are stored. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals in accordance with the AABB. Refrigerators and freezers shall be provided with a thermometer accurate to plus or minus two (2) degrees Fahrenheit. (I)

C. Medications shall be stored: (I)

1. Under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety and security;

2. In accordance with manufacturer's directions and in accordance with all applicable state, federal, and local laws and regulations;

3. Separately from poisonous substances, such as cleaning and germicidal agents, or body fluids;

4. In a manner that provides for separation between topical and oral medications, and which provides for separation of each resident's medication;

5. In medicine preparation rooms or cabinets that are well-lighted and of sufficient size to permit orderly storage and preparation of medications. Keys to the medicine preparation room, cabinet, refrigerator or medication cart at the staff work area shall be under the control of a designated licensed nurse.

D. Nonlegend medications that can be obtained without a prescription such as aspirin, milk of magnesia and mineral oil, may be retained and labeled as stock in the facility for administration as ordered by a physician or other legally authorized healthcare provider.

E. The medications prescribed for a resident shall be protected from use by any other individuals. For those residents who have been authorized by a physician or other legally authorized healthcare provider to self-administer medications, such medications shall be stored in accordance with facility policies and procedures. (I)

F. Prescribed and over-the-counter medications may be maintained at bedside upon physician orders if kept in an individual cabinet or compartment that is locked, such as the drawer of the resident's night stand, in the room of each resident who has been authorized in writing to self-administer by a physician or other legally authorized healthcare provider, in accordance with facility policies and procedures. (II)

G. Medications listed in Schedule II of the Federal Controlled Substance Act shall be stored in separately locked, permanently affixed, compartments within a locked medicine preparation room, cabinet or a medication cart, unless otherwise authorized by a change in the state or federal law pertaining to the unit dose distribution system. (I)

1307. Medication Control and Accountability (II)

A. Records of receipt, administration and disposition of all medications shall be maintained in sufficient detail to enable an accurate reconciliation.

B. Medication, supplies and devices shall not be administered and/or provided to residents beyond the expiration date of those items. (I)

C. Medications that have been discontinued may be secured in the staff work area with a written order by the attending physician. Such medications shall not be held beyond a ninety-day (90-day) period unless so ordered by the physician or other legally authorized healthcare provider, but in no case held beyond the expiration date of the medication.

D. Separate control sheets shall be maintained on any controlled substances listed in Schedules II, III, IV, and V, State and Federal Controlled Substance Act. This record shall contain the following information: date, time administered, name of resident, dose, signature of individual administering, name of physician or other legally authorized healthcare provider ordering the medication and all scheduled controlled substances balances (See Section 1303.G).

1308. Emergency Medications (II)

A. Each facility shall maintain, upon the advice and written approval of the Medical Director and consultant pharmacist, an emergency medication kit or cart of designated medicines and equipment at each staff work area for the use of physicians or other legally authorized healthcare providers in treating the emergency needs of residents. As an exception, the facility may determine that one (1) emergency medication kit can be readily accessible to, and adequately meet the needs of two (2) or more staff work areas. If such is the case, the facility's written policies shall include the location(s) of the emergency medication kit(s) and the justification for this determination. There shall not be less than one (1) emergency medication kit on each resident floor.

B. The emergency medication kit or cart shall be sealed and stored in a secured area to prevent unauthorized access and to assure a proper environment for preservation of the medications within, but in such a manner as to allow immediate access.

C. An inventory of medications maintained in the kit shall be attached to or placed in the kit. Another inventory list shall be maintained at the staff work area for quick reference.

D. Whenever the emergency medication kit or cart is opened, the use of contents shall be documented by the nursing staff and it shall be restocked and resealed by the pharmacist within four (4) business days.

1309. Disposition of Medications

A. Upon discharge of a resident, unused medications, biologicals, medical supplies and solutions may be released to the resident, family member, or responsible party, unless prohibited by facility policies and procedures, the attending physician or other legally authorized healthcare provider.

B. When resident medications, biologicals, medical supplies or solutions have deteriorated or exceeded their expiration date or there are partially unused medications, or medication containers are misbranded, they shall be destroyed by a licensed nurse or other legally authorized healthcare provider or returned to the pharmacy. (II)

C. When noncontrolled legend drugs, biologicals, medical supplies and solutions are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the name of the individual performing the destruction and witnessed by a licensed nurse or pharmacist. (I)

D. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.61-4. (I)

SECTION 1400—MEAL SERVICE

1401. General (II)

A. Facility meal service programs shall be inspected and approved by the Department, and shall be regulated, inspected, and graded pursuant to R.61-25.

B. When meals are catered to a facility, such meals shall be obtained from a meal service establishment graded by the Department, pursuant to R.61-25. (I)

C. If food is prepared at a central kitchen and delivered to separate facilities or separate buildings and/or floors of the same facility, provisions shall be made for proper maintenance of food temperatures and a sanitary mode of transportation that are approved by the Department.

D. Food shall be prepared by methods that conserve the nutritive value, flavor and appearance. The food shall be palatable, properly prepared, and sufficient in quantity and quality to meet the daily nutritional needs of the residents in accordance with written dietary policies and procedures.

E. Efforts shall be made to accommodate the religious, cultural, and ethnic preferences of each resident and consider variations of eating habits, unless the orders of a physician or other legally authorized healthcare provider contraindicate.

F. Nourishment stations, if provided, shall contain a handwashing sink equipped for handwashing, equipment for serving nourishment between scheduled meals, refrigerator, and storage cabinets.

G. At least one (1) dietary refrigerator shall be provided on each resident floor and shall have a thermometer accurate to plus or minus two (2) degrees Fahrenheit. In addition, if a refrigerator(s) is in a resident room for food storage, the same thermometer requirement applies.

H. Medications, nursing supplies, or biologicals shall not be stored in the dietary department or any refrigerator or storage area utilized by the dietary department.

I. The preparation of meals shall only be conducted in areas of the facility that have been approved by the Department. Extended operations of a facility's meal service program shall not be located in rooms used for other purposes, such as, sleeping, living, laundry.

1402. Food and Food Storage (II)

A. The storage, preparation, serving, transportation of food, and the sources from which food is obtained shall be in accordance with R.61-25.

B. Home canned food shall be prohibited.

C. At least a three-day supply of staple foods and a two-day supply of perishable foods shall be maintained on the premises. Supplies shall be appropriate to meet the requirements of the menu and special or therapeutic diets.

D. All food in the facility shall be from food sources approved or considered satisfactory by the Department, and shall be clean, wholesome, free from spoilage, free from adulteration and misbranding, and safe for human consumption. (I)

1403. Food Equipment and Utensils

A. The storage, cleaning and sanitizing of equipment and utensils utilized shall be in accordance with R.61-25. (II)

B. There shall be written procedures for cleaning, disinfecting and sanitizing all equipment and meal service work areas.

C. Drinking containers made of porous materials shall not be used unless the containers have smooth liners which can be easily cleaned. These containers and/or liners shall be sanitized at least weekly or more often as necessary and identified for individual resident use. Disposable containers shall be replaced at least weekly. (II)

1404. Meals and Services (II)

A. All facilities shall provide meal services to meet the daily nutritional needs of the residents in accordance with the dietary reference intakes (DRIs) of the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences.

B. The dining area shall provide a comfortable and relaxed environment. Table service shall be planned in an attractive and colorful manner for each meal.

C. A minimum of three (3) nutritionally-adequate meals in each twenty-four-hour (24-hour) period shall be provided for each resident unless otherwise directed by the resident's physician or other legally authorized healthcare provider. Residents shall be allowed to choose between a variety of foods offered. Personal preferences as to the times residents receive their meals may be honored. This may include offering smaller, more frequent meals, or snacks, or postponing meals to honor a resident's request, for example, to sleep or not to eat. The condition of the resident shall dictate the manner in which meal service is adjusted to suit personal preferences. Meal service systems, for example, four-meal plans and/or buffet dining, may be offered in order to facilitate the resident receiving a variety of foods.

D. Not more than fourteen (14) hours shall elapse between the scheduled serving of the evening meal and breakfast the following day.

EXCEPTION: There may be up to sixteen (16) hours between the scheduled serving of the evening meal and breakfast the following day if approved by the resident's attending physician and the resident, and if a nourishing snack is provided after the evening meal.

E. Food shall be cut, chopped, ground or blended to meet individual needs.

F. The same menu items shall not be repetitively served during each seven (7)day period except to honor specific, individual resident requests. Substitutes of similar nutritive value shall be offered to residents who refuse food served.

G. Food and snacks shall be available and offered between meals at no additional cost to the residents. Individual resident food and snack preferences shall be honored when reasonable.

1405. Meal Service Staff

A. The meal service operations shall be under the direction of a dietitian or qualified food service supervisor who shall be responsible for supervising the meal service staff, planning, preparation and serving of food and the maintenance of proper records. A staff member shall be designated, by name or position, to act in the absence of this person. (II)

B. A qualified food service supervisor shall be a person who: (II)

1. Is a graduate of a dietetic technician training program approved by the American Dietetic Association;

2. Is a graduate of a course of study meeting the requirements of the American Dietetic Association and approved by the state;

3. Is certified by the Certifying Board for Dietary Managers of the Dietary Managers Association and maintains that credential;

4. Has completed a Dietary Managers Association approved course curriculum necessary to take the certification examination required to become a certified dietary manager; or

5. Has at least three (3) years of training and experience in meal service supervision and management in a military service equivalent in content to the programs described in Sections 1405.B.1 through 1405.B.3.

C. A qualified food service supervisor shall receive consultation from a dietitian who is available on a full-time, part-time or consultant basis. (II)

D. There shall be a dietitian available to provide dietary review, menu planning, and consultation. If a dietitian is not a staff member of the facility, there shall be a valid contract for services between the facility and the dietitian. (II)

E. All meal service staff shall wear clean clothes, maintain personal cleanliness, and conform to hygienic practices while on duty. Shoes worn by meal service staff shall be closed-toed. Only authorized persons shall be allowed in the kitchen. (II)

F. Sufficient staff members shall be available to serve food and to provide individual attention and assistance, as needed. (II)

G. There shall be trained staff members to supervise the preparation and serving of the proper diet to the residents including having sufficient knowledge of food values in order to make appropriate substitutions when necessary. (II)

H. Residents shall not be permitted to engage in food preparation unless the following criteria are met: (II)

1. The ICP of the resident has indicated food preparation as suitable and/or beneficial to the resident;

2. The resident is directly supervised by staff members, for example, shall be in the food preparation area with the resident.

I. Meal service staff shall have the responsibility of accompanying the food to the floor, when necessary.

1406. Diets (II)

A. All diets shall be prescribed, dated and signed by the physician and be prepared in conformance with physicians' orders giving consideration to individual resident preferences.

B. The necessary equipment for preparation of resident diets shall be available and utilized.

C. A diet manual published within the previous five (5) years shall be available and shall address at a minimum:

1. Food sources and food quality;

2. Food protection storage, preparation and service;

3. Meal service staff health and cleanliness;

4. Dietary Reference Intakes (DRIs) of the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences food serving recommendations;

5. Menu planning, including plans appropriate to special needs, for example, diabetic, low-salt, low-cholesterol, or other diets appropriate for the elderly and/or infirm.

1407. Menus

A. Menus shall be planned and written at a minimum of four (4) weeks in advance and dated as served. The current week's menu, including routine and special diets and any substitutions or changes made, shall be readily available. At least the current day's menu shall be posted in one (1) or more conspicuous places in a public area. All substitutions made on the master menu shall be recorded in writing. Cycled menus shall be rotated so that the same weekly menu is not duplicated for at least a period of two (2) weeks.

B. Each menu shall be approved in writing by a dietitian before meals are prepared and served.

C. A file of tested recipes, adjusted to appropriate yield, shall correspond to items on the posted menus.

1408. Ice and Drinking Water (II)

A. Ice from a water system in accordance with R.61-58, shall be available and precautions taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside the ice container and allowed to air dry. The ice scoop and holding tray shall be sanitized daily.

B. Potable drinking water shall be available and accessible to residents at all times.

C. The use of common cups shall be prohibited.

D. Ice delivered to resident areas in bulk shall be in nonporous, covered containers that shall be cleaned after each use.

E. Drinking fountains of a sanitary angle jet design shall be properly regulated and maintained. There shall be no possibility of the mouth or nose becoming submerged. If drinking fountains are not provided, single service cups shall be used.

SECTION 1500—EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1501. Emergency Care (II)

The facility shall provide for the care of residents in an emergency and make available appropriate equipment and services to render emergency resuscitative and life-support procedures.

1502. Disaster Preparedness (II)

A. All facilities shall develop, by contact and consultation with their county emergency preparedness agency, a suitable written plan for actions to be taken in the event of a disaster and/or emergency evacuation. In the event of mass casualties, the facility shall provide resources as available. The plan shall be updated, as appropriate, annually, or as needed, and rehearsed at least annually. A record of the rehearsal, including its date and time, a summary of actions and recommendations, and the names of participants shall be maintained.

B. The disaster and emergency evacuation plan shall include, but not be limited to:

1. A sheltering plan to include:

a. Facility occupancy at the time of the disaster;

b. Name, address and phone number of the sheltering facility or facilities to which the residents will be relocated during a disaster;

c. A letter of agreement signed by an authorized representative of each sheltering facility which shall include: the number of relocated residents that can be accommodated; sleeping, feeding, and medication plans for the relocated residents; and provisions for accommodating relocated staff members and volunteers. The letter shall be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Horry, Jasper, and Georgetown counties, at least one (1) sheltering facility shall be located in a county other than these counties.

2. A transportation plan, to include agreements with entities for relocating residents, which addresses:

a. The relocation needs of the residents and staff contingent upon the type of disaster or emergency confronted;

b. Procedures for providing appropriate medical support, food, water and medications during relocation based on the needs and number of the residents;

c. Estimated time to accomplish the relocation during normal conditions;

d. Primary and secondary routes to be taken to the sheltering facility.

3. A staffing plan for the relocated residents, to include:

a. How care will be provided to the relocated residents, including licensed and nonlicensed staff members that will meet the staffing requirements of Section 605 for residents who are relocated;

b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility;

c. Co-signed statement by an authorized representative of the sheltering facility if staffing, bedding, or medical supplies are to be provided by the sheltering facility.

C. In instances where there are proposed changes in licensed bed capacity, the disaster and emergency evacuation plan shall be updated to reflect the new licensed bed capacity and submitted to the Department along with the application for bed capacity change.

D. Only those nursing homes located in the coastal counties of Beaufort, Charleston, Colleton, Horry, Jasper, or Georgetown may request exemption from an emergency evacuation order.

1. Facilities in the above counties may elect to seek an exemption from having to evacuate the facility in the event the Governor issues a Mandatory Evacuation Order for an impending hurricane. Facilities located in Beaufort, Charleston, Colleton, Horry, Jasper, or Georgetown counties may

request an exemption from an emergency evacuation order if the facility has previously submitted the following to the Department:

- a. A Critical Data Sheet, updated annually, that certifies emergency power supply is available for a minimum of seventy-two (72) hours, a seventy-two (72) hour supply of food, water, and medical supplies is on site, and that adequate staff will be available and on duty to provide continual care for the residents;
 - b. A copy of the engineer's report concerning the wind load the facility should withstand; and
 - c. A current approved evacuation plan prior to a declared emergency.
2. Once the prerequisites are met and an emergency has been declared, the facility shall draw down the census of the facility and then contact the Department to request an exemption from the evacuation order.
 3. A facility shall comply with the mandatory evacuation order unless an exemption from evacuation of the facility for a specific storm has been received from the Department.

1503. Licensed Bed Capacity During An Emergency (II)

A. A facility desiring to temporarily admit residents in excess of its licensed bed capacity due to an emergency shall:

1. Request that the Department concur that an emergency situation exists by contacting the Department;
2. Determine the maximum number of residents to be temporarily admitted;
3. Establish an anticipated date for discharge of the temporary residents;
4. Outline how and where the temporary residents will be housed; and
5. Contact the county emergency preparedness agency to advise of additional residents.

B. The facility shall not require the residents temporarily admitted during the emergency situation to undergo tuberculin screening or submit to an admission history and physical examination.

C. The facility shall notify the Department when the resident census has returned to, or moves below, normal bed capacity by discharge or transfer to licensed beds.

D. If the event occurs after normal business hours, the facility shall contact the Department promptly during the next business day.

E. The facility shall resolve in advance all other issues related to the temporary residents (for example, staff, physician orders, additional food, and handling of medications) by memorandum of agreements, internal policies and procedures, and emergency planning documents.

1504. Emergency Call Numbers (II)

Although the facility may be in a location that has access to "911" services, emergency call data shall be immediately available, posted in a conspicuous place, at least at every staff work area, and shall include, at a minimum, the telephone numbers of fire and police departments, ambulance service, and the Poison Control Center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of physicians and staff members to be notified in case of emergency.

1505. Continuity of Essential Services (II)

There shall be a written plan to be implemented to assure the continuation of essential resident support services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the workforce resulting from inclement weather or other causes.

1506. Use of the Facility or Services in Response to a Public Health Emergency (II)

The Department, in coordination with the guidelines of the State Emergency Operations Plan, may, for such period as the state of public health emergency exists and as may be reasonable and necessary for emergency response, require a nursing home to provide services or the use of its facility if the services are reasonable and necessary to respond to the public health emergency as a condition of licensure, authorization, or the ability to continue doing business as a nursing home. When the Department needs the use or services of the facility to isolate or quarantine individuals during a public health emergency, the management and supervision of the nursing home shall be coordinated with the Department to assure protection of existing residents and compliance with the regulation in accordance with S.C. Code Section 44-4-310.

SECTION 1600—FIRE PREVENTION

1601. Arrangements for Fire Department Response and Protection (II)

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, for example, fire plan and evacuation plan. (I)

B. Facilities located outside a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be maintained on file in the facility and a copy shall be forwarded to the Department. If the agreement is changed, a copy shall be forwarded to the Department. (I)

C. Fire protection for all facilities shall meet all of the requirements of the South Carolina State Fire Marshal's Office.

1602. Tests (II)

Fire protection and suppression systems shall be maintained and tested at least annually in accordance with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to nursing homes.

1603. Fire Response Training (I)

A. Each staff member shall receive training within forty-eight (48) hours of his or her first day on the job in the facility and at least annually thereafter, addressing at a minimum, the following:

1. Fire plan;
2. Reporting a fire;
3. Use of the fire alarm system;
4. Location and use of fire-fighting equipment;
5. Methods of fire containment;
6. Specific responsibilities, tasks, or duties of each individual when a facility fire occurs.

B. A plan for the evacuation of residents, staff members, and visitors, to include procedures and evacuation routes out of the facility, in case of fire or other emergencies, shall be established and posted in conspicuous public areas throughout the facility.

1604. Fire Drills (I)

A. An unannounced fire drill shall be conducted at least quarterly for all shifts. Records of drills shall be maintained at the facility, indicating the date, time, shift, description, an evaluation of the drill, and the names of staff members directly involved in responding to the drill. Should fire drill requirements be mandated by statute or regulation, then compliance with that statute or regulation shall supersede the provisions of this section.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1603.

SECTION 1700—INFECTION CONTROL AND ENVIRONMENT

1701. Staff Practices (II)

A. Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable regulations and guidelines of the Occupational Safety and Health Administration, for example, the Bloodborne Pathogens Standard; the Centers for Disease Control and Prevention, for example, Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee; and R.61-105; and other applicable state, federal, and local laws and regulations.

B. There shall be an infection control/QI committee that meets at least annually to address infection control issues consisting of the medical director and representatives from at least administration, nursing, dietary, and housekeeping staff to assure compliance with this regulation regarding infection control.

C. There shall be a tuberculosis infection control program per CDC guidelines. A facility licensed nurse shall be designated at each facility to coordinate the tuberculosis infection control program.

1702. Tuberculosis Risk Assessment (I)

A. All facilities shall conduct an annual tuberculosis risk assessment (See Section 101.JJJ) in accordance with CDC guidelines (See Section 102.B.9) to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification, for example, low risk, medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and residents and the frequency of screening. A risk classification shall be determined for the entire facility. In certain settings, such as, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, resident population, job type, or location within the setting may have separate risk classifications.

1703. Staff Tuberculosis Screening (I)

A. Tuberculosis Status. Prior to date of hire or initial resident contact, the tuberculosis status of direct care staff shall be determined in the following manner in accordance with the applicable risk classification:

B. Low Risk:

1. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All staff (within three (3) months prior to contact with residents) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8–10) weeks after that exposure to *M. tuberculosis* ended.

C. Medium Risk:

1. Baseline two-step TST or a single BAMT: All staff (within three (3) months prior to contact with residents) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic testing (with TST or BAMT): Annually, of all staff who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff about symptoms of TB disease (including the staff and/or direct care volunteers responses), documenting the questioning of the staff about the presence of symptoms of TB disease, and instructing the staff to report any such symptoms immediately to the Administrator or director of nursing. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8–10) weeks after that exposure to *M. tuberculosis* ended.

D. Baseline Positive or Newly Positive Test Result:

1. Staff with a baseline positive or newly positive test result for *M. tuberculosis* infection (for example, TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, for example, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). These staff members will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be

encouraged to follow the recommendations made by a physician with TB expertise (for example, the Department's TB Control program).

2. Staff with positive TST results (regardless of when that conversion was first documented) shall document that conversion, document a subsequent negative chest radiograph and receive a negative assessment for signs and symptoms of TB before they may be hired or begin employment, as appropriate.

3. Staff who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician, and permitted to return to work only with approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician.

1704. Resident Tuberculosis Screening (I)

A. Tuberculosis Status. Prior to admission, the tuberculosis status of a resident shall be determined in the following manner in accordance with the applicable risk classification:

B. For Low Risk and Medium Risk:

1. Admission/Baseline two-step TST or a single BAMT: All residents within one (1) month prior to admission unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly-admitted resident has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered within one (1) month prior to admission to the facility to serve as the baseline. In the institutional nursing home setting, residents admitted from other parts of that institutional campus who have had TB screening done which meets the requirements outlined in this section and which was done within the last six (6) months will not be required to undergo additional initial screening.

a. A facility may admit a resident with at least the first step of the TB screening process completed prior to admission and the second step within fourteen (14) days of admission.

b. A facility may admit, when appropriate, only those residents referred by South Carolina Department of Social Services (SCDSS) Adult Protective Services subject to documenting a current chest radiograph (negative for TB) and a negative assessment for signs and symptoms of TB followed by two-step TST completed within fourteen (14) days of admission.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for residents upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all residents who have had exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8–10) weeks after that exposure to *M. tuberculosis* ended.

C. Baseline Positive or Newly Positive Test Result:

1. Residents with a baseline positive or newly positive test result for *M. tuberculosis* infection (for example, TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, for example, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). Routine repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician. These residents will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (for example, the Department's TB Control program).

2. Residents with positive TST results (regardless of when that conversion was first documented) shall document that conversion, document a subsequent negative chest radiograph and receive a negative assessment for signs and symptoms of TB before they may be admitted, as appropriate.

3. Residents who are known or suspected to have TB disease shall be transferred from the facility if the facility does not have an Airborne Infection Isolation room (See Section 101.G), required to undergo evaluation by a physician, and permitted to return to the facility only with approval by the Department's TB Control program.

1705. Isolation Procedures (II)

A. An infection isolation room shall be made available if ordered by the attending physician for a resident who has a communicable disease that poses a threat to the health or safety of other residents or who for some other reason requires isolation and only to the extent that is required to protect the resident and others.

B. Should it be determined that the facility is unable to care for the resident to the degree which assures the health and safety of the resident and the other residents of the facility, the resident shall be relocated to a facility that can meet his or her needs.

C. The facility may accept residents with contagious pulmonary tuberculosis and provide appropriate treatment, provided that CDC guidelines are met.

1. Residents with contagious pulmonary tuberculosis shall be separated, for example, Airborne Infection Isolation room, transfer, from all other residents until declared noncontagious by a Department TB physician.

2. When residents with contagious pulmonary tuberculosis are to remain in the facility for treatment instead of being transferred to another facility, isolation procedures shall follow CDC guidelines, including Airborne Infection Isolation requirements.

3. Airborne Infection Isolation rooms may be required to have negative pressure as determined by the facility's tuberculosis risk assessment (See Section 101.JJJ) in the manner designated by guidelines established by the Department.

D. When isolation precautions are implemented, signs directing individuals to the staff work area for further information shall be posted at the entrance to the resident room.

1706. Vaccinations (II)

A. Hepatitis B.

1. All direct care staff who perform tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps shall have the hepatitis B vaccination series unless the vaccine is medically contraindicated or an individual is offered the series and declined. In either case, the decision shall be documented.

2. Each staff member with eligibility as identified in Section 1706.A.1 who elects vaccination shall start the initial dose of the three-dose series within ten (10) days of the date hired and complete the series within six (6) months.

B. Influenza.

1. Direct care staff and residents shall have an annual influenza vaccination unless the vaccine is medically contraindicated or the person is offered the vaccination and declined. In either case, the decision shall be documented.

2. Persons receiving influenza vaccination shall, as appropriate, receive influenza vaccination each influenza season from October through March. Consideration may be made for availability issues, such as, vaccine shortages.

C. Pneumococcal. Upon admission, residents shall be immunized for Streptococcus pneumoniae. Residents shall be vaccinated for Streptococcus pneumoniae unless the vaccine is medically contraindicated or the resident is offered the vaccination and declined. In either case, the decision shall be documented.

1707. Housekeeping (II)

A. The facility and its grounds shall be uncluttered, clean, and free of vermin and offensive odors. There shall be sufficient cleaning supplies and equipment available. Housekeeping shall at a minimum include:

1. Cleaning each specific area, including storage areas, of the facility. Accumulated waste material shall be removed daily or more often if necessary;

2. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area. Cleaning and disinfection shall be appropriate to the area and the equipment's purpose or use and shall include resident room preparation for new occupants;

3. Disposable materials and equipment shall be used by one (1) resident only, in accordance with manufacturer's recommendations and then disposed of in an acceptable manner;

4. Storage of chemicals indicated as harmful on the product label, cleaning materials, and supplies in cabinets or well-lighted closets and rooms, inaccessible to residents;

5. Cleaning of all exterior areas, such as, porches and ramps, and removal of safety impediments such as snow, ice and standing water;

6. Keeping facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.

B. All air filters shall be maintained free of excess dust and combustible material. Filters shall be replaced or cleaned when the resistance has reached a value of recommended replacement by the manufacturer.

C. Dry dusting and dry sweeping are prohibited.

1708. Infectious Waste (II)

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in a manner compliant with R.61-105.

1709. Pets (II)

A. Healthy domestic pets that are free of fleas, ticks, and intestinal parasites, and have been screened by a veterinarian within the past twelve (12) months prior to entering the facility, have received required inoculations, if applicable, and that present no apparent threat to the health and safety of the residents, may be permitted in the facility.

B. Pets shall be permitted in resident dining areas only during times when food is not being served and shall not be allowed in the kitchen. If the dining area is adjacent to a food preparation or storage area, those areas shall be effectively separated by walls and closed doors while pets are present.

1710. Clean and Soiled Linen and Clothing (II)

A. Clean Linen and Clothing.

1. Proper storage facilities shall be provided for keeping clean linen, restraints and resident clothes in sanitary condition prior to use. Clean linen not stored separately shall be covered. Clean linen and clothing storage rooms shall be used only for the storage of clean linen and clothing. Clean linen and clothing shall be separated from storage of other materials.

2. A supply of clean, sanitary linen and clothing shall be available at all times.

3. Clean linen and clothing shall be stored and transported in a sanitary manner, for example, covered.

B. Soiled Linen and Clothing.

1. A soiled linen storage room shall be provided.

2. Soiled linen and clothing shall neither be sorted, rinsed, nor washed outside the laundry service area.

3. Provisions shall be made for collecting and transporting soiled linen and clothing.

4. Soiled linen and clothing shall be kept in enclosed or covered nonabsorbent containers or washable laundry bags.

5. Soiled linen and clothing shall not be transported through resident rooms, kitchens, food preparation or storage areas.

6. If linen chutes are used, the soiled linen and clothing shall be enclosed in bags before placing in chute.

7. Facilities shall utilize Standard Precautions in the handling of all soiled linen and clothing. Labeling or color-coding of bagged soiled linen and clothing is sufficient provided all on-site or off-site handlers recognize the containers as requiring compliance with Standard Precautions.

1711. Laundry (II)

A. Facility-based laundry services shall be conducted in a clean, safe, and well-ventilated area, divided into specific clean and soiled processing areas and properly insulated to prevent transmission of noise, heat, steam, and odors to resident care areas. The facility shall assure that nonfacility-based laundry services to the nursing home exercise every precaution to render all linen safe for reuse.

B. Laundry services shall not be conducted in resident rooms, dining rooms, or in locations where food is prepared, served, or stored. As an element of the resident's ICP, folding of clean personal laundry by residents is permitted in resident rooms.

C. Clean and soiled processing areas shall either be in separate rooms or be provided with ventilation to prevent cross-contamination.

SECTION 1800—QUALITY IMPROVEMENT PROGRAM

There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care, treatment and services provided by the facility.

SECTION 1900—DESIGN AND CONSTRUCTION

1901. General (II)

A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each resident. A facility shall be designed so all residents have access to required services.

1902. Codes and Standards (II)

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

B. Unless specifically required otherwise in writing by the Department, all existing facilities shall meet the construction codes and regulations for the building and its essential equipment and systems in effect at the time the accepted construction documents were professionally stamped and issued.

C. Any facility that closes, has its license revoked, or surrenders its license and applies for re-licensure at the same site shall be considered a new building and shall meet the current codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for re-licensing.

1903. Submission of Plans (II)

A. An architect and/or engineer registered in South Carolina shall prepare the plans and specifications. Unless directed otherwise by the Department, plans shall be submitted at the schematic, design development, and final stages. All plans shall be drawn to scale. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until the Department receives a plan approval. During construction, the Owner shall employ a registered architect and/or engineer for observation. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic inspections throughout each project.

B. Plans and specifications shall be submitted to the Department for new construction and for a project that has an effect on:

1. The function of a space;
2. The accessibility to or of an area;
3. The structural integrity of the facility;
4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);
5. Doors;
6. Walls;
7. Ceiling system assemblies;
8. Exit corridors;
9. Life safety systems; or
10. Increase in occupant load or licensed capacity of the facility.

C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, or other, that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.

E. A facility with construction work in violation of codes or standards shall be brought into compliance with applicable codes and standards.

1904. Construction Permits (II)

All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by the Department.

1905. Utility Rooms

A. Soiled Utility Room: A facility shall provide at least one (1) soiled utility room per work station which contains a clinical sink, work counter, hand wash sink, waste receptacle and soiled linen receptacle.

B. Clean Utility Room: A facility shall provide at least one (1) clean utility room per work station which contains a counter with hand wash sink and space for the storage and assembly of supplies for nursing procedures.

SECTION 2000—FIRE PROTECTION EQUIPMENT AND SYSTEMS

2001. Fire Alarms and Sprinklers (II)

A. A facility shall include a partial, manual, automatic, and supervised fire alarm system. A facility shall arrange the fire alarm system to transmit an alarm automatically to a third party by an approved method. A facility shall provide a fire alarm system that notifies all areas and floors of the building by audible and visual alarm. A facility shall provide a fire alarm system that shuts down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. A facility shall include all fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems that connect to the main fire alarm system and trigger the system when activated.

C. A facility shall include a sprinkler system.

D. A facility shall include a fire alarm pull station in or near each work station.

2002. Emergency Generator Service

A. Facilities shall provide certification that construction and installation of the emergency generator service comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

B. An emergency generator shall deliver emergency electrical service during interruption of the normal electrical service to the distribution system as follows:

1. Exit lights and exit directional signs;
2. Exit access corridor lighting;
3. Lighting of means of egress and staff work areas;
4. Fire detection and alarm systems;
5. In resident care areas, such as sleeping areas and personal care areas;
6. Signal system;
7. Equipment necessary for maintaining telephone service and all life safety systems.
8. Elevator service that will reach every resident floor when rooms are located on other than the ground floor;
9. Fire pump;
10. Equipment for heating resident rooms;
11. Public restrooms;
12. Essential mechanical equipment rooms;
13. Battery-operated lighting and a receptacle in the vicinity of the emergency generator;
14. Alarm systems, water flow alarm devices, and alarms required for medical gas systems; and
15. Resident records when solely electronically based.

SECTION 2100—PREVENTIVE MAINTENANCE

A facility shall keep the structure, component parts, amenities and equipment in good repair, operating condition, and documented. A facility shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

SECTION 2200—EQUIPMENT AND SYSTEMS

2201. Gases (I)

A. Gases, flammable and nonflammable, shall be handled and stored in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

B. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place. In "Smoke-Free" facilities, "No Smoking" signs shall not be required in and in the vicinity of resident rooms where oxygen is being administered provided all 4 of the following conditions are met:

1. Smoking is prohibited;
2. The facility nonsmoking policy is strictly enforced;
3. "Smoke-Free" signs are strategically placed at all major entrances; and
4. A facility shall have "No Smoking" signs in, and in the vicinity of, resident rooms where oxygen is stored as well as all other required areas.

2202. Furnishings and Equipment (I)

A. A facility shall maintain the physical plant free of fire hazards or impediments to fire prevention.

B. A facility shall not permit portable electric or unvented fuel heaters.

C. Fireplaces and fossil-fuel stoves, such as, wood-burning, shall have partitions or screens or other means to prevent burns. Fireplaces shall be vented to the outside. A facility shall not use unvented gas logs. Gas fireplaces shall have a remote gas shutoff within the room and not inside the fireplace.

D. A facility shall require all wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows to be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant.

SECTION 2300—WATER SUPPLY, HYGIENE, AND TEMPERATURE CONTROL

A. Plumbing fixtures that require hot water and that are accessible to residents shall be supplied with water that is thermostatically controlled to a temperature of at least one hundred (100) degrees Fahrenheit and not to exceed one hundred twenty (120) degrees Fahrenheit at the fixture. (I)

B. The water heater or combination of heaters shall be sized to provide at least six (6) gallons per hour per licensed bed at the temperature range indicated in Section 2300.A. (II)

C. Hot water supplied to the kitchen equipment and utensil washing sink shall be supplied at one hundred twenty (120) degrees Fahrenheit provided all kitchen equipment and utensils are chemically sanitized. For facilities sanitizing with hot water, the sanitizing compartment of the kitchen equipment and utensil washing sink shall be capable of maintaining water at a temperature of at least one hundred eighty (180) degrees Fahrenheit. (II)

D. Hot water provided for washing linen and clothing shall not be less than one hundred sixty (160) degrees Fahrenheit. Should chlorine additives or other chemicals that contribute to the margin of safety in disinfecting linen and clothing be a part of the washing cycle, the minimum hot water temperature shall not be less than one hundred ten (110) degrees Fahrenheit, provided hot air drying is used. (II)

SECTION 2400—ELECTRICAL

2401. General

A facility shall maintain all electrical installations and equipment in a safe, operable condition in accordance with the applicable codes and shall be inspected at least annually by a licensed electrician, registered engineer, or certified building inspector.

2402. Panelboards (II)

A facility shall label the panelboard directory to conform to the room numbers and/or designations.

2403. Lighting

A. A facility shall provide adequate lighting in spaces occupied by persons, machinery, and equipment within buildings, approaches to buildings, and parking lots. (II)

B. A facility shall provide adequate artificial light and sufficient illumination for reading, observation, and activities. A facility shall provide general lighting in all parts of every resident room and at least one (1) light fixture for night lighting in every resident room. A facility shall provide a reading light for each client.

C. A facility shall provide lighting in hallways, stairs, and other means of egress at all times.

2404. Receptacles (II)

A. A facility shall provide duplex grounding type receptacles in each resident room with one (1) duplex receptacle at the head of each bed in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina Fire Marshal.

B. Each resident bed location shall have a minimum of two (2) duplex receptacles.

C. Each resident bed location shall be supplied by at least two (2) branch circuits.

D. Duplex receptacles for general use shall be installed approximately fifty (50) feet apart in all corridors and within twenty-five (25) feet of the ends of corridors.

2405. Ground Fault Protection (I)

A. A facility shall have ground fault circuit-interrupter protection for all outside receptacles and bathrooms.

B. A facility shall have ground fault circuit-interrupter protection for any receptacle within six (6) feet of a sink or any other wet location. If the sink is an integral part of the metal splashboard grounded by the sink, the entire metal area is considered part of the wet location.

2406. Exit Signs (I)

A. A facility shall identify all required exits and ways to access thereto with electrically-illuminated exit signs bearing the words "Exit" in red letters.

B. A facility shall mark changes in egress direction with exit signs with directional arrows.

C. A facility shall maintain exit signs in corridors that indicate two (2) directions of exit, where appropriate.

SECTION 2500—HEATING, VENTILATION, AND AIR CONDITIONING (HVAC)

A. A facility shall not install a HVAC supply or return grill within three (3) feet of a smoke detector. (I)

B. A facility shall not install HVAC grills in floors. (II)

C. Return air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. The system shall not discharge in a manner that would be an irritant to the residents, staff, or volunteers. (II)

D. A facility shall have each shower, bath, and restroom with either operable windows or have approved mechanical ventilation. (II)

SECTION 2600—GENERAL CONSTRUCTION REQUIREMENTS

2601. Common Areas

A. A facility shall provide a minimum of thirty (30) square feet per bed of living, recreational, and dining area combined, excluding bedrooms, halls, kitchens, bathrooms, and rooms not available to the residents.

B. A facility shall provide all required care, treatment, and services in a manner that does not require residents to ambulate from one site to another outside the building(s), nor impedes residents from ambulating from one site to another due to the presence of physical barriers.

C. A facility shall ensure methods of visual and auditory privacy between resident and staff, volunteers, and visitors.

D. A facility shall provide physical space for private resident, family, and responsible party visiting.

E. A facility shall provide accommodations for family privacy after a resident's death.

2602. Resident Rooms

A. With the exception of furniture unless otherwise allowed by facility policy, a resident shall have the choice of bringing familiar items from home as part of the furnishing to his or her room, for example, wall pictures, paintings, or vases. Each resident room shall be equipped with the following as a minimum for each resident:

1. A comfortable single bed having a mattress with moisture-proof cover, sheets, blankets, bedspread, pillow, and pillowcases. Roll-away type beds, cots, bunkbeds, and folding beds shall not be used. It is permissible to utilize a recliner in lieu of a bed or remove a resident bed and place the mattress on a platform or pallet provided the physician or other authorized healthcare provider has approved it and the decision is documented in the ICP. (II)

EXCEPTION: In the case of a married couple sharing the same room, a double bed is permitted if requested. For all other requirements, this shall be considered a bedroom with two (2) beds. A roll-away type bed or cot may be temporarily used for family or responsible party staying overnight with the resident.

2. A facility shall provide a closet or wardrobe, a bureau consisting of at least three drawers, and a compartmentalized bedside table or nightstand to adequately accommodate each resident's personal clothing, belongings, and toilet articles. Built-in storage is permitted.

3. A comfortable chair shall be available for each resident occupying the room. If the available square footage of the resident room will not accommodate a chair for each resident or if the provision of multiple chairs impedes resident ability to freely and safely move about within his or her room, the facility shall provide at least one (1) chair and have additional chairs available for temporary use in the resident's room by visitors.

B. If hospital-type beds are used, there shall be at least two (2) lockable casters on each bed, located either diagonally or on the same side of the bed.

C. Beds shall not be placed in corridors, solaria, or other locations not designated as resident room areas. (I)

D. No resident room shall be located in a basement.

E. Access to a resident room shall not be by way of another resident room, toilet, bathroom, or kitchen.

F. A facility shall provide equipment such as bedpans, urinals, and hot water bottles, necessary to meet resident needs. Permanent positioning of a portable commode at bedside shall only be permitted if the room is private, the commode is maintained in a sanitary condition, and the room is of sufficient size to accommodate the commode. (II)

G. Side rails may be utilized when required for safety and when ordered by a physician or other authorized healthcare provider. When there are special concerns, such as residents with Alzheimer's disease and/or related dementia, side rail usage shall be monitored by staff members as per facility policies and procedures. (I)

H. In semi-private rooms, when personal care is being provided, arrangements shall be made to ensure privacy, for example, portable partitions or cubicle curtains when needed or requested by a resident.

I. A facility shall provide at least one (1) private room for assistance in addressing resident compatibility issues, resident preferences, and accommodations for residents with communicable disease.

J. Infants and small children shall not be assigned to a room with an adult resident unless requested by residents and families.

K. A facility shall provide cubicle curtains with built-in curtain tracks in all multiple bed rooms that will shield each resident completely. Curtains shall be flameproof.

L. Beds must be placed at least three (3) feet apart.

M. A facility shall provide at least one (1) private room in each nursing unit for purposes of medical isolation, incompatibility, personality conflicts, or other.

2603. Resident Room Floor Area

A. Each resident room shall have an outside window. This window shall not open onto a common area screened porch. (I)

B. The resident room floor area is a usable or net area and does not include wardrobes (built-in or freestanding), closets, or the entry alcove to the room. The following is the minimum floor space allowed: (II)

1. Rooms for only one (1) resident: one hundred (100) square feet for the licensed bed (there shall be compliance with the minimum square footage requirements of Section 2603.B.2 in instances when family members or responsible party routinely utilize a separate bed for overnight stays with the resident);

2. Rooms for more than one (1) resident: eighty (80) square feet per licensed bed.

C. There shall be at least three (3) feet between beds. (II)

2604. Visitor Accommodations

A. Visitor designated or guest rooms shall not be utilized by residents, prospective residents, or staff members of the facility.

B. No supervisory care shall be given to visitors of the facility, for example, first aid response by staff, tray service, or other.

C. Visitors shall be made aware of those provisions and accommodations available so that they may serve themselves, for example, towels, sheets, soap.

D. Any conduct of the visitors which may have an adverse effect on the residents and/or facility must be promptly and prudently handled, for example, resident and/or staff abuse.

E. Those visiting as well as the residents with whom they are visiting shall be made fully aware of the conditions under which their stay is acceptable.

F. A facility shall provide adequate space for privacy of the family and significant others at the time of the resident's death.

2605. Baths and Restrooms

A. A facility shall have an appropriate number of restrooms to accommodate residents, staff, and visitors. A facility shall have one (1) toilet for each (4) four licensed beds or fraction thereof and one (1) bathtub or shower for each (12) twelve licensed beds or fraction thereof.

B. A facility shall have accessible restrooms during all operating hours.

C. A facility shall equip all restrooms with at least one (1) toilet fixture, toilet paper installed in a holder, a lavatory supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle. A facility shall provide soap, bath towels, and washcloths to each resident as needed. A facility shall not store bath linens assigned to specific residents in centrally located restrooms.

EXCEPTION: A facility may store bath linens assigned to specific residents that are for immediate use in a single occupancy (one (1) resident) restroom or a restroom shared by occupants of adjoining rooms, for a maximum of six (6) residents. A facility shall implement a method that distinguishes linen assignment and discourages common usage. (II)

D. A facility shall have approved grab bars securely fastened on all toilet fixtures used by residents.

E. A facility shall provide privacy at toilet fixtures and urinals.

F. A facility shall provide restrooms for persons with disabilities in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

G. A facility shall completely cover all restroom floors with an approved, nonabsorbent covering. A facility shall have restroom walls with nonabsorbent, washable surfaces to the highest level of splash.

H. A facility shall provide grab bars on at least one (1) side of every toilet.

2606. Work Stations

A. A facility shall provide work stations for nursing and/or other direct care staff. The facility shall design and construct (or set up) work stations in a manner conducive to the type of care provided by the facility or that specific area of the facility and the types of residents served.

B. At or near each work station, a facility shall have a telephone, an area for maintaining resident records and making entries, and a toilet and hand washing sink.

C. At or near each work station, a facility shall make provisions for the following:

1. Secured storage of medications, which may be accomplished by the use of a separately secured medication cart, container, cabinet, or room, provided:

a. The method or methods used are of sufficient size to allow for clean and orderly storage of medications;

b. Separations are provided for the storage of each resident's medications;

c. Separations are provided for oral and topical medications.

2. Work space or area for the preparation of medications, which may be a counter, table top, or a separate room, to include being a part of a separate medication room.

D. A staff work area shall be provided for each sixty (60) licensed beds or a fraction thereof.

E. A facility shall not have any resident room located more than one hundred fifty (150) feet from the work station serving that resident room.

F. A facility shall have utility areas or rooms for separate storage of clean and soiled supplies and equipment at or near each work station. A facility shall require each utility area to contain a hand washing sink, work counter, waste receptacle, and space for the storage of supplies.

2607. Signal System (II)

A. A facility shall have a signal system for residents consisting of a call button for each bed, bath, and toilet. A light shall be at or over each resident room door visible from the corridor. A facility shall be a master station that indicates room location and has an indicating alarm in a location continuously monitored by staff.

B. A facility shall have an audio-visual device that cannot be interrupted located in all utility rooms, medicine preparation rooms, lounges, storage rooms and areas where staff congregate.

C. Activation of signal system shall be by pull cord or electronic device. A pull cord shall hang to a maximum of four (4) inches above finished floor.

D. A radio frequency system shall meet all of the requirements listed in this Section and the most current version of UL1069.

2608. Doors (II)

A. A facility shall have opaque doors on restrooms for the purpose of privacy.

B. A facility shall require all glass doors, including sliding or patio type doors, to have a contrasting or other indicator that causes the glass to be observable, for example, a decal located at eye level.

C. Doors that have locks shall be lockable with one action.

D. A facility shall have provisions for emergency entry if resident room doors are lockable.

E. Any locked room door in the facility shall have the ability to unlock and open from inside the room.

2609. Elevators (II)

A facility shall have elevators inspected and tested upon installation, prior to first use, and annually thereafter by a certified elevator inspector.

2610. Handrails and Guardrails (II)

A. A facility shall provide handrails on at least one (1) side of each corridor.

B. A facility shall provide guardrails forty-two (42) inches high on all porches, walkways, and recreational areas (such as decks) elevated thirty (30) inches or more above grade in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

2611. Janitor's Closet (II)

A facility shall have at least one (1) lockable janitor's closet per work station. A facility shall equip each closet with a mop sink or receptor and space for the storage of supplies and equipment.

2612. Storage Areas

A. A facility shall provide adequate general storage areas for resident and staff or volunteer belongings and equipment. A facility shall provide at least ten (10) square feet of general storage per bed throughout the facility.

B. A facility shall provide separate storage for beds, wheel chairs, and other equipment.

C. A facility shall not store supplies and equipment directly on the floor. A facility shall not store supplies and equipment susceptible to water damage or contamination under sinks or other areas with a propensity for water leakage. (II)

2613. Telephone Service

A. A facility shall make at least one (1) telephone available and easily accessible on each floor of the facility for use by residents and/or visitors for their private, discretionary use. Telephones shall be portable to accommodate bedridden or ambulatory-impaired residents. Telephones capable of only local calls are acceptable for this purpose, provided other arrangements exist to offer residents discretionary access to a telephone capable of long distance service.

B. A facility shall provide at least one (1) telephone on each floor for staff members and volunteers to conduct routine business of the facility and to summon assistance in the event of an emergency.

2614. Location

A. Transportation. A facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. A facility shall have a parking area to reasonably satisfy the needs of residents, staff members, volunteers, and visitors.

C. Access to firefighting equipment. A facility shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

2615. Outdoor Area.

A. A facility shall enclose all unsafe, unprotected physically hazardous outdoor areas with a fence or natural barrier the size, shape and density to effectively impede travel to the hazardous area. The outdoor hazardous areas of a facility include, but are not limited to, steep grades, cliffs, open pits, high voltage electrical equipment, roads exceeding two (2) lanes excluding turn lanes, ponds, and swimming pools. (I)

B. A facility shall have a gate in any fence required as part of a fire exit from the building and the gate in the fence shall unlock in case of emergency in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal. (I)

C. A facility shall protect mechanical or equipment rooms open to the outside of the facility from unauthorized individuals. (II)

SECTION 2700—SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2800—GENERAL

Conditions arising that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Amended by State Register Volume 16, Issue No. 2, eff February 28, 1992; State Register Volume 32, Issue No. 6, eff June 27, 2008; State Register Volume 33, Issue No. 6, eff June 26, 2009; State Register Volume 40, Issue No. 3, Doc. No. 4543, eff March 25, 2016.