

East Coast Worldwide Florida Statutes for Tattoo and Body Piercing

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Florida Statutes

381.0075 Regulation of body-piercing salons.—

(1) LEGISLATIVE INTENT.—It is the intent of the Legislature to protect the health, safety, and welfare of the public from the spread of infectious diseases from practices that prick, pierce, or scar the skin and therefore, to that end, to regulate body-piercing salons.

(2) DEFINITIONS.—As used in this section:

(a) “Body piercing” means for commercial purposes the act of penetrating the skin to make, generally permanent in nature, a hole, mark, or scar. “Body piercing” does not include the use of a mechanized, pre-sterilized ear-piercing system that penetrates the outer perimeter or lobe of the ear or both.

(b) “Body-piercing salon” means a place where body piercing occurs.

(c) “Department” means the Department of Health.

(d) “Establishment” means a body-piercing salon as defined in this section.

(e) “Jewelry” means any personal ornament inserted into a pierced area other than the outer perimeter or lobe of the ear.

(f) “Licensee” means any person licensed under this section who is responsible for compliance with this section and the rules adopted under this section.

(g) “Operator” means an individual designated by a licensee to control the operation of an establishment.

(h) “Person” means any individual, partnership, corporation, or association.

(i) “Safe level” means not more than 50 colonies of microorganisms per 4 square inches of equipment or device surface.

(j) “Sanitization” means the effective bactericidal treatment of surfaces of equipment and devices by a product registered by the United States Environmental Protection Agency which provides a sufficient concentration of chemicals and enough time to reduce the bacterial count, including pathogens, to a safe level.

(k) “Sterilization” means the use of procedures that destroy all microbial life, including viruses, on the equipment or device.

(l) “Stop-use order” means a written notice from the department to a licensee requiring the licensee to remove a piece of equipment or cease conducting a particular procedure because the equipment is not being operated or the procedure conducted in accordance with the requirements of this section or any rule adopted pursuant thereto.

(m) “Temporary establishment” means a body-piercing establishment that operates at a fixed location for a period of time of not more than 14 consecutive days in conjunction with a single event or celebration.

(3) EXEMPTIONS.—This section does not apply to the practice of any licensed health care professional under the regulatory jurisdiction of the department as long as the person does not hold himself or herself out as a body-piercing establishment.

(4) LICENSE REQUIRED.—

(a) A person may not operate an establishment unless it is licensed under this section.

(b) Any person operating an establishment must obtain a license from the department annually.

(c) A license for an establishment is not transferable from one place or person to another.

(d) A license automatically expires on September 30 of each year unless renewed by the department upon the request of the licensee.

(e) A current license must be displayed in a public area of the establishment.

(f) A person operating a temporary establishment must receive a temporary license from the department prior to operation. The department must be contacted at least 7 days prior to commencement of operation of the establishment and must conduct an inspection of the establishment to ensure compliance with licensing requirements prior to issuing the temporary license.

(5) LICENSE APPLICATION.—

(a) A person must apply to the department for an establishment license prior to commencement of operation and must apply for annual renewal of the license in order to continue operation.

(b) Application for an initial license or the renewal of a license must be on a form provided by the department and must be accompanied by the annual or prorated fee required in this section.

(c) The licensee must report any change in the application information to the department before the change may be put into operation.

(6) FEES.—

(a) Fees assessed under this section shall be reasonably calculated to cover the cost of regulation under this section, may be used only to meet the costs of carrying out the requirements of this section, and are nonrefundable.

(b) A person applying for initial licensure or reactivation of an expired license at the beginning of the licensing period or for renewal of a license shall pay the full fee. All other applicants, whether for initial licensure or reactivation of an expired license, shall pay a prorated fee based on the number of quarters left until September 30.

(c) Fees must be received by the department within 30 days after receipt of written notification from the department that a fee is due. Failure to pay timely will result in the assessment of a late fee. Fees are payable to the county health department in the county where the establishment is located.

(d) The fees assessed under this section are, unless prorated, as follows:

1. The annual license fee, or license renewal fee, for a body-piercing salon is \$150.
2. Each late fee is \$100.
3. The fee for a temporary establishment license is \$75.

(7) MINORS.—A person may not perform body piercing on a minor without the written notarized consent of the minor's parent or legal guardian, and an establishment may not perform body piercing on a minor under the age of 16 unless the minor is accompanied by a parent or legal guardian.

(8) PROHIBITED ACTS; PENALTIES; INJUNCTION.—

(a) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:

1. Owning, operating, or soliciting business as an establishment in this state without first procuring a license from the department, unless specifically exempted by this section.
2. Obtaining or attempting to obtain a license to operate an establishment by means of fraud, misrepresentation, or concealment.

(b) Each of the following acts constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083:

1. Failing to maintain the records required by this section or knowingly making false entries in such records.
2. Failing to comply with the requirements regarding minors set forth in subsection (7).

(c) In addition to any other punishment provided for, the court may suspend or revoke the license of any licensee under this section who has been found guilty of any violation of paragraph (a) or paragraph (b).

(d) If the department or any state attorney has probable cause to believe that an establishment or person has violated any provision of paragraph (a), an action may be brought by the department or the state attorney to enjoin such establishment or person from continuing such violation, or engaging therein or doing any acts in furtherance thereof, and the court may provide any other relief it deems appropriate.

(9) ENFORCEMENT.—

(a) The department shall inspect or investigate an establishment as necessary, but at least annually, to ensure compliance with this section. Department personnel may, at any reasonable time, enter any establishment licensed under this section or any premises the department has reason to believe is being operated or maintained in violation of this section, to determine compliance with this section or any rule adopted under this section.

(b) The department may impose an administrative fine, not to exceed \$1,000 per violation per day, for the violation of any provision of this section, any rule adopted

under this section, or any term or condition of any license issued under this section by the department.

(c) In determining the amount of fine to be levied for a violation, as provided in paragraph (b), the following factors shall be considered:

1. The severity of the violation and the extent to which the provisions of this section, the rules adopted under this section, or any terms or conditions of any license issued under this section were violated.
2. Actions taken by the licensee to correct the violation.
3. Any previous violations by the licensee.

(d) The department may issue a stop-use order, or institute legal action for injunctive or other relief, to enforce any provision of this section.

(e) The department may cancel, revoke, or suspend a license to operate an establishment if the licensee:

1. Fails to pay any fee required by this section;
2. Obtains or attempts to obtain a license under this section by fraud, misrepresentation, or concealment; or
3. Violates any provision of this section or any rule adopted under this section.

(f) 1. The department may issue a citation that contains an order of correction or an order to pay a fine, or both, for any violation of this section or the rules adopted under this section, when the violation of the section or rule is enforceable by an administrative or civil remedy or when the violation of the section or rule is a misdemeanor of the second degree. A citation constitutes a notice of proposed agency action.

2. A citation must be in writing and must describe the particular nature of the violation, including specific reference to the provision of law or rule allegedly violated.

3. The fines imposed by a citation may not exceed \$1,000 for each violation. Each day the violation exists constitutes a separate violation for which a citation may be issued.

4. The department shall inform the recipient of a citation, by written notice pursuant to ss. 120.569 and 120.57, of the right to an administrative hearing to contest the citation within 21 days after the date the citation is received. The citation must contain a conspicuous statement that if the recipient fails to pay any fine levied against the recipient within the time allowed or fails to appear to contest the citation after having requested a hearing, the recipient has waived the recipient's right to contest the citation and must pay the maximum fine.

5. The department may reduce or waive any fine imposed by a citation. In determining whether to reduce or waive a fine, the department must consider the gravity of the violation, the person's attempts at correcting the violation, and the person's history of previous violations for which enforcement actions were taken under this section.

6. Any person who willingly refuses to sign and accept a citation issued by the department commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

7. This paragraph provides an alternative means of enforcing this section, but does not prohibit the department from enforcing this section or the rules adopted under this section by any other means. However, the department may use only a single method of enforcement for each violation.

(g) The department shall deposit all fines it collects under this section in the County Health Department Trust Fund for use in providing services specified in this section.

(10) RULES.—The department has authority to adopt rules to implement this section. Such rules may include sanitation practices, sterilization requirements and procedures, patient record content requirements, personnel record retention requirements, patient notification requirements and procedures, physical plant requirements, light requirements, and enforcement procedures.

(11) BODY-PIERCING SALONS; SPECIFIC REQUIREMENTS.—

(a) A body-piercing salon must:

1. Properly sterilize all instruments that pierce the skin, directly aid in piercing the skin, or may come in contact with instruments that pierce the skin, through such means as storage in trays with other instruments or contact with forceps, in accordance with the sterilization procedures in this section.
2. Sanitize all equipment indirectly used in body piercing, including any beds, tables, headrests, armrests, legrests, or handrails.
3. Use protective infection barriers such as gloves and masks when serving a customer. If the protective barriers are contaminated, they must be properly disposed of immediately. Protective barriers may only be used once and only for one customer.
4. To the degree possible, thoroughly cleanse the area to be pierced with an antiseptic solution before and after the piercing.
5. Use only jewelry that is made of implant grade high-quality stainless steel, solid gold of at least 14K weight, niobium, titanium, platinum, a dense, low-porosity plastic, or silver and that is free of nicks, scratches, or irregular surfaces.
6. Provide each customer with written instructions on the proper care of the pierced area so as to prevent infection.
7. Maintain a record of each customer's visit for a period of not less than 2 years, including, but not limited to, the customer's name, date of visit, and area pierced and the name of the person performing the piercing.
8. Report any injury or any complaint of injury to the department on forms prescribed by the department and provide a copy of the report to the complainant.

(b) Sterilization procedures must include the following:

1. Proper autoclaving must be done according to the autoclave manufacturer's instructions.
 2. There must be a sterilization indicator in each autoclaving to monitor the sterilization procedure. The indicator must indicate exposure to steam and 250° Fahrenheit.
 3. Contaminated instruments must be sterilized in the following manner:
 - a. The contaminated instruments must be thoroughly cleansed with an antiseptic solution, according to the instructions for the antiseptic solution, and hot water.
 - b. The contaminated instruments and all other instruments, must be packaged properly and loaded correctly into the autoclave.
 - c. The contaminated instruments must be sterilized by autoclave.
 4. All sterilized instruments must be stored and handled in a manner that maintains sterility.
 5. Autoclaves must be cleaned regularly and serviced at least once a year.
 6. Each body-piercing salon utilizing autoclave sterilization techniques must post the sterilization procedures and ensure that personnel responsible for performing the sterilization procedures are adequately trained.
 7. All staff must be trained in proper infection-control procedures.
 8. Presterilized, prewrapped, disposable instruments may be used, but must be used in accordance with the manufacturer's instructions.
- (c) The body-piercing salon must be in compliance with s. 381.0098.

381.00771 Definitions of terms

As used in ss. 381.00771-381.00791, the term:

- (1) "Active license or registration" means a current license or registration issued by the department that is not suspended or revoked.
- (2) "Department" means the Department of Health.
- (3) "Guest tattoo artist" means a person who is licensed, registered, or certified to practice tattooing in a jurisdiction outside of this state who is registered with the department to practice tattooing in this state.
- (4) "Operator" means a person designated by a tattoo establishment or temporary establishment to control the operation of the establishment.
- (5) "Stop-use order" means a written notice from the department to a licensee or registrant requiring him or her to remove any tattooing equipment or supplies, or cease conducting any particular procedures, because the equipment or supplies are not being used or the procedures are not being conducted in accordance with ss. 381.00771-381.00791 or any rule adopted under those sections.

(6) “Tattoo” means a mark or design made on or under the skin of a human being by a process of piercing and ingraining a pigment, dye, or ink in the skin.

(7) “Tattoo artist” means a person licensed under ss. 381.00771-381.00791 to practice tattooing.

(8) “Tattoo establishment” means any permanent location, place, area, structure, or business where tattooing is performed.

(9) “Temporary establishment” means any location, place, area, or structure where tattooing is performed during, and in conjunction with, a convention or other similar event that does not exceed 14 consecutive days.

381.00773 Application of ss. 381.00771-381.00791; exemption.—

(1) Except for s. 381.00787, which applies to all persons, ss. 381.00771-381.00791 do not apply to a person licensed to practice medicine or dentistry under chapter 458, chapter 459, or chapter 466 who performs tattooing exclusively for medical or dental purposes.

(2) Sections 381.00771-381.00791 apply exclusively to the tattooing of human beings and do not apply to the tattooing of any animal.

History.—s. 2, ch. 2010-220.

381.00775 Tattoo artists; licensure; registration of guest tattoo artists.—

(1) Except as provided in s. 381.00773, a person may not tattoo the body of any human being in this state unless the person is licensed as a tattoo artist or registered as a guest tattoo artist under this section.

(2)(a) A person seeking licensure as a tattoo artist must apply to the department in the format prescribed by the department. An application must include:

1. The name and residence address of the applicant.
2. The name and street address of each tattoo establishment and temporary establishment at which the applicant intends to practice tattooing in this state.

(b) The department shall issue a license to an applicant who:

1. Is 18 years of age or older.
2. Submits a completed application.
3. Pays the applicable license fee established in s. 381.00781.
4. Submits proof of successful completion of an education course approved by the department on blood-borne pathogens and communicable diseases.

5. Submits proof of passage of an examination approved by the department on the material presented in the education course.

(c) The department shall approve one or more education courses and examinations that allows a person to complete the requirements of subparagraphs (b)4. and 5. in person or through an Internet website.

(d) A tattoo artist must, within 30 days after a change, notify the department of any change in the following information disclosed in his or her most recent application for issuance or renewal of his or her tattoo artist license in the format prescribed by the department:

1. The name and residence address of the tattoo artist.
2. The name and street address of each tattoo establishment in this state at which the tattoo artist has practiced tattooing for more than 14 days since the most recent renewal of his or her tattoo artist license or, if the license has not been renewed, since the license was issued.

(3)(a) A person seeking registration as a guest tattoo artist must apply to the department in the format prescribed by the department. An application must include:

1. The name and residence address of the applicant.
2. The name and street address of each tattoo establishment and temporary establishment at which the applicant will practice under the guest tattoo artist registration.

(b) The department shall issue a guest tattoo artist registration to an applicant who:

1. Is 18 years of age or older.
2. Submits a completed application.
3. Pays the applicable registration fee established in s. 381.00781.
4. Holds an active license, registration, or certification issued by a jurisdiction outside this state, whether by another state, the District of Columbia, any possession or territory of the United States, or any foreign jurisdiction, if:
 - a. The education and examination requirements of the license, registration, or certification substantially meet or exceed the requirements of subparagraphs (2)(b)4. and 5.; or
 - b. The applicant submits proof of successful completion of an education course approved by the department under subparagraph (2)(b)4. and proof of passage of an examination approved by the department under subparagraph (2)(b)5.

(4)(a) A tattoo artist license is valid for 1 year and must be renewed annually.

(b) A guest tattoo artist registration is valid for 14 days. A guest tattoo artist may apply for reregistration before or after expiration of his or her current registration.

(5) A license or registration issued by the department under this section is not transferable.

381.00777 Tattoo establishments; licensure; temporary establishments.—

(1)(a) Except as provided in s. 381.00773, a person may not tattoo the body of any human being in this state except at a tattoo establishment or temporary establishment licensed under this section.

(b) A person may not operate a tattoo establishment or temporary establishment in this state unless the establishment is licensed under this section.

(2) A person seeking licensure of a tattoo establishment must apply to the department in the format prescribed by the department. An application must include:

(a) The registered business name, including any fictitious names under which the tattoo establishment conducts business in the state.

(b) The street address and telephone number of the tattoo establishment.

(c) The name, mailing address, and telephone number of the tattoo establishment's operator.

(d) The name and address of the tattoo establishment's registered agent for service of process in the state.

(3) The department shall issue a tattoo establishment license to an applicant, if:

(a) The applicant submits a completed application.

(b) The applicant pays the applicable license fee established in s. 381.00781.

(c) The establishment complies with all applicable local building, occupational, zoning, and health codes.

(4) A temporary establishment must meet the same requirements for licensure as a permanent tattoo establishment.

(5)(a) A license is valid only for the location listed on the license. A tattoo establishment must notify the department in the format prescribed by the department before any change of the licensed location. A tattoo establishment with more than one location must obtain a separate license for each location.

(b) A tattoo establishment license is valid for 1 year and must be renewed annually.

(c) A temporary establishment license is valid for the duration of a convention or other similar event for which the license is issued not to exceed 14 consecutive days.

(6) A license issued by the department under this section is not transferable.

381.00779 Practice requirements.—

(1) A tattoo establishment or temporary establishment must:

- (a) Display an active license for the establishment in a manner that is easily visible to the public at all times while tattooing is performed at the establishment.
- (b) Ensure that each tattoo artist and guest tattoo artist, while practicing tattooing at the establishment, meets all applicable requirements of ss. 381.00771-381.00791.
- (c) Maintain sanitary conditions of the establishment at all times.
- (d) Comply with all state and local health codes and ordinances.
- (e) Allow the department to inspect the establishment pursuant to subsection (4).
- (f) Comply with s. 381.0098 and rules adopted under that section.

(2) A tattoo artist or guest tattoo artist must:

- (a) Display his or her active license in a manner that is easily visible to the public at all times while practicing tattooing.
- (b) Practice tattooing exclusively at an establishment licensed under ss. 381.00771-381.00791.

(c) Maintain sanitary conditions of the establishment at all times.

(d) Comply with all state and local health codes and ordinances.

(3) A tattoo artist or guest tattoo artist may tattoo the body of a minor child only to the extent authorized in s. 381.00787. A tattoo establishment or temporary establishment must keep, for the period prescribed by the department, each written notarized consent submitted under s. 381.00787(2)(c) by the parent or legal guardian of a minor child who is tattooed at the establishment.

(4) The department may inspect and investigate each tattoo establishment and temporary establishment as necessary to ensure compliance with ss.

381.00771-381.00791. However, the department shall inspect each tattoo establishment at least annually and shall inspect each temporary establishment before and, as necessary, during a convention or similar event with which the establishment is connected.

381.00781 Fees; disposition.—

The department shall establish by rule the following fees:

- (1) For the initial licensure of a tattoo establishment and the renewal of such license, a fee not to exceed \$250 per year.
- (2) For licensure of a temporary establishment, a fee not to exceed \$250.

- (3) For the initial licensure of a tattoo artist and the renewal of such license, a fee not to exceed \$150 per year.
- (4) For registration or reregistration of a guest tattoo artist, a fee not to exceed \$45.
- (5) For reactivation of an inactive tattoo establishment license or tattoo artist license. A license becomes inactive if it is not renewed before the expiration of the current license.

381.00783 Grounds for discipline; administrative penalties.—

(1) The following acts constitute grounds for which disciplinary action specified in subsection (2) may be taken by the department against any tattoo establishment, temporary establishment, tattoo artist, guest tattoo artist, operator of a tattoo establishment, or unlicensed person engaged in activities regulated under ss.

381.00771-381.00791:

- (a) Providing false information on an application for licensure or registration.
- (b) Violating a state or local health code or ordinance.
- (c) Violating any provision of ss. 381.00771-381.00791, rule adopted under those sections, or lawful order of the department.
- (d) Being found guilty of or pleading nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of tattooing or the operation of a tattoo establishment or temporary establishment.
- (e) Committing fraud, deceit, negligence, or misconduct in the practice of tattooing or the operation of a tattoo establishment or temporary establishment.
- (f) Aiding, procuring, or assisting a person to unlawfully practice tattooing or unlawfully operate a tattoo establishment or temporary establishment.
- (g) Failing to keep the written notarized consent of the parent or legal guardian of a minor child who is tattooed at a tattoo establishment or temporary establishment for the period specified pursuant to s. 381.00779(3) or knowingly making false entries in a parent's or legal guardian's written notarized consent.

(2) When the department determines that a person commits any of the acts set forth in subsection (1), the department may enter an order imposing one or more of the following penalties:

- (a) Refusal to issue a license or registration or renew a license.
- (b) Suspension or revocation of a license or registration.
- (c) Imposition of an administrative fine not to exceed \$1,500 for each count or separate violation.
- (d) Issuance of a reprimand.
- (e) Placement of the licensee or registrant on probation for a specified period and subject to the conditions that the department may specify.

- (f) Issuance of a stop-use order.
- (g) Corrective action.
- (3) The department shall impose stricter penalties for the repetition of violations and as the severity of violations escalate, distinguishing lesser violations from those that endanger the public health.
- (4) Disciplinary proceedings shall be conducted as provided in chapter 120.

381.00785 Criminal penalties.—

- (1) A person may not:
 - (a) Operate a tattoo establishment or temporary establishment in this state without a license.
 - (b) Practice tattooing in this state without a tattoo artist license or guest tattoo artist registration, except as provided in s. 381.00773.
 - (c) Practice tattooing in this state at any place other than a tattoo establishment or temporary establishment, except as provided in s. 381.00773.
 - (d) Obtain or attempt to obtain a license or registration by means of fraud, misrepresentation, or concealment.
- (2) A person who violates this section commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

381.00787 Tattooing prohibited; penalty.—

- (1) A person may not tattoo the body of a minor child younger than 16 years of age unless the tattooing is performed for medical or dental purposes by a person licensed to practice medicine or dentistry under chapter 458, chapter 459, or chapter 466.
- (2) A person may not tattoo the body of a minor child who is at least 16 years of age, but younger than 18 years of age, unless:
 - (a) The minor child is accompanied by his or her parent or legal guardian;
 - (b) The minor child and his or her parent or legal guardian each submit proof of his or her identity by producing a government-issued photo identification;
 - (c) The parent or legal guardian submits his or her written notarized consent in the format prescribed by the department;
 - (d) The parent or legal guardian submits proof that he or she is the parent or legal guardian of the minor child; and
 - (e) The tattooing is performed by a tattoo artist or guest tattoo artist licensed under ss. 381.00771-381.00791 or a person licensed to practice medicine or dentistry under chapter 458, chapter 459, or chapter 466.

(3) A person who violates this section commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. However, a person who tattoos the body of a minor child younger than 18 years of age does not violate this section, if:

(a) The person carefully inspects what appears to be a government-issued photo identification that represents that the minor child is 18 years of age or older.

(b) The minor child falsely represents himself or herself as being 18 years of age or older and presents a fraudulent identification.

(c) A reasonable person of average intelligence would believe that the minor child is 18 years of age or older and that the photo identification is genuine, was issued to the minor child, and truthfully represents the minor child's age.

381.00789 Rulemaking.—

The department shall adopt rules to administer ss. 381.00771-381.00791. Such rules may include, but are not limited to, rules defining terms; prescribing educational requirements for tattoo artists and guest tattoo artists, health and safety requirements, sanitation practices, and sterilization requirements and procedures; and providing requirements for tattoo equipment, customer notification, the contents of customer records, the retention of records, and physical plants. The department shall consult with representatives of the tattooing industry in this state during the development of such rules.

History.—s. 10, ch. 2010-220.

381.00791 Local laws and ordinances.—

Sections 381.00771-381.00791 do not preempt any local law or ordinance of a county or municipality that imposes regulations on tattoo establishments, temporary establishments, tattoo artists, or the practice of tattooing which are in addition to those sections.

381.0098 Biomedical waste.—

(1) **LEGISLATIVE INTENT.**—Except as otherwise provided herein, the Department of Health shall regulate the packaging, transport, storage, and treatment of biomedical waste. The Department of Environmental Protection shall regulate onsite and offsite incineration and disposal of biomedical waste. Consistent with the foregoing, the Department of Health shall have the exclusive authority to establish treatment efficacy standards for biomedical waste and the Department of Environmental Protection shall

have the exclusive authority to establish statewide standards relating to environmental impacts, if any, of treatment and disposal including, but not limited to, water discharges and air emissions. An interagency agreement between the Department of Environmental Protection and the Department of Health shall be developed to ensure maximum efficiency in coordinating, administering, and regulating biomedical wastes.

(2) DEFINITIONS.—As used in this section, the term:

(a) “Biomedical waste” means any solid or liquid waste which may present a threat of infection to humans. The term includes, but is not limited to, nonliquid human tissue and body parts; laboratory and veterinary waste which contains human-disease-causing agents; discarded disposable sharps; human blood, blood products, and body fluids; and other materials which in the opinion of the department represent a significant risk of infection to persons outside the generating facility. The term does not include human remains that are disposed of by persons licensed under chapter 497.

(b) “Biomedical waste generator” means a facility or person that produces or generates biomedical waste. The term includes, but is not limited to, hospitals, skilled nursing or convalescent hospitals, intermediate care facilities, clinics, dialysis clinics, dental offices, health maintenance organizations, surgical clinics, medical buildings, physicians’ offices, laboratories, veterinary clinics, and funeral homes where embalming procedures are performed.

(c) “Department” means the Department of Health.

(d) “Sharps” mean those biomedical wastes which as a result of their physical characteristics are capable of puncturing, lacerating, or otherwise breaking the skin when handled.

(e) “Treatment” means any process, including steam treatment, chemical treatment, and microwave shredding, which changes the character or composition of biomedical waste so as to render it noninfectious. For the purposes of this section, treatment does not include the incineration of biomedical waste.

(3) OPERATING STANDARDS.—The department shall adopt rules necessary to protect the health, safety, and welfare of the public and to carry out the purpose of this section. Such rules shall address, but need not be limited to, definitions of terms, the packaging of biomedical waste, including specific requirements for the segregation of the waste at the point of generation; the safe packaging of sharps; the placement of the waste in containers that will protect waste handlers and the public from exposure; the appropriate labeling of containers of waste; written operating plans for managing biomedical waste; and the transport, storage, and treatment of biomedical wastes.

(4) PERMITS AND FEES.—

(a) All persons who generate, store, or treat biomedical waste shall obtain a permit from the department prior to commencing operation, except that a biomedical waste

generator generating less than 25 pounds of biomedical waste in each 30-day period shall be exempt from the registration and fee requirements of this subsection. A biomedical waste generator need not obtain a separate permit if such generator works less than 6 hours in a 7-day period at a location different than the location specified on the permit. The department may issue combined permits for generation, storage, and treatment as appropriate to streamline permitting procedures. Application for such permit shall be made on an application form provided by the department and within the timeframes and in the manner prescribed by department rule.

(b) Once the department determines that the person generating, storing, or treating biomedical waste is capable of constructing a facility or operating in compliance with this section and the rules adopted under this section, the department shall grant the permit.

(c) If the department determines that the person generating, storing, or treating biomedical waste does not meet the provisions outlined in this section or the rules adopted under this section, the department shall deny the application for the permit pursuant to provisions of chapter 120. Such denial shall be in writing and shall list the circumstances for denial. Upon correction of such circumstances, the permit shall be issued.

(d) The permit for a biomedical waste facility may not be transferred. When the ownership, control, or name of a biomedical waste facility is changed and continues to operate, the new owner shall apply to the department, upon forms provided by the department, for issuance of a permit in the timeframe and manner prescribed by rule of the department.

(e) The department shall establish a schedule of fees for such permits. Fees assessed under this section shall be in an amount sufficient to meet the costs of carrying out the provisions of this section and rules adopted under this section. The fee schedule shall not be less than \$50 or more than \$400 for each year the permit is valid. Fees may be prorated on a quarterly basis when a facility will be in operation for 6 months or less before the annual renewal date. The department shall assess the minimum fees provided in this subsection until a fee schedule is adopted by rule of the department. Facilities owned and operated by the state shall be exempt from the payment of any fees.

(f) Fees collected by the department in accordance with provisions of this section and the rules adopted under this section shall be deposited into a trust fund administered by the department for the payment of costs incurred in the administration of this section.

(g) Permits issued by the department shall be valid for no more than 5 years. However, upon expiration, a new permit may be issued by the department in accordance with this section and the rules of the department.

(h) The department may develop a streamlined process for permitting biomedical waste storage facilities that accept and store only sharps collected from the public, which may include the issuance of a single permit for each applicant that develops or sponsors a sharps collection program.

(5) TRANSPORTERS.—Any person who transports biomedical waste within the state must register with the department prior to engaging in the transport of biomedical waste in accordance with rules adopted by the department. A registration may not be transferred from one biomedical waste transporter to another. If the ownership or name of a biomedical waste transporter is changed and the owner intends to continue operation of the transporter, the owner must apply to the department on departmental forms within the timeframes and in the manner prescribed by department rule. The department may charge registration fees in the same manner as is provided in paragraphs (4)(e) and (f). The department may exempt from this requirement any person who, or facility that, transports less than 25 pounds of such waste on any single occasion.

(6) TRACKING SYSTEM.—The department shall adopt rules for a system of tracking biomedical waste.

(a) Such system shall, at a minimum, provide for tracking of the transportation of the waste from the generator to the treatment or incineration facility, including a means for providing the generator of the waste assurance that the waste is received by the treatment or incineration facility, and shall include the identification of the entity transporting the waste on the container.

(b) Inspections may be conducted for purposes of compliance with this section. Any such inspection shall be commenced and completed with reasonable promptness. If the officer, employee, or representative of the department obtains any samples, prior to leaving the premises he or she shall give the owner, operator, or agent in charge a receipt describing the sample obtained.

(c) Any person who fails to comply with the provisions of this subsection commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(7) ENFORCEMENT AND PENALTIES.—Any person or public body in violation of this section or rules adopted under this section is subject to penalties provided in ss. 381.0012 and 381.0061. However, an administrative fine not to exceed \$2,500 may be imposed for each day such person or public body is in violation of this section. The department may deny, suspend, or revoke any biomedical waste permit or registration if the permittee violates this section, any rule adopted under this section, or any lawful order of the department.

(8) PREEMPTION OF AUTHORITY TO REGULATE.—The regulation and inspection of biomedical waste generators is hereby preempted by the state. Nothing in this chapter

shall be construed to affect a local government's zoning and land use authority over biomedical waste generators. Acute care hospitals, licensed under chapter 395, which utilize a certified onsite treatment process involving grinding and treatment, may dispose of such treated biomedical waste in the normal municipal solid waste stream upon notifying the local governments that are responsible for solid waste collection and disposal.

Florida Administrative Code

64E-16

64E-16.001 General.

(1) This chapter prescribes minimum sanitary practices relating to the management of biomedical waste, including segregation, handling, labeling, storage, transport, and treatment. This chapter applies to all facilities that generate, transport, store, or treat biomedical waste to ensure that the waste is properly handled to protect public health. Further, this chapter prescribes minimum standards for permitting biomedical waste generators, storage facilities and treatment facilities, and for registering biomedical waste transporters.

(2) This chapter does not apply to biomedical waste incinerators. This chapter does not apply to linen incinerators. This chapter does not apply to linen that is to be laundered and re-used. Further, this chapter does not apply to dead bodies that are disposed of by a person licensed under the provisions of Chapter 470, F.S., or to the transport of bodies, parts of bodies, or tissue specimens in furtherance of lawful examination, investigation, or autopsy conducted pursuant to Section 406.11, F.S. Specimens or samples collected for laboratory testing or use in medical research or teaching are not considered biomedical waste until such time as the material is discarded.

(3) The Department of Health shall regulate the packaging, transport, storage, and treatment of biomedical waste. The Department of Environmental Protection shall regulate biomedical waste incineration and biomedical waste disposal.

(4) Health care providers shall inform their home user clients verbally and in writing of the recommended method for handling biomedical waste generated in the home setting. Health care providers who deliver in-home medical services shall remove or have removed by a registered biomedical waste transporter all biomedical waste generated during the performance of these services.

(5) Home users should segregate and package their biomedical waste in a manner that reduces the chance of exposure to the public.

(6) Inspections, permitting and enforcement of emergency medical services that generate biomedical waste shall be performed by the Bureau of Emergency Medical Services.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098 FS. History—New 6-19-89, Amended 12-14-92, 1-23-94, 6-3-97, Formerly 10D-104.001.

64E-16.002 Definitions.

For the purpose of this chapter, the following words and phrases shall have the meanings indicated:

(1) American Society for Testing Materials, also referred to as ASTM – A technical society with headquarters located at 100 Barr Harbor Drive, West Conshohocken, Pennsylvania 19428-2959, which publishes national standards for the testing and quality assurance of materials.

(2) Biomedical waste – Any solid or liquid waste which may present a threat of infection to humans, including nonliquid tissue, body parts, blood, blood products, and body fluids from humans and other primates; laboratory and veterinary wastes which contain human disease-causing agents; and discarded sharps. The following are also included:

(a) Used, absorbent materials saturated with blood, blood products, body fluids, or excretions or secretions contaminated with visible blood; and absorbent materials saturated with blood or blood products that have dried.

(b) Non-absorbent, disposable devices that have been contaminated with blood, body fluids or, secretions or excretions visibly contaminated with blood, but have not been treated by an approved method.

(3) Biomedical waste generator – A facility or person that produces biomedical waste. The term includes hospitals, skilled nursing or convalescent hospitals, intermediate care facilities, clinics, dialysis clinics, dental offices, health maintenance organizations, surgical clinics, medical buildings, physicians' offices, laboratories, veterinary clinics and funeral homes.

(a) Mobile health care units, such as bloodmobiles, that are part of a stationary biomedical waste generator, are not considered individual biomedical waste generators.

(b) Funeral homes that do not practice embalming are not considered biomedical waste generators.

(4) Body fluids – Those fluids which have the potential to harbor pathogens, such as human immunodeficiency virus and hepatitis B virus and include blood, blood products, lymph, semen, vaginal secretions, cerebrospinal, synovial, pleural, peritoneal,

pericardial and amniotic fluids. In instances where identification of the fluid cannot be made, it shall be considered to be a regulated body fluid. Body excretions such as feces and secretions such as nasal discharges, saliva, sputum, sweat, tears, urine, and vomitus shall not be considered biomedical waste unless visibly contaminated with blood.

(5) Contaminated – Soiled by any biomedical waste.

(6) Decontamination – The process of removing pathogenic microorganisms from objects or surfaces, thereby rendering them safe for handling.

(7) Department – The Department of Health or its representative county health department.

(8) Disinfection – A process which results in a minimum Log 6 kill against the vegetative organisms listed in Table 1, and a minimum Log 4 kill against *Bacillus stearothermophilus* spores utilizing steam or a minimum Log 4 kill against *Bacillus Subtilis* spores utilizing dry heat, chemicals, or microwave shredding.

(9) Facility – All contiguous land, structures, and other appurtenances which are owned, operated, and licensed as a single entity which may consist of several generating, treatment, or storage units.

(10) Hazardous waste – Those materials defined in Chapter 62-730, F.A.C.

(11) Health Care Provider – Any person who provides medical care or personal services, as that term is defined in Section 400.402, F.S., to another individual.

(12) Home User – An individual who generates biomedical waste as a result of self-care or care by a family member or other non health care provider.

(13) Leak resistant – Prevents liquid from escaping to the environment in the upright position.

(14) Outer container – Any rigid type container used to enclose packages of biomedical waste.

(15) Packages – Any material that completely envelops biomedical waste. This includes red bags, sharps containers and outer containers.

(16) Person – Any individual, partnership, corporation, association, or public body engaged in the generation, storage, transport, or treatment of biomedical waste.

(17) Point of origin – The room or area where the biomedical waste is generated.

(18) Public sharps collection program – A cooperative program designed as a non-profit community service to assist the home user in the safe disposal of discarded sharps.

(19) Puncture resistant – Able to withstand punctures from contained sharps during normal usage and handling.

(20) Restricted – The use of any measure, such as a lock, sign, or location, to prevent unauthorized entry.

(21) Saturated – Soaked to capacity.

- (22) Sealed – Free from openings that allow the passage of liquids.
- (23) Sharps – Objects capable of puncturing, lacerating, or otherwise penetrating the skin.
- (24) Sharps container – A rigid, leak and puncture resistant container, designed primarily for the containment of sharps, clearly labeled with the phrase and international biological hazard symbol as described in Section 64E-16.004(2)(a), F.A.C., and manufactured with dyes meeting the requirements for incidental metals as described in Section 64E-16.004(2)(b)1.b., F.A.C.
- (25) Sterilization – A process which results in a minimum Log 6 kill against *Bacillus stearothermophilus* spores utilizing steam or a minimum Log 6 kill against *Bacillus Subtilis* spores utilizing dry heat, chemicals, or microwave shredding.
- (26) Storage – The holding of packaged biomedical waste for a period longer than three days at a facility or in a transport vehicle.
- (27) Transfer – The movement of biomedical waste within a facility.
- (28) Transport – The movement of biomedical waste away from a facility.
- (29) Transport vehicle – A motor vehicle, as defined in Section 320.01, F.S., a rail car, watercraft or aircraft, used for the transportation of biomedical waste.
- (30) Treatment – Any process, including steam, chemicals, microwave shredding, or incineration, which changes the character or composition of biomedical waste to render it noninfectious by disinfection or sterilization.
- Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098, 395.002(13), 395.1011 FS. History–New 6-19-89, Amended 4-2-90, 12-14-92, 1-23-94, 8-20-95, 6-3-97, Formerly 10D-104.002.

64E-16.003 Facility Policies and Procedures.

- (1) All biomedical waste facilities shall comply with the following:
- (a) Biomedical waste mixed with hazardous waste, as defined in Chapter 62-730, F.A.C., Hazardous Waste, shall be managed as hazardous waste.
- (b) Biomedical waste mixed with radioactive waste shall be managed in a manner that does not violate the provisions of Chapter 64E-5, F.A.C. The biomedical waste shall be managed in accordance with the provisions of Chapter 64E-16, F.A.C., after the radioactive component has decayed in storage as provided for in Chapter 64E-5, F.A.C., or is otherwise not regulated under Chapter 64E-5, F.A.C. The packaging requirements of Chapter 64E-5, F.A.C., shall be followed, unless the requirements of Chapter 64E-16, F.A.C., are more restrictive.

(c) Any other solid waste or liquid, which is neither hazardous nor radioactive in character, combined with untreated biomedical waste, shall be managed as untreated biomedical waste.

(d) All surfaces contaminated with spilled or leaked biomedical waste shall be decontaminated as part of the cleaning process.

(2) Each biomedical waste facility shall implement a written operating plan to manage biomedical waste, in accordance with this chapter. This plan shall be available for review by the department and facility personnel. The plan shall include the following: a description of training for personnel; procedures for segregating, labeling, packaging, transporting, storing, and treating, biomedical waste; procedures for decontaminating biomedical waste spills; and a contingency plan for emergencies. Facilities which have multiple specialty services shall include procedures specific to each specialty if procedures vary. Plans shall be updated when regulations, facility policies, or procedures change.

(a) Each facility or their designee shall train new personnel who handle biomedical waste as part of their work responsibilities. This training shall be provided prior to commencement of duties related to biomedical waste handling. Refresher training shall be completed annually by all personnel who handle biomedical waste. Training shall detail compliance with the facility's operating plan and Chapter 64E-16, F.A.C., and shall be maintained as a part of the operating plan.

(b) All biomedical waste management records shall be maintained for 3 years and shall be available for review by the department.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098, 395.002(13), 395.1011 FS. History—New 6-19-89, Amended 4-2-90, 12-14-92, 1-23-94, 8-20-95, 6-3-97, Formerly 10D-104.003.

64E-16.004 Storage and Containment.

(1) Storage.

(a) Storage of biomedical waste at the generating facility shall not exceed 30 days. The 30 day period shall commence when the first non-sharps item of biomedical waste is placed into a red bag or sharps container, or when a sharps container containing only sharps is sealed.

(b) Storage of biomedical waste in a place other than at the generating facility shall not exceed 30 days. The 30 day storage period shall begin on the day the waste is collected from the generator.

(c) Indoor storage areas shall have restricted access and be designated in the written operating plan. They shall be located away from pedestrian traffic, be vermin and insect

free, and shall be maintained in a sanitary condition. They shall be constructed of smooth, easily cleanable materials that are impervious to liquids.

(d) Outdoor storage areas, including containers and trailers, shall, in addition to the above criteria, be conspicuously marked with the international biological hazard symbol as described in paragraph 64E-16.004(2)(b), F.A.C., and shall be secured against vandalism and unauthorized entry. The international biological hazard symbol on an outdoor storage area shall be a minimum of six inches in diameter.

(2) Containment.

(a) Packages of biomedical waste shall remain sealed until treatment, except when compacted in accordance with the requirements of this chapter as stated in Section 64E-16.006(2), F.A.C. Ruptured or leaking packages of biomedical waste shall be placed into larger packaging without disturbing the original seal.

(b) All packages containing biomedical waste shall be visibly identifiable with the international biological hazard symbol and one of the following phrases: "BIOMEDICAL WASTE", "BIOHAZARDOUS WASTE", "BIOHAZARD", "INFECTIOUS WASTE", or "INFECTIOUS SUBSTANCE". The symbol shall be red, orange, or black and the background color shall contrast with that of the symbol or comply with the requirements cited in subpart Z of 29 C.F.R. subparagraph 1910.1030(g)(1)(C), Occupational Exposure to Bloodborne Pathogen Standard.

(c) Bags.

1. Biomedical waste, except sharps, shall be packaged and sealed at the point of origin in impermeable, red plastic bags or, at the discretion of the generator, into sharps containers. The international biological hazard symbol shall be at least six inches in diameter on bags 19" x 14" or larger, and at least one inch in diameter on bags smaller than 19" x 14". Each plastic bag shall meet the following physical properties:

a. Impact resistance of 165 grams and tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag. Impact resistance shall be determined using ASTM D-1709-91, and tearing resistance shall be determined using ASTM D-1922-89.

b. Incidental sum concentrations of lead, mercury, hexavalent chromium and cadmium shall be no greater than 100 ppm for dyes used in the coloration of bags.

(d) Sharps containers.

1. Sharps shall be discarded at the point of origin into single use or reusable sharps containers. Needles and scalpel blades shall not be placed directly into double-walled corrugated containers. Sharps containers must be sealed when full. A sharps container is considered full when materials placed into it reach the designated fill line, or, if a fill

line is not indicated, when additional materials cannot be placed into the container without cramming or when no additional materials are to be placed in the container.

2. Permanently mounted sharps container holders shall bear the phrase and the international biological hazard symbol described in paragraph 64E-16.004(2)(a), F.A.C., if this information on the sharps container is concealed by the sharps container holder.

3. Reusable sharps containers shall only be emptied into a treatment cart or directly into a treatment unit. They shall be constructed of smooth, easily cleanable materials, and shall be decontaminated after each use.

4. The international biological hazard symbol shall be at least one inch in diameter on sharps containers.

(e) All outer containers shall be rigid, leak-resistant and puncture-resistant. Reusable outer containers shall be constructed of smooth, easily cleanable materials and shall be decontaminated after each use.

(f) The international biological hazard symbol shall be at least six inches in diameter on outer containers 19" x 14" or larger, and at least one inch in diameter on outer containers less than 19" x 14".

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098, 395.002(13), 395.1011 FS. History—New 6-19-89, Amended 4-2-90, 12-14-92, 1-23-94, 8-20-95, 6-4-97, Formerly 10D-104.004.

64E-16.005 Labeling.

(1) Biomedical waste bags and sharps containers shall be labeled with the generator's name and address unless treatment occurs at the generating facility.

(a) If a bag or sharps container is placed into a larger bag prior to transport, the label for the exterior bag shall comply with subsection 64E-16.005(1), F.A.C. Inner bags and inner sharps containers are exempt from the labeling requirements of subsection 64E-16.005(1), F.A.C.

(b) Outer containers shall be labeled with the transporter's name, address, registration number, and 24-hour telephone number prior to transport.

(2) The transporter may provide labels for bags or sharps containers that are generator-specific, such as bar codes or specific container numbers. Use of these generator-specific labels satisfies the requirements of paragraph 64E-16.005(1)(a), F.A.C.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098, 395.002(13), 395.1011 FS. History—New 6-19-89, Amended 4-2-90, 12-14-92, 1-23-94, 8-20-95, 6-3-97, Formerly 10D-104.005.

64E-16.006 Generator Requirements.

(1) A biomedical waste generator shall not negotiate for the transport of biomedical waste with a person who is not registered with the department as a biomedical waste transporter.

(2) Compacting packages of biomedical waste within the generating facility, except recognizable human tissue, bulk liquids, or sharps, is acceptable provided the following conditions are met:

(a) Packages of biomedical waste shall not be compacted to a density greater than 22 pounds per cubic foot.

(b) Compacted packages of biomedical waste shall not be subjected to further compacting.

(c) Any residual or incidental liquid shall be contained within the inner bag or outer container. Should the inner bag or outer container rupture during compaction, residual or incidental liquids shall be disposed of directly into the sanitary sewer, an on-site sewage treatment and disposal system, or other system approved to receive such wastes by the Department of Environmental Protection or the department;

(d) Discharge of noxious air shall be kept to a minimum through use of HEPA filters having a pore size of 2 microns or less, negative pressure rooms, or other safety methods;

(e) Compacted packages of biomedical waste shall be treated by incineration or other approved treatment process. Treatment processes, such as steam, chemical, gas, dry heat, or microwaving, shall be considered by the department upon written request and microbiological evidence that the proposed process provides the same degree of treatment for compacted waste as for uncompacted waste. Steam treatment systems shall be tested against *Bacillus stearothermophilus* spores, as described in subsection 64E-16.007(2), F.A.C. Other proposed treatment processes shall demonstrate efficacy using subsection 64E-16.007(4), F.A.C.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098, 395.002(13), 395.1011 FS. History—New 6-19-89, Amended 4-2-90, 12-14-92, 1-23-94, 8-20-95, 6-3-97, Formerly 10D-104.006.

64E-16.007 Treatment.

(1) Biomedical waste shall be treated by steam, incineration, or an alternative process approved by the department as described in subsection 64E-16.007(4), F.A.C., prior to disposal. Treatment shall occur within 30 days of collection from the generator.

(2) Steam treatment units shall subject loads of biomedical waste to sufficient temperature, pressure, and time to demonstrate a minimum Log 4 kill of *Bacillus stearothermophilus* spores placed at the center of the waste load, and shall be operated in accordance with the following:

(a) Before placing a steam treatment unit into service, operating parameters such as temperature, pressure, and treatment time shall be determined according to the following:

1. Test loads of biomedical waste which consist of the maximum weight and density of biomedical waste to be treated shall be prepared. Separate loads of red bags, sharps containers, boxes, and compacted waste shall be prepared if they are to be treated separately.

2. Prior to treatment, *Bacillus stearothermophilus* spores shall be placed at the bottom and top of each treatment container, at the front of each treatment container at a depth of approximately one-half of the distance between the top and bottom of the load, in the approximate center of each treatment container, and in the rear of each treatment container at a depth of approximately one-half of the distance between the top and bottom of the load.

3. If the operating parameters used during the treatment of the test loads demonstrate a minimum Log 4 kill of *Bacillus stearothermophilus* spores at all locations, the steam treatment unit shall operate under those parameters when placed into service. If the operating parameters fail to provide a minimum Log 4 kill of *Bacillus stearothermophilus* spores at all locations, treatment time, temperature, or pressure shall be increased and the tests must be repeated until a minimum Log 4 kill of *Bacillus stearothermophilus* spores is demonstrated at all locations. The steam treatment unit shall be operated under those parameters when placed into service. Tests shall be repeated and new parameters established if the type of biomedical waste to be treated is changed.

(b) When operating parameters have been established and documented using the criteria in paragraph 64E-16.007(2)(a), F.A.C., the steam treatment unit may be placed into service.

(c) The steam treatment unit shall be serviced for preventive maintenance in accordance with the manufacturer's specifications. Records of maintenance shall be onsite and available for review.

(d) Unless a steam treatment unit is equipped to continuously monitor and record temperature and pressure during the entire length of each treatment cycle, each package of biomedical waste to be treated will have a temperature tape or equivalent test material such as a chemical indicator placed on a non-heat conducting probe at the center of each treatment container in the load that will indicate if the treatment temperature and pressure have been reached. Waste shall not be considered treated if

the tape or equivalent indicator fails to show that a temperature of at least 250 degrees F (121 degrees C) was reached during the process.

(e) Each steam treatment unit shall be evaluated for effectiveness with spores of *Bacillus stearothermophilus* at least once each 7 days for permitted treatment facilities, or once each 40 hours of operation for generators who treat their own biomedical waste. The spores shall be placed at the center of the waste load. Evaluation results shall be maintained onsite and available for review.

(f) A written log shall be maintained for each steam treatment unit. The following shall be recorded for each usage:

1. The date, time, and operator name,
2. The type and approximate amount of waste treated,
3. The post-treatment confirmation results by either:
 - a. recording the temperature, pressure, and length of time the waste was treated, or
 - b. the temperature and pressure monitoring indicator,

(g) A current written operating procedure shall specify, at a minimum, the following:

1. Parameters, determined from testing, that provide consistent treatment, such as exposure time, temperature, and pressure.
2. Identification of standard treatment containers and placement of the load in the steam treatment unit.

(3) Incineration of biomedical waste shall be achieved in a biological waste incinerator permitted by the Department of Environmental Protection.

(4) An alternative treatment process, such as chemical, gas, dry heat, or microwave shredding, shall be considered by the department upon receipt of a written request. The written request shall be directed to the State Health Officer and shall include:

- (a) The specific treatment process and type of facility for which acceptance is sought;
- (b) The reason for the request;

(c) Microbiological evidence, using the organisms listed in Table 1, that the proposed process provides sterilization or a satisfactory level of disinfection. Using the protocol described in subsection 64E-16.007(4), F.A.C., alternative treatment systems must show either:

1. For disinfection, a minimum Log 6 kill for the vegetative organisms listed in Table 1 and a minimum Log 4 kill against *Bacillus stearothermophilus* spores utilizing steam or a minimum Log 4 kill against *Bacillus Subtilis* spores utilizing dry heat, chemicals, or microwave shredding, or
2. For sterilization, a minimum Log 6 kill against *Bacillus stearothermophilus* spores utilizing steam or a minimum Log 6 kill against *Bacillus Subtilis* spores utilizing dry heat, chemicals, or microwave shredding.

Table 1

1. Bacteria

a. *Bacillus* spores – mandatory, species determined by treatment process

Any two

b. *Enterococcus faecalis*

c. *Pseudomonas aeruginosa*

d. *Staphylococcus aureus*

e. *Nocardia* species

2. *Mycobacteria* species – any one

a. *Mycobacterium bovis*

b. *Mycobacterium fortuitum*

3. Fungus – any one

a. *Candida albicans*

b. *Aspergillus fumigatus*

4. Protozoa – *Giardia intestinalis* or similar

5. Virus – Poliovirus or similar.

(d) Each step of the efficacy testing must be thoroughly described in the application for approval. A detailed description of the treatment process, preparation of organisms, preparation of test loads, recovery of organisms, and raw data must be provided.

(e) To begin the efficacy testing, two challenge loads must be sterilized. These loads must be composed of materials commonly found in biomedical waste (tissues, sharps, plastics, glass, woven materials, blood and blood products, etc.), and must be of adequate quantity to equal the maximum capacity of the treatment system. The test load must be fully described (weight, moisture content, composition, etc.).

(f) The purity of all organisms and spores must be certified by a clinical or commercial laboratory. Each organism must be processed separately and placed in the test load in the most difficult location to treat. Before each test run, the total number of viable test organisms must be determined and documented. Treatment of the test load must take place within thirty minutes of inoculating the load with the test organism.

(g) The test load containing the test organism must be processed without the agent (e.g., chemical, microwaves, etc.) used to kill the test organisms. If this agent is a liquid, it must be replaced with an equal amount of sterile saline solution or tapwater. After the test load has completed one cycle in the treatment device, a minimum of three grab samples must be taken from the test load and the number of test organisms present determined. If the number of organisms recovered after the test run is less than Log 6, the number of organisms originally introduced into the device must be increased, and the run must be performed again, until at least Log 6 organisms are recovered. If the number of organisms recovered from the test run is Log 6 or greater, there is an

adequate number of organisms being introduced into the device, and the inoculum size should be equal to this number.

(h) Using the inoculum size determined in the above procedure, the second sterilized test load must be inoculated separately. During these test runs, the chemical or physical agent used to treat the waste must be used.

(i) After each test run is completed, the log kill for that particular organism or spore must be calculated. The number of organisms that were not recovered from the initial (non-treating) test run must be subtracted from the number of organisms that were introduced into the second (treatment) run. The number of organisms that survive the treatment process must be subtracted from the first calculation. The resulting figure is the log kill provided by the treatment process.

(j) Approved alternative treatment processes, except single-use, shall meet the requirements of paragraph 64E-16.007(2)(e), F.A.C.

(5) Biomedical waste may be disposed into a sanitary sewer system, an onsite sewage treatment and disposal system, or other system approved to receive such waste by The Department of Environmental Protection or the department, if it is in a liquid or semi-solid form and aerosol formation is minimal.

(6) Body tissues that have been histologically fixed are considered treated biomedical waste. Tissues prepared by frozen sectioning only are not considered treated.

(7) Acute care hospitals, licensed under Chapter 395, F.S., which utilize a certified onsite treatment process involving grinding and treatment, may dispose of such treated biomedical waste in the normal municipal solid waste stream upon notifying the local government responsible for solid waste collection and disposal under the following conditions:

(a) For the purposes of this chapter, certified shall mean that the treatment process is steam treatment, or has been approved as an alternative biomedical waste treatment process under subsection 64E-16.007(4), F.A.C.

(b) For the purposes of this chapter, grinding shall also mean shredding or hammermilling.

(c) If grinding takes place prior to treatment, procedures that minimize the chance of exposure to waste handlers must be developed and implemented should the grinder fail or become jammed.

(d) Individuals operating the treatment unit must be trained in all aspects of its operation, including contingency procedures.

(e) Acute care hospitals must inform the department in writing of the installation of the unit at least 30 days prior to placing the unit into service.

(f) Inspection of the unit, including treatment and maintenance records, will occur during the annual inspection for the hospital's biomedical waste permit.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098, 395.002(13), 395.1011 FS. History--New 6-19-89, Amended 12-14-92, 1-23-94, 8-20-95, 6-3-97, Formerly 10D-104.007.

64E-16.008 Biomedical Waste Transport.

- (1) No registered transporter may knowingly accept biomedical waste for transport unless it has been properly segregated, packaged, and labeled.
- (2) Each registered transporter shall provide the generator with a receipt of pick-up.
- (3) During transport, no registered transporter shall compact biomedical waste or allow it to leak into the environment.
- (4) Transfer of biomedical waste from one transport vehicle to another is not allowed unless the transfer occurs at a permitted storage or treatment facility, except as provided in paragraph 64E-16.008(10)(a), F.A.C. Intermodal transfers of biomedical waste are allowed provided transport shipping seals remain intact.
- (5) Any registered transporter who unknowingly fails to comply with subsection (3) or (4), of this rule, because such biomedical waste has not been properly segregated or separated from other solid wastes by the generating facility is not guilty of a violation under this rule.
- (6) No registered transporter shall knowingly deliver biomedical waste for storage or treatment to a facility which does not have a valid permit issued by the department.
- (7) All transport vehicles containing biomedical waste shall be visibly identified with the business name, registration number, a 24 hour telephone number, and placards showing the phrase and the international biological hazard symbol as described in paragraph 64E-16.004(2)(a), F.A.C. The symbol shall be at least six inches in diameter.
- (8) All transport vehicles containing biomedical waste shall be fully enclosed and secured when unattended.
- (9) Registered transporters shall notify the department within one working day by telephone and shall submit a follow-up report to the department within 10 days, in writing, if there is an accident that results in a spill of biomedical waste.
- (10) In case of an emergency situation, including mechanical failure, the following is allowed:
 - (a) If the emergency occurs during transport, biomedical waste may be transferred to another transport vehicle, including a rental vehicle, without being at a storage or treatment facility.
 - (b) If a rental vehicle is used, the department shall be notified of its use on the first working day after the emergency. A copy of the written authorization from the rental

agency stating awareness of the intended use of the vehicle shall be submitted to the department within seven days.

(c) Biomedical waste shall be removed and transported to a permitted storage or treatment facility within 24 hours of the emergency.

(d) Before return to the rental agency, the vehicle shall be decontaminated.

Rulemaking Authority 381.0098 FS. Law Implemented 381.0098 FS. History—New 6-3-97, Formerly 10D-104.0073.

64E-16.009 Registration of Biomedical Waste Transporters.

(1) Biomedical waste transporters shall be registered with the department. Biomedical waste generators transporting less than 25 pounds of their own biomedical waste, in their own transport vehicle, on any single occasion, are exempt from transporter registration, fee, and placarding requirements of this chapter.

(2) Each owner or operator of a transport vehicle shall submit to the department a completed application for registration on form DH 4106, herein incorporated by reference.

(3) Biomedical waste transporter registrations shall expire on September 30 each year. Renewal applications will not be considered complete without the submission of an annual report on form DH 4109, herein incorporated by reference. Biomedical waste transporters with valid registrations, on the effective date of this chapter, shall renew their registration by September 30 following the expiration date of their existing registration.

(4) Registered transporters shall notify the department in writing within 30 days of any changes made to their registration form currently on file with the department.

(5) Any registered biomedical waste transporter is subject to having their biomedical waste transporter registration denied, suspended, or revoked, pursuant to Section 381.0098, F.S., and in accordance with the procedural requirements of Section 120.60, F.S., upon a finding by the department that the transporter:

(a) Has submitted false or inaccurate information in the application or annual report;

(b) Has violated the provisions of any statute or rule which the department is authorized to enforce;

(c) Has refused to allow inspection of records or equipment by department personnel.

Rulemaking Authority 381.0098 FS. Law Implemented 381.0098 FS. History—New 6-3-97, Formerly 10D-104.0074.

64E-16.010 Inspections.

(1) Department personnel shall inspect registered transport vehicles, permitted generators, storage, and treatment facilities at least once a year. Those facilities exempted from the registration and fee requirements under Section 381.0098(4), F.S., shall be inspected at least once every three years. Reinspections may be conducted when a facility is found to be in non-compliance with this chapter. Results of each inspection shall be recorded on a form provided by the department.

(2) To provide consistency of inspections throughout the state, all department personnel who inspect biomedical waste facilities shall attend training annually, which shall be approved by the Bureau of Environmental Health Programs.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098 FS. History—New 12-14-92, Amended 1-23-94, 8-20-95, 6-3-97, Formerly 10D-104.0075.

64E-16.011 Permits.

(1) All biomedical waste facilities, except those facilities operating under a Department of Environmental Protection permit, shall obtain a permit from the department annually. Application forms and annual report forms used by the public may be obtained from the environmental health section of the county health department in the county of their location or from the Department of Health, Bureau of Facility Programs, 4052 Bald Cypress Way, Bin #A08, Tallahassee, Florida 32399-1710. All forms listed in this section are incorporated by reference.

(a) A biomedical waste generator, who produces or treats less than 25 pounds of biomedical waste in each 30 day period, shall be exempt from all permit and fee requirements of this chapter.

(b) Application for an initial biomedical waste generator permit or exemption from permitting shall be submitted to the department on form DH 4089, Application for Biomedical Waste Generator Permit/Exemption, 8/98. Biomedical waste treatment facilities which were constructed prior to December 31, 1995, or for which an operation permit was submitted to the Department of Environmental Protection prior to December 31, 1995, shall meet the requirements of this chapter at the time of renewal of their existing permit.

(c) Application for an initial biomedical waste storage facility permit shall be submitted to the department on form DH 4107, Application for Biomedical Waste Storage Permit, 8/98.

(d) Application for an initial biomedical waste treatment facility permit shall be submitted to the department on form DH 4111, Application for a Biomedical Waste Treatment Permit, 8/01. Renewals will not be considered complete without the submission of an

annual report submitted on form DH 4110, Biomedical Waste Treatment Facility Annual Report, 8/01.

(e) Application for an initial biomedical waste sharps collection program permit shall be submitted to the department on form DH 4108, Application for Biomedical Waste Sharps Collection Program Permit, 8/98.

(f) Permits shall not be transferable from one person to another. In the event of an address or name change, an amended application for permit shall be submitted to the department. A permitted generator may work at a branch office for no more than six hours in any seven day period without applying for an additional permit. These generators must notify the local county health department biomedical waste coordinator of the existence and operating hours of the branch office.

1. In the event of a change of ownership of the facility or a newly constructed facility, an application for an initial permit shall be submitted to the department within 30 days of the commencement of business.

2. When a facility is leased by the owner to a second party for operation, the second party shall apply to the department for an initial permit within 30 days of the commencement of business. The second party shall be held responsible for the operation and maintenance of the facility.

(g) Permits shall expire on September 30 each year. The permit, or a copy thereof, shall be maintained within the facility and shall be made available for review by department personnel.

(2) Persons engaged in a sharps collection program with single or multiple facility locations may operate under a single permit provided:

(a) The sharps collection program is open to the general public;

(b) A list identifying the location of each facility is attached to the application; and,

(c) Each facility meets the applicable permit requirements.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098 FS. History—New 12-14-92, Amended 1-23-94, 6-3-97, Formerly 10D-104.0076, Amended 11-5-02.

64E-16.012 Fees.

(1) State-owned and operated biomedical waste facilities are exempt from the permit fee.

(2) Fee schedule.

Generator Permit:

Treatment Permit:

Storage Permit:

Transporter Registration (one vehicle):

No fee or combination of fees shall exceed the maximum amount established by the statute.

(3) All fees collected pursuant to this section shall be placed in a specially designated account within the individual county health department trust fund to be used to meet the cost of administering the biomedical waste program described in this chapter.

Rulemaking Authority 381.006, 381.0098(4) FS. Law Implemented 381.006, 381.0098 FS. History—New 12-14-92, Amended 1-23-94, 6-3-97, Formerly 10D-104.0078, Amended 1-12-09.

64E-16.013 Enforcement and Penalties.

Rulemaking Authority 381.006, 381.0098(5) FS. Law Implemented 381.0012, 381.002(13), 381.0025, 381.006, 381.0061, 381.0098, 395.1011, 775.082, 775.083 FS. History—New 6-19-89, Amended 12-14-92, 1-23-94, 6-3-97. Formerly 10D-104.008, Amended 11-5-02, Repealed 12-2-15.

64E-19

64E-19.001 General.

Rulemaking Authority 381.0075(10) FS. Law Implemented 381.0075, FS. History—New 1-24-00, Repealed 12-29-16.

64E-19.002 Definitions

(1) “Aftercare instructions” – means verbal and written instructions that the customer should follow to promote healing of the pierced area.

(2) “Antiseptic” – means an agent that inhibits the growth and multiplication of disease-causing microorganisms.

(3) “Aseptic techniques” – means methods used in piercing procedures to prevent contamination of a pierced area by pathogenic organisms.

- (4) "Body piercing area" – means the specific area within a salon where body-piercing procedures are conducted.
- (5) "Contaminated" – means the presence of microorganisms on inanimate objects.
- (6) "Department" – means the Department of Health and its representative county health departments.
- (7) "Formal training" – means a course of instruction that is presented under classroom conditions to detail compliance with the requirements of this chapter, including safety, sanitation, and sterilization requirements and standard precautions for preventing the transmission of infectious diseases.
- (8) "Equipment" – means all machinery, including fixtures, containers, vessels, tools, devices, implements, furniture, display and storage areas, sinks and all other apparatus and appurtenances used in connection with the operation of a body-piercing salon.
- (9) "Handsink" – means a lavatory equipped with hot and cold running water under pressure, used solely for washing hands, arms or other portions of the body.
- (10) "Hot water" – means water which attains and maintains a temperature of at least 100 degrees Fahrenheit.
- (11) "Injury" – means any unexpected complication, damage, harm, hurt, or impairment to a customer's body structure or function that is caused by a piercing and required the attention of a licensed practitioner.
- (12) "Instruments" – means hand pieces and other tools that may come in contact with a customer's body or be exposed to body fluids during body-piercing procedures.
- (13) "Licensed practitioner" means any physician, osteopathic physician, or dentist, licensed under Chapters 458, 459, and 466, F.S. The term also includes an Advanced Registered Nurse Practitioner or Certified Physician's Assistant who performs medical acts of diagnosis, treatment, and operation pursuant to a protocol between an ARNP or PA and a Florida-licensed physician, osteopathic physician or dentist.
- (14) "Minor" – means any person who has not attained the age of 18 years, except as provided in Sections 743.01 and 743.015, F.S.
- (15) "Oral piercing" – means a piercing in any portion of the mouth, including the tongue, lip and cheeks.
- (16) "Notifiable disease" – shall have the same meaning as Rule 64D-3.029, F.A.C.
- (17) "Piercer" – means any person who performs body-piercing procedures in an establishment regulated under this chapter.
- (18) "Procedure surface" – means any surface of an inanimate object or any associated work area that may require sanitizing, as specified in Section 381.0075(11), F.S.
- (19) "Sanitizer" – means a disinfectant or germicide registered with the United States Environmental Protection Agency.

(20) “Single use” – means products or items that are intended for one-time, one-person use and are disposed of after use on each customer such as, cotton swabs or balls, tissues or paper products, paper or plastic cups, gauze and sanitary coverings, razors, instruments that pierce the skin, and protective gloves.

(21) “Spore” – means a highly resistant dehydrated form of a bacterial cell, such as those of the genus *Bacillus*.

(22) “Standard precautions” – means a set of guidelines and controls, published by the Center for Disease Control and Prevention (CDC), which includes specific recommendations for the use of gloves, masks, protective eye wear and/or other protective equipment when contact with blood or body fluids containing blood is anticipated. These guidelines and controls may be found in “Recommendations for Prevention of HIV Transmission in Health-Care Settings”, Morbidity and Mortality Weekly Report (MMWR), August 21, 1987, Vol. 36, No. (SU02); 001; “Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings,” MMWR, June 24, 1988, Vol. 37, No. 24; “Guidelines for Prevention and Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public Safety Workers, MMWR, June 23, 1989, Vol. 38, No. S-6; and MMWR; and “Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures,” July 12, 1991, Vol. 40, No. (RR08); 1-9. These guidelines are hereby incorporated by reference into this chapter.”

Rulemaking Authority 381.0075(10) FS. Law Implemented 381.0075(10) FS. History—New 1-24-00, Amended 10-27-10.

64E-19.003 Forms.

(1) All forms listed in this section are incorporated by reference. Forms used by the public may be obtained from the county health department in the county of their location or the Department of Health, 4052 Bald Cypress Way, BIN A08, Tallahassee, Florida 32399-1710.

(a) DH Form 4124, 11/02, Body Piercing Salon Inspection Report.

(b) DH Form 4122, 9/02, Body Piercing Salon Injury Report.

(c) DH Form 4121, 11/02, Body Piercing Salon Citation of Violation.

(d) DH Form 4123, 10/99 Body Piercing Salon Stop Use Order.

(2) Upon receipt of a properly completed DH Form 4120, 10/99, Application for a Body Piercing Salon License, the department shall process the application in accordance with the provisions of Chapter 120.60, F.S., and agency procedures.

64E-19.004 Requirements for Premises.

(1) Structural, electrical, mechanical, ventilation, and plumbing components of buildings shall comply with local building and zoning codes. Walls, floors, ceilings, and equipment in all areas of a salon shall be maintained in a clean condition and in good repair.

(2) Walls, floors, and procedure surfaces of equipment in areas where body-piercing procedures are conducted, where equipment and instruments are cleaned, and in restrooms shall be smooth non-absorbent and washable; except that, wooden floors may be used in these areas provided they are, at a minimum, varnished or sealed with a commercial water repelling coating and maintained as such. After use by each customer, all procedure surfaces shall be cleaned and sanitized with a sanitizer that has a demonstrated tuberculocidal activity, as indicated by the product label.

(3) Effective measures shall be taken by the salon operator to protect against the entrance, breeding or presence of insects, vermin and rodents in a salon. Openings to the outside shall be protected by such means as self-closing doors, screened or closed windows or controlled air currents. Screening material shall not be less than 16 mesh to the inch.

(4) There shall be a minimum of forty-five (45) square feet of floor space in the body piercing area for each person performing body piercing in the salon. Each salon shall have an area that can be screened from public view for customers requesting privacy. Multiple body piercing stations shall be separated by such means as dividers, curtains or partitions that are cleanable.

(5) Each salon shall be provided with an artificial light source equivalent to a minimum of twenty (20) foot candles three (3) feet off the floor, except that at least one hundred (100) foot candles shall be provided at the level where the body piercing procedure is being performed, and where instruments and sharps are assembled. Spotlighting may be used to achieve the one hundred foot candle requirement.

(6) A handsink separate from handsinks in restrooms, liquid soap, and disposable single-use paper towels shall be readily accessible and located within each body piercing area or centrally located within the overall work room or area, so each piercing area has access to the handsink. One handsink shall serve no more than three body piercing personnel. Hot water at handsinks shall not exceed 120 degrees Fahrenheit.

(7) Restrooms shall be supplied with liquid soap, toilet tissue, single-use paper towels, and a waste receptacle.

(8) At least one waste receptacle shall be provided in each body piercing area. Solid waste shall be collected, stored, and disposed of in a manner and frequency that does not create a sanitary nuisance, as that term is defined in Chapter 386, F.S. Biomedical waste, as that term is defined in Section 381.0098(2)(a), F.S., shall be managed in accordance with Chapter 64E-16, F.A.C.

(9) Other equipment and supplies necessary for providing body-piercing services and for cleaning and sterilizing instruments shall be provided. This includes at least a separate one-compartment sink with hot and cold running water under pressure for cleaning instruments, an autoclave, instruments and single use supplies for performing piercings, work tables or counters, customer chairs, and storage cabinets or containers for storing clean and sterilized instruments and supplies. All surfaces of equipment shall be made of smooth, non-absorbent and non-porous material. Each one-compartment sink and autoclave must have an adequate size, depth or capacity to submerge or otherwise accommodate the instruments being cleaned or autoclaved. Salons that use ultrasonic units with heating elements to clean their instruments, shall not be required to have hot water at the one-compartment sink; provided the heating elements can heat the cleaning solution to at least the minimum temperature required by this chapter and maintain that temperature throughout the cleaning cycle.

(10) Animals shall not be allowed in a body-piercing salon, except as provided under Section 413.08, F.S. Aquariums with fish shall be allowed in waiting rooms and nonprocedural areas.

(11) Except for first aid purposes, smoking, eating, or drinking is prohibited in areas where body-piercing procedures are performed or where instruments and supplies are cleaned and stored.

(12) Water supplies shall comply with the provisions of Chapter 64E-8 or 62-550, F.A.C.

(13) Sewage disposal shall comply with the provisions of Chapter 64E-6 or 62-600, F.A.C.

(14) There shall not be a direct opening between a body piercing salon and any building or portion of a building used as living or sleeping quarters or as a food establishment. This shall be accomplished, at a minimum, by a solid floor to ceiling wall of separation. Rulemaking Authority 381.0075(10) FS. Law Implemented 381.0075(10), (11) FS. History—New 1-24-00, Amended 10-27-10.

64E-19.005 Requirements for Sterilizing Jewelry and Instruments.

(1) All non-disposable instruments used for body piercing shall be cleansed and sterilized after each use in the manner prescribed in Section 381.0075(11), F.S., including the temperature requirements. Autoclave sterilization shall be conducted for

the cycle of time and corresponding operating pressure recommended by the manufacturer of the autoclave. Sanitizers used in the cleaning process must have demonstrated tuberculocidal activity, as indicated by the product label, and be registered with the U.S. Environmental Protection Agency. Jewelry may be sterilized with a liquid chemical sterilant that is cleared for use by the U.S. Food and Drug Administration as long as the jewelry is sterilized according to the procedures on the product label.

(2) Unless otherwise specified by the autoclave manufacturer, instruments that are to be autoclaved must be packed individually in single use paper peel-packs or other containers designed for sterilizing instruments and marked with the expiration date. The expiration date shall not exceed 30 days from the date autoclaved.

(3) All sterilized instruments shall remain stored in sterilized containers until just prior to performing a body piercing procedure. Where several instruments are sterilized at the same time in the same container, such as in a single use setup, once the container is opened, any instruments not used immediately in a procedure must be resterilized.

(4) In addition to the indicator requirements of Section 381.0075(11)(b)2., F.S., body-piercing salons shall demonstrate, using spore destruction tests, that their autoclaves are capable of attaining the minimum operating standards specified in subsection (1), above. These tests shall be performed every 40 hours of autoclave operation, but not less than on a quarterly basis. A log shall be kept to document the hours of autoclave operation, and the spore tests shall be verified through an independent laboratory.

(5) Autoclaves shall be cleaned at the frequency recommended by the manufacturer. Autoclaves shall be serviced at the frequency recommended by the manufacturer, but not less than once a year. A copy of the manufacturer's instructions for cleaning and servicing the autoclave must be maintained on file in the salon.

(6) All clean or packaged sterilized instruments and supplies shall be stored in clean, dry closed cabinets or tightly covered containers.

Rulemaking Authority 381.0075(10) FS. Law Implemented 381.0075(10), (11) FS.

History—New 1-24-00, Amended 1-28-03.

64E-19.006 Piercing Procedures.

(1) Persons performing body-piercing procedures must use aseptic techniques and sterile instruments as specified in Section 381.0075(11)(a)1., F.S., at all times during the practice of body piercing. Before and after performing piercing procedures, piercers must thoroughly wash their hands in hot running water with liquid soap, rinse their hands and dry them with single-use disposable paper towels.

(2) When performing body-piercing procedures, piercers shall wear disposable sterile medical gloves. Gloves shall be discarded after the completion of each procedure on an individual customer in accordance with Chapter 64E-16, F.A.C. Should gloves become torn, punctured, or otherwise contaminated, piercers shall rewash their hands immediately using the procedure described in subsection (1), above, and put on a new pair of sterile gloves.

(3) Piercers shall wear protective eyewear if the piercer determines that spattering is likely to occur.

(4) Only jewelry and instruments that are sterilized and free of nicks, scratches, or irregular surfaces, and prepackaged single use sterile gauze or cotton swabs shall be used in piercing procedures. Jewelry must meet the requirements of Section 381.0075(11)(a)5., F.S.

(5) Single use items contaminated prior to or during the procedure shall be discarded immediately and replaced with new ones before the procedure may resume.

(6) Any skin or mucous membrane surface to receive a body piercing procedure shall be free of rash, infection or any other visible disease condition.

(7) Piercers shall be free of any infection or any other visible disease condition that may be transmitted as a result of carrying out the piercing procedure.

(8) Preparation and Care of the Pierced Area.

(a) If shaving is necessary prior to a body-piercing procedure, a single-use disposable razor shall be used. In accordance with Section 381.0075(11)(a)4., F.S., before performing a body piercing procedure, the skin and surrounding area where the piercing is to be done shall be thoroughly cleansed with a solution labeled as an antiseptic for preparation of the skin 1) prior to surgery, or 2) prior to an injection. The antiseptic solution shall be used in accordance with the manufacturer's instructions. A single use sterile gauze pad or other suitable sterile product shall be used for applying the antiseptic solution. Before an oral piercing procedure, customers must rinse their mouths with an antiseptic mouthwash.

(b) In the event of blood flow, all products used to check the flow of blood or to absorb blood shall be sterile single-use products.

(c) Upon completion of the body piercing procedure, piercers must apply an antiseptic solution to the pierced area with a sterile single-use cotton swab or gauze pad.

Rulemaking Authority 381.0075(10) FS. Law Implemented 381.0075(10), (11) FS.

History—New 1-24-00, Amended 1-28-03, 10-27-10.

64E-19.007 Other Operations.

(1) Informed Consent. Verbal and written educational information, approved by county health departments, shall be given to customers wanting to receive body-piercing procedures before the procedures begin. The information shall provide, at a minimum, a brief description of the piercing procedure, any precautions to be taken by the customer before the piercing, a description of the risks and possible consequences of body piercing services, instructions for care and restrictions following a piercing procedure, and restrictions against the piercing of minors prescribed by this chapter and Section 381.0075, F.S. Prior to the piercing, customers shall sign and date a statement indicating they received and discussed the information with the operator or piercer. Operators and piercers shall sign and date the statement as well, and retain the original with all other required records. A copy of the statement shall be provided to the customer upon request of the customer. The operator shall also post in public view the name, address and phone number of the county health department having jurisdiction over the facility and the procedure for filing a complaint.

(2) Reporting Complaints of Injuries. As specified in Section 381.0075(11)(a)8., F.S., any injury or complaint of injury, suspected infections that required treatment by a licensed practitioner, or any notifiable diseases resulting from the body-piercing procedure that become known to the operator shall be reported to the local county health department by the operator within 72 hours of the operator becoming aware of the complaint or condition. The report shall be submitted on DH Form 4122, 9/02, Body Piercing Salon Injury Report.

(3) Customer Records. Records must be maintained in accordance with Section 381.0075(11)(a)7., F.S., and shall include the following:

- (a) The customer's address and telephone number;
- (b) Their date of birth, race and sex;
- (c) Their physician's name, address and telephone number;
- (d) The name, telephone number and address of an emergency contact person for the customer;
- (e) A list of allergies, including allergies to medicines or topical solutions used by the establishment;
- (f) History of bleeding disorders;
- (g) The date of the customer's initial visit and any subsequent visits;
- (h) The body part or location that was pierced;
- (i) A description of the jewelry used in the piercing;
- (j) A description of any complications that occurred at the time of the piercing procedure;
- (k) Copies of the signed statement for receipt of educational information required in subsection 64E-19.007(1), F.A.C., of this chapter;

- (l) Copies of the written notarized parental consent statements required by Section 381.0075(7), F.S., for minors. The statements must describe the type of piercings that will be performed on the minor;
- (m) The signature and printed name of the persons performing the piercings at each visit.
- (4) Other Facility Records. The following records must also be maintained by the body-piercing salon.
 - (a) Autoclave maintenance records and spore test results required in subsections 64E-19.005(4), and (5), F.A.C., of this chapter;
 - (b) A copy of this chapter and Section 381.0075, F.S.;
 - (c) Records on operators and all persons performing body-piercing services in the salon. Such records shall include their full names, dates of birth, sex, home addresses and telephone numbers, their dates of hire, and their duties and responsibilities. Such records shall be maintained for at least 2 years after a person's employment ends;
 - (d) Documentation of training required by this chapter and Section 381.0075(11)(b)6., F.S., for operators and piercers;
 - (e) A complete description of all body piercing procedures provided.
- (5) Records required by this section shall be maintained at each salon for the current licensing period. Records may be stored elsewhere after that time frame, but they must be stored in accordance with this chapter and be made available for review by the department upon request of the department.
- (6) Training.
 - (a) Operators and piercers shall complete formal training that meets the requirements of subsection 64E-19.002(7), F.A.C., of this chapter. When formal training courses are not available within a one hundred-mile radius of the body-piercing salon where the piercer is employed, piercers may substitute the successful completion of a correspondence course. Correspondence courses must meet the same subject matter requirements as formal training in order to qualify as acceptable substitutes for formal training.
 - (b) The training required initially for each operator and piercer shall include all of the subjects listed in subsection 64E-19.002(7), F.A.C. Operators and piercers shall receive training annually thereafter in any one subject or combination of subjects listed in subsection 64E-19.002(7), F.A.C.
 - (c) Each formal training course shall include written material which covers the required subjects, such as a core training manual; or audio-visual presentations which cover the required subjects, such as slides or videos; and a question and answer period or format for trainees. A certificate, card, or other form of written documentation shall be provided to trainees who successfully complete the course.

(d) Operators and piercers must complete the required training prior to assuming responsibilities in a salon.

(e) Training courses required by this chapter must be presented by a person or persons who possess the knowledge, experience and credentials to teach the required subjects as cited in “Knowledge, Experience, and Credentials for Trainers per Chapter 64E-19, F.A.C.,” May 16, 2002, herein incorporated by reference and available upon request from the Bureau of Facility Programs, 4052 Bald Cypress Way, BIN A08, Tallahassee, Florida 32399-1710. Any individual or organization requesting the department to review their training courses for compliance with the requirements of this chapter shall submit copies of their training materials to the Bureau of Facility Programs, at the above address. The materials submitted must include credentials of trainers and persons compiling the training materials, a copy of the classroom or correspondence course curriculum, and copies of written materials to be received by trainees. The bureau shall review the materials and inform the applicant of its findings within 30 days from receipt of the last training materials received from the applicant. When changes are made to a training course that has been reviewed and accepted by the department, those changes shall also be submitted to the bureau for review prior to implementing the changes. Rulemaking Authority 381.0075(10) FS. Law Implemented 381.0075(7), (10), (11) FS. History—New 1-24-00, Amended 1-28-03, 10-27-10.

64E-19.008 Enforcement.

Rulemaking Authority 381.0075(10) FS. Law Implemented 381.0075(9)(a) FS. History—New 1-24-00, Repealed 12-29-16.

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64E-28.001 Scope of Chapter Rules.

Rulemaking Authority 381.00789 FS. Law Implemented 381.00787, 381.00791 FS. History—New 9-5-12, Repealed 12-29-16.

64E-28.002 Definitions.

(1) Alcohol-based hand sanitizer – An antimicrobial skin sanitizer which contains a minimum concentration of at least 60% alcohol.

- (2) Aseptic technique – Practices used by a tattoo artist to prevent cross contamination.
- (3) Compromised package – A wet, torn, or stained package.
- (4) Contaminated – means the presence of disease-causing organisms on inanimate objects or surfaces.
- (5) Cross contamination – The act of spreading disease-causing organisms from one surface to another.
- (6) Department – The Department of Health and its representative county health departments.
- (7) Disinfect – The use of a product registered with the United States Environmental Protection Agency (USEPA) as a tuberculocidal disinfectant which results in the reduction in the number of disease-causing organisms on objects or surfaces, thereby rendering them safe for handling and use.
- (8) Equipment – All machinery, including fixtures, containers, vessels, tools, devices, implements, furniture, display and storage areas, sinks and all other apparatus and appurtenances used in connection with the operation of a tattoo establishment.
- (9) Fixed – Incapable of being moved.
- (10) Government-issued photo identification – A document issued by a state, federal, or foreign government containing the photo of the person it is identifying.
- (11) Inactive license – A tattoo establishment or artist license which has not been renewed on or before the date of expiration.
- (12) Instruments – Hand pieces and other tools that may come in contact with a customer's body or be exposed to body fluids during tattooing procedures.
- (13) Minor – An individual who is less than eighteen (18) years of age.
- (14) Person – Any individual, partnership, corporation, association, or public body.
- (15) Registered business name – The name, as registered with the Department of State, under which a tattoo establishment operates.
- (16) Registered agent for service of process – A person, as registered with the Department of State, authorized by a tattoo establishment to receive legal notices for the establishment.
- (17) Single-use – means products or items that are intended for one-time, one-person use and are disposed of after use on each customer, such as cotton swabs or balls, gauze pads, tissues or paper products, sanitary coverings, razors, instruments that pierce the skin, and protective gloves.
- (18) Spore strip – A device used to monitor the sterilization process in a steam autoclave to ensure destruction of *Geobacillus stearothermophilus* spores.
- (19) Sterilization – The use of a steam autoclave to destroy all forms of microbial life, including spores.

(20) Tattoo artist – A tattoo artist as defined in Section 381.00771, F.S., including an artist who performs cosmetic tattooing.

(21) Unobstructed access – A situation where an artist can wash their hands and return to the tattooing area without recontaminating their hands by handling an object such as a door knob.

Rulemaking Authority 381.00789 FS. Law Implemented 381.00789 FS. History–New 9-5-12.

64E-28.003 Licensure Requirements for a Tattoo Artist.

(1) An applicant seeking initial licensure as a tattoo artist shall submit a completed application for licensure to the department on form DH 4147, 8/12, Application for Tattoo Artist License, which is incorporated herein by reference and which can be obtained from the environmental health section of the county health department, which has jurisdiction for the tattooing program in the county where the tattoo artist lives, or from the internet at <https://www.flrules.org/Gateway/reference.asp?No=Ref-01524>, or <http://www.floridahealth.gov/environmental-health/tattooing/contacts.html>. An application shall be considered complete if all of the information requested on the form is provided, along with the fee specified in Rule 64E-28.011, F.A.C., and the following documentation is attached:

(a) A copy of a government issued photo identification confirming the applicant is at least 18 years of age.

(b) A copy of the certificate of training proving completion of a department approved course on blood-borne pathogens and communicable diseases with having achieved a minimum score of seventy percent (70%) on the course examination.

(2) A tattoo artist's license is valid, throughout the state of Florida, for one year from the date it is issued.

(3) A tattoo artist seeking licensure renewal shall:

(a) Annually, submit a completed application for license renewal on Form DH 4147 before the date of expiration.

1. An application shall be considered complete if all of the information requested on the form is provided, along with the fee specified in Rule 64E-28.011, F.A.C.

2. A license which has not been renewed on or before the date of expiration shall be deemed inactive. If this day falls on a weekend or holiday, a tattoo artist license must be renewed on or before the first working day after the date of expiration.

(b) Not perform tattooing without an active license.

(4) A tattoo artist license shall not be transferrable from one person to another.

64E-28.004 Registration Requirements for a Guest Tattoo Artist.

(1) A guest tattoo artist seeking registration by the department shall:

(a) Submit, at least fourteen (14) days prior to practicing tattooing in any licensed tattoo establishment or licensed temporary tattoo establishment, a completed application for registration to the department on Form DH 4150, 7/12, Application for Guest Tattoo Artist Registration, which is incorporated herein by reference and which can be obtained from the environmental health section of the county health department, which has jurisdiction for the tattooing program in the county where the tattoo artist lives, or from the internet at <https://www.flrules.org/Gateway/reference.asp?No=Ref-01525>, or <http://www.floridahealth.gov/environmental-health/tattooing/contacts.html>. An application shall be considered complete if all of the information requested on the form is provided, along with the fee specified in Rule 64E-28.011, F.A.C., and the following documentation is attached:

1. A copy of a government issued photo identification confirming the applicant is at least 18 years of age.
2. A copy of an active license, registration, or certification in another jurisdiction.
3. A copy of the certificate of training proving completion of a course on blood-borne pathogens and communicable diseases, which meets the requirements specified in paragraph (b).

(b) Complete a department approved course on blood-borne pathogens and communicable diseases with having achieved a minimum score of seventy percent (70%) on the course examination.

1. Completion of the educational course mentioned in paragraph (b), shall not be required when a tattoo artist has completed a blood-borne pathogens and communicable diseases course as a requirement for license, registration, or certification in a jurisdiction outside of the state and, as determined by the department, the course requirements met or exceeded those prescribed in Sections 381.00775(2)(b)4. and 5., F.S., and Rule 64E-28.006, F.A.C.

2. A tattoo artist may submit a course curriculum to the department and request the department conduct a review for determination of the requirements specified in subparagraph (1)(b)1. Requests for curriculum review shall be submitted prior to submission of a completed application for registration of a guest artist.

(2) A guest tattoo artist's registration is valid for up to fourteen (14) consecutive days, throughout the State of Florida.

(3) A guest tattoo artist shall not perform tattooing without an active guest tattoo artist registration.

(4) A guest tattoo artist registration shall not be transferrable from one person to another.

Rulemaking Authority 381.00789 FS. Law Implemented 381.00775 FS. History—New 9-5-12.

64E-28.005 Licensure Requirements for a Tattoo Establishment.

(1) Licensure of a permanent tattoo establishment:

(a) Prior to performing tattooing, a completed application shall be submitted to the county health department on form DH 4151, 8/12, Application for Tattoo Establishment Licensure, which is incorporated herein by reference and which can be obtained from the environmental health section of the county health department, which has jurisdiction for the tattooing program in the county where the establishment is physically located, or from the internet at <https://www.flrules.org/Gateway/reference.asp?No=Ref-01526>, or <http://www.floridahealth.gov/environmental-health/tattooing/contacts.html>. An application shall be considered complete if all of the information requested on the form is provided, along with the fee specified in Rule 64E-28.011, F.A.C.

(b) A license for a tattoo establishment is valid for one year from the date it is issued.

(c) A license which has not been renewed on or before the date of expiration shall be deemed inactive. If this day falls on a weekend or holiday, a tattoo artist license must be renewed on or before the first working day after the date of expiration.

(2) Licensure of a temporary tattoo establishment:

(a) A completed application to be submitted to the county health department on form DH 4151 at least thirty (30) days prior to performing tattooing. An application shall be considered complete if all of the information requested on the form is provided, along with the fee specified in Rule 64E-28.011, F.A.C.

(b) A license for a temporary tattoo establishment is valid for up to fourteen (14) consecutive days in conjunction with a convention or similar event for which the license is issued.

(3) No tattooing shall be performed at an establishment that does not have an active license.

(4) A tattoo establishment license shall not be transferrable from one location or person to another.

Rulemaking Authority 381.00789 FS. Law Implemented 381.00777 FS. History—New 9-5-12.

64E-28.006 Education Course Requirements.

(1) All educational courses per Section 381.00775(2)(b)4., F.S., shall be approved by the department. Any person seeking approval of an education course shall submit a request for determination of compliance with the requirements of this rule to the Department of Health, Bureau of Community Environmental Health, 4052 Bald Cypress Way, Bin #A08, Tallahassee, FL 32399. All requests for course approval shall be handled in accordance with Section 120.60, F.S. Requests for course approval shall include submission of the following documentation:

- (a) A copy of the credentials of trainers and persons compiling the curriculum.
- (b) A copy of the curriculum.
- (c) Copies of training materials.
- (d) A copy of the test to be given.
- (e) A copy of the answers to the test questions.
- (f) A copy of the certificate of training to be issued.

(2) The course shall meet the following criteria:

- (a) Utilize a classroom-based or internet-based delivery method.
- (b) Be specific to the tattoo industry.
- (c) Be a minimum of three (3) hours in length, excluding the examination.
- (d) Include an opportunity for interactive questions and answers with the person conducting the training.
- (e) Include, at a minimum, education and training on blood-borne pathogens, such as human immunodeficiency virus and hepatitis B and C viruses, and communicable diseases, such as hepatitis A, staphylococcal including those of methicillin-resistant *Staphylococcus aureus*, tuberculosis, impetigo, scabies, ringworm, molluscum contagiosum, herpes simplex, and herpes zoster, and the prevention of such transmission. This information shall include:

- 1. Identification of the disease,
- 2. Identification of the infectious agent,
- 3. Mode of transmission,
- 4. Incubation period,
- 5. Period of communicability; and,
- 6. Prevention of transmission in a tattoo setting.

(f) Be followed by a written examination covering the materials in the course. The examination shall contain a minimum of fifty (50) questions with a passing score of at least seventy percent (70%).

(g) Ensure identity verification and validation for each student taking the internet or classroom course and test.

(3) In addition to that specified in paragraphs (2)(b)-(g), above, internet-based courses shall meet the following criteria:

(a) Each course section shall have a minimum time to finish that section before it is possible to move on to the next section.

(b) Identity verification and validation shall occur prior to the initiation of the internet course, using an identity verifying technology that seeks verification through internet databases using information that is specific to the student's identity. Following initial identity verification, validation shall occur at least every hour during the course and prior to completing the test.

(c) The course shall automatically terminate when a student fails to answer an identity validation question during a 60-second response time period or a student provides more than one incorrect answer to a validation question. Upon termination, a one-hour waiting period is required before the student is allowed to register again.

(d) At a minimum, the course provider shall include on the internet registration form, initial blocks in which the student indicates agreement with the following information:

1. That the student who registers for the course is the person taking the course.
2. That the student will be asked time-limited identity validation questions during the internet course. The validation questions will ask the student questions about themselves based on information provided by them and obtained through internet databases as described in paragraph (b), above. Failure by a student to answer an identity validation question during a 60-second response time period or a student providing more than one incorrect answer to an identity validation question will cause the course to automatically terminate. Upon termination, a 1-hour waiting period is required before the student is allowed to register again.

(e) A student shall be prevented from proceeding with the internet course should they fail to indicate agreement with each stipulation listed in paragraph (d), above.

(f) A subject matter expert representing the course provider shall be available by telephone or via electronic means during normal business hours to assist students.

(4) In order to ensure that the requirements of this rule section are met, the department may annually register and take the course, as any interested student would.

(5) The course provider shall notify the department in writing within 30 days of determining that a student has attempted or acquired certification by committing fraud, deceit, false statements, or perjury. When this is determined, the course provider shall revoke the certificate.

(6) Any reference to department approval shall state no more than: "This course is approved by the Florida Department of Health for tattoo artist licensure under Section 381.0775, F.S., and Chapter 64E-28, F.A.C."

(7) Course approval is not transferrable from person to person.

64E-28.007 Operational Requirements for a Tattoo Establishment.

- (1) Tattoo establishments shall have walls, a floor, and a ceiling. Floors and walls located in the tattooing area, the area where items are cleaned and sterilized, and in the restrooms shall be constructed of non-absorbent, easily cleanable materials. The entire establishment shall be maintained in clean condition and good repair.
- (2) There shall not be a direct opening between a tattoo establishment and any building or portion of a building used as living or sleeping quarters. This shall be accomplished, at a minimum, by a solid floor to ceiling wall of separation.
- (3) A tattoo establishment shall not be located in an area where food is prepared.
- (4) Eating and drinking, except for the purpose of administering first aid, and smoking are prohibited in areas where tattooing is performed or where instruments and supplies are cleaned and stored.
- (5) Water supplies shall comply with the provisions of Chapter 64E-8 or 62-550, F.A.C.
- (6) Sewage disposal shall comply with the provisions of Chapter 64E-6 or 62-200, F.A.C.
- (7) The establishment shall use effective measures to protect against the entrance, breeding, and presence of vermin, such as insects and rodents. Openings to the outside shall be protected by such means as self-closing doors, closed windows, or screening. If screening is used, it shall not be less than sixteen (16) mesh to the inch.
- (8) Animals shall not be allowed in a tattoo establishment, except as provided under Section 413.08, F.S. Aquariums with fish shall be allowed in waiting rooms and non-procedural areas only.
- (9) Each tattoo establishment shall have an artificial light source equivalent to at least one hundred (100) foot candles in the tattooing area and in the area where items are cleaned and sterilized.
- (10) Restrooms shall be supplied with toilet tissue, a hand sink supplied with running water under pressure, liquid soap, a dispenser with single-use paper towels, and a waste receptacle. Signage shall be posted in the restroom to instruct employees that they must thoroughly wash their hands before returning to work.
- (11) A handsink with unobstructed access shall be located within each tattoo area or centrally located within the overall workroom area, so that each tattoo artist has access to the handsink for handwashing.
 - (a) The handsink shall be supplied with running water under pressure, liquid soap, a dispenser with single-use paper towels, and a waste receptacle.

(b) A restroom handsink may be used as the handsink provided that it is located within the tattoo establishment and it meets the above stated requirements.

(12) At a minimum, contaminated, reusable items shall be cleaned manually in a sink, separate from the handsink(s), or mechanically in an ultrasonic machine prior to sterilization.

(a) If items are manually cleaned in a sink, the sink shall be deep enough to allow complete submersion of the items. Gloves shall be worn when manual cleaning is performed.

(b) If items are cleaned in an ultrasonic machine, the machine shall be used in accordance with the manufacturer's instructions, which shall be available for review by the department at the time of inspection.

(c) After cleaning, items shall be rinsed and allowed to air dry or shall be dried with single-use paper towels prior to packaging for sterilization.

(d) If only individually packaged, pre-sterilized, single-use items are used in the establishment, the cleaning sink and ultrasonic machine requirements do not apply.

(13) A tattoo establishment shall have a steam autoclave for sterilizing instruments.

(a) The autoclave shall be used in accordance with the manufacturer's instructions for packaging, loading, and processing items.

(b) The autoclave shall be maintained to ensure proper operation.

1. The autoclave shall be cleaned at the frequency recommended by the manufacturer and shall be serviced at least once a year or at the frequency recommended by the manufacturer.

2. A copy of the manufacturer's instructions for operating, cleaning, and servicing the autoclave shall be maintained in the tattoo establishment and shall be available for review by the department at the time of an inspection.

(14) When using an autoclave, sterilization shall be verified through:

(a) A chemical indicator strip placed inside one packet in each load to monitor the sterilization procedure. The strip must indicate exposure to steam and the autoclave operating temperature.

(b) Testing with spore strips at a minimum frequency of every 40 hours of operation of the autoclave, but not less than on a quarterly basis.

1. Test results shall be confirmed by an independent laboratory.

2. In the event of positive results, the autoclave shall be immediately taken out of service and all unused items processed in the autoclave since the most recent negative test results shall be considered non-sterile.

3. While the autoclave remains out of service, tattooing may continue provided either another properly functioning autoclave is placed in service in the establishment or all single-use, pre-sterilized instruments are used.

4. When the improperly functioning autoclave has been restored to proper function, which shall be confirmed by follow-up testing, it may be placed back in service.
- (15) Each tattoo establishment shall maintain autoclave sterilization records onsite. The records shall, at a minimum, include the following information:
- (a) Autoclave log showing cumulative run time, quantity and types of items sterilized on a given date, and the date spore strip testing was conducted.
 - (b) Spore strip results provided by an independent laboratory.
- (16) If only individually packaged, pre-sterilized, single-use items are used, an autoclave shall not be required nor the requirements specified in subparagraphs 12., 13., 14., and 15., of this rule.
- (a) Individually packaged, pre-sterilized, single-use items shall be sterilized with ethylene gas or gamma rays and shall be labeled with the expiration date by the manufacturer.
 - (b) If a package containing pre-sterilized, single-use items has been compromised, the contents shall be discarded.
- (17) Packages of sterile items, which are sterilized by the tattoo establishment, shall be labeled with the date of autoclaving. If any package has been compromised, the items shall be re-sterilized.
- (18) All packages of sterile items shall be stored in a clean, dry, covered container or in a clean, dry cabinet until just prior to use.
- (19) Work chairs, tables, stands, cabinets, and counter tops shall have a smooth, non-porous, easily cleanable surface, and shall be cleaned and disinfected after each customer.
- (20) If any liquid product is not in its original container, the container into which the product has been placed shall be labeled with the name of the product.
- (21) Each tattoo establishment shall maintain the following records:
- (a) Customer records, including parental consent;
 - (b) Autoclave sterilization records and maintenance records;
 - (c) Documentation identifying the method of sterilization utilized by the manufacturer if the information is not printed on the packaging of the item.
 - (d) The records stated in paragraphs (a), (b), and (c), above, shall be maintained for two years with those records for the current licensing period maintained onsite in the establishment and available for review by the department at the time of inspection.
 - (e) Personnel records of each tattoo artist who works in the establishment. The record shall contain the tattoo artist's name, address, date of birth, and the license number issued by the department. Personnel records shall be maintained for at least 2 years after an artist's employment ends.

(22) A tattoo establishment shall allow the department to conduct, at minimum, annual inspections for the purpose of ensuring compliance with Sections 381.00771-.00791, F.S., and these rules. Results of each inspection shall be recorded on DH Form 4153, 7/12, Tattoo Establishment Inspection Report, herein incorporated by reference and which can be obtained at <https://www.flrules.org/Gateway/reference.asp?No=Ref-01527>, or from the environmental health section of the county health department having jurisdiction.

(23) Biomedical waste shall be managed in accordance with Section 381.0098, F.S., and Chapter 64E-16, F.A.C. Regular solid waste shall be collected, stored and disposed of in a manner and at a frequency that does not create a sanitary nuisance, as defined in Chapter 386, F.S.

(24) Tattoo establishments, currently operating on the effective date of this rule, which are not in full compliance with the handsink and cleaning sink requirements shall have six months from the effective date of this rule to comply with the requirements.

Rulemaking Authority 381.00789 FS. Law Implemented 381.00779 FS. History—New 9-5-12.

64E-28.008 Operational Requirements for a Temporary Tattoo Establishment.

(1) A licensed temporary establishment shall meet the operational requirements set forth in Rule 64E-28.007, F.A.C., with the following exceptions.

(2) A temporary establishment shall have rigid perimeter walls, a rigid floor, and a rigid ceiling. Floors in the tattooing area and the area where items are cleaned and sterilized shall be constructed of nonabsorbent, easily cleanable materials. The entire establishment shall be maintained in clean condition and good repair.

(3) If any tattoo items are sterilized by an artist prior to a temporary event, spore test results confirmed by an independent laboratory, shall be available for review by the department at the time of inspection.

(4) A temporary establishment shall allow the department to conduct, at minimum, an initial inspection prior to and, if deemed necessary, during the convention or similar event for the purpose ensuring compliance with Sections 381.00771-.00791, F.S., and these rules. Results of each inspection shall be recorded on DH Form 4153, 7/12, Tattoo Establishment Inspection Report.

Rulemaking Authority 381.00789 FS. Law Implemented 381.00779 FS. History—New 9-5-12.

64E-28.009 Standards of Practice for a Tattoo Artist or Guest Tattoo Artist.

(1) A tattoo artist shall ensure that a customer record is completed for each customer. The record shall, at a minimum, include the following:

- (a) Name of tattoo artist.
- (b) Customer's name, age, and birthdate.
- (c) Description and location of tattoo on the customer's body.
- (d) Signature of the customer.
- (e) Signature of the artist.
- (f) Date(s) tattooing procedure is performed.

(2) Pursuant to Section 381.00787, F.S., a tattoo artist shall not tattoo the body of a minor less than sixteen (16) years of age.

(3) If tattooing a minor who is sixteen (16) or seventeen (17) years of age, a tattoo artist shall:

(a) Inspect copies of a government-issued photo identification for both the minor and for the parent or legal guardian of the minor. If the photo identification for the minor does not show a birth date, a copy of the minor's birth certificate shall be provided.

(b) Obtain a signed and notarized consent by the minor's parent or legal guardian on form DH 4146 , 7/12, Written Notarized Consent For Tattooing of a Minor Child, Age 16 through 17 Years Old, which is incorporated herein by reference and which can be obtained from the environmental health section of the county health department, which has jurisdiction for the tattooing program in the county where the tattoo artist lives or the tattoo establishment is physically located, or from the internet at <https://www.flrules.org/Gateway/reference.asp?No=Ref-01528>, or <http://www.myfloridaeh.com/community/Tattoo/index.html>.

(c) Complete the requirements of subsection (1).

(4) Prior to or after performing a tattoo procedure on a customer, a tattoo artist shall provide information on aftercare to the customer, both verbally and in writing.

(5) Prior to setup for a tattoo procedure, a tattoo artist shall:

- (a) Ensure that the skin area where a tattoo is to be applied is visibly healthy.
- (b) Wash their hands thoroughly using liquid soap, rinse them, and dry them using single-use paper towels.

(6) Prior to performing a tattoo procedure, a tattoo artist shall cleanse the area of the skin where the tattoo will be placed using a using a clean, single-use paper towel or pad and a solution labeled as an antiseptic. The antiseptic solution shall be used in accordance with the manufacturer's instructions.

(7) If hair is to be removed from the area to be tattooed, either a single-use razor shall be used, or clippers which are capable of being disinfected. If hair removal is done after cleansing, the area shall be re-cleansed as specified in subsection (6), above.

(8) While performing a tattoo procedure, a tattoo artist shall:

(a) Use aseptic techniques, including barrier covers on instruments and equipment that may come into contact with the tattoo artist or the customer during the tattoo procedure. Should an artist choose to not use a barrier cover on the tattoo machine, they must disinfect the machine upon completion of the tattoo procedure.

(b) Use only sterile needle bars, sterile needle tubes, and single-use, sterile needles.

(c) Wear new, disposable examination gloves, which shall be discarded after the completion of each single tattooing session.

1. Should the gloves become torn, punctured, or otherwise contaminated outside the general scope of tattooing, or should the gloves come in contact with any object or surface other than the customer's skin or items being used in the procedure, the gloves shall be removed and discarded and the tattoo artist shall thoroughly wash their hands or apply an alcohol-based hand sanitizer and re-glove before resuming the tattoo session.

2. In the event a tattoo artist must leave the tattooing area, the gloves shall be removed and discarded. The artist shall thoroughly wash their hands or apply an alcohol-based hand sanitizer and re-glove before resuming the tattoo session.

(d) Discard any sterile, single-use items that become contaminated and replace them with sterile items before resuming the procedure.

(e) Use a stencil that is single-use and clean. The product used to apply the stencil shall be packaged as a single dose or dispensed from a product container as a single customer dose.

(f) Any item used for freehand artistry on the customer shall be single-use and discarded after use unless an antiseptic is applied to the skin after marking the skin.

(g) Use inks, dyes, and pigments which are intended for tattooing.

1. Inks shall be used in accordance with the manufacturer's instructions.

2. Individual portions of inks, dyes, or pigments shall be dispensed into clean single-use cups for each customer.

(9) Any item which an artist adds to a tattoo machine to stabilize the needle shall be either single-use or a reusable item that has been disinfected.

(10) Upon completion of a tattooing procedure, a tattoo artist shall:

(a) Remove any excess ink from the customer's skin with a single-use clean paper towel or pad.

- (b) Use a clean glove, single-use paper towel, or single-use pad to apply a moisturizing ointment or lotion that is packaged as a single dose or is dispensed from a product container as a single customer dose.
 - (c) If needed, cover the tattooed area with a clean nonstick bandage.
 - (d) Remove and discard any barriers used to cover instruments and equipment and disinfect both the tattoo machine and the work area with a tuberculocidal disinfectant registered with the USEPA.
 - (e) Remove any reusable instruments from the tattooing area in preparation for cleaning, rinsing, drying, and sterilization.
 - (f) Discard any unused ink, dye, or pigment.
 - (g) Thoroughly wash and rinse hands and dry them with clean single-use paper towels.
- Rulemaking Authority 381.00787, 381.00789 FS. Law Implemented 381.00779 FS. History—New 9-5-12.*

64E-28.011 Fee Schedule.

(1) Tattoo Artist License and Renewal	\$60.00
(2) Guest tattoo Artist Registration and Re-registration	\$35.00
(3) Tattoo Establishment License	\$200.00
(4) Temporary Establishment License	\$200.00
(5) Reactivation of Tattoo Artist License	\$25.00
(6) Reactivation of Tattoo Establishment License	\$75.00

Rulemaking Authority 381.00789 FS. Law Implemented 381.00781 FS. History—New 9-24-12.

Changelog

No Changes have been made to this document 8/23/2023