DRAFT

Substantial rewording of Rule 64E-16 Biomedical Waste. See Florida Administrative Code for present text.

CHAPTER 64E-16

BIOMEDICAL WASTE

64E-16.001 General.

(1) These rules do not apply to biomedical waste incinerators; funeral homes that do not practice embalming; linen that is to be laundered and re-used; contaminated, single-use medical devices that are intended to be reprocessed, provided the devices are placed in packaging separate from biomedical waste with written designation for reprocessing; discarded prescription drugs which are managed in accordance with Rule 61N-1.023, F.A.C.; 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 for use in medical research or teaching, are not considered biomedical waste until such time as the material is discarded; farm operations and agricultural businesses; or human remains that are disposed of by persons licensed under Chapter 497, F.S.

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

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

Rulemaking Authority 381.0098(3) FS. Law Implemented 381.006(8), 381.0098 FS. History–New 6-19-89, Amended 12-14-92, 1-23-94, 6-3-97, Formerly 10D-104.001, Amended _____.

64E-16.002 Definitions.

Words and phrases used in this Chapter have the same meaning as in section 381.0098, F.S., unless defined below:

(1) ASTM International (ASTM) – A technical society which publishes national standards for the testing and quality assurance of materials.

(2) Biological indicator – A device used to monitor the treatment process that consists of a specific population of bacterial spores known to be resistant to the mode of disinfection or sterilization being monitored.

(3) 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; or such items that have dried.

(b) Non-absorbent, disposable devices that have been contaminated with blood, body fluids, or secretions or excretions visibly contaminated with blood.

(4) Biomedical waste facility – Any person or facility that generates, stores, transports, or treats biomedical waste in Florida.

(5) Body fluids – Those fluids including blood, blood products, lymph, semen, vaginal secretions, and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids, which have the potential to harbor pathogens. In instances where identification of the fluid cannot be made, it must 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 must not be considered biomedical waste unless visibly contaminated with blood.

(6) Change of control – A sale, merger, consolidation or acquisition of a facility in which another corporation, entity or person takes control; or when any change in the ownership of more than fifty percent occurs.

(7) Contaminated – Soiled by any biomedical waste.

(8) Decontamination – The process of removing pathogens from an inanimate surface with the use of a United States Environmental Protection Agency (EPA) registered tuberculocidal disinfectant in accordance with the manufacturer's instructions or

any other equivalent method rendering surfaces free from pathogens.

(9) Health care practitioner – Any person that is licensed to provide medical, nursing, veterinary, or dental care pursuant to chapter 457; chapter 458; chapter 459, chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 466; chapter 467; chapter 468; chapter 474; chapter 478; chapter 486; chapter 490; or chapter 491, F.S.

(10) Home-user – An individual who generates biomedical waste as a result of self-medical care or medical care by a family member or other non-health care practitioner.

(11) Leak resistant – Prevents liquid from escaping into the environment.

(12) Mobile biomedical waste facility – A biomedical waste facility that is capable of moving from one physical address to another physical address and is not part of a permitted or exempted stationary facility or does not return daily to a permitted or exempted physical address. Mobile health care units, such as bloodmobiles, that are part of a stationary biomedical waste generator, are not considered individual biomedical waste generators.

(13) Package – A sealed red bag, sealed sharps container, or sealed transport container used to enclose biomedical waste.

(14) Parametric monitoring – A system to monitor the treatment of biomedical waste through the measurement of specific parameters such as time, temperature, pressure, steam, or chemical concentration in place of using biological indicators.

(15) Person – Any individual, partnership, corporation, association, or public body.

(16) Personnel – A person or body of persons who handle biomedical waste, including performing procedures that generate biomedical waste, as part of their responsibilities within a biomedical waste facility.

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

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

(19) Receipt – Written documentation, including electronic format, which specifies the type of biomedical waste; amount of biomedical waste; name, number, and physical address of biomedical waste facilities receiving and shipping the waste; transporter number (when applicable); and date of pick up, delivery, receipt, or treatment. When weight is documented, it must be exact.

(20) Remediation services – The clean-up and removal of biomedical waste from an accident, crime, or trauma scene location.

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

(22) Reuse – To use again for the same or similar purpose. For the purpose of this chapter, this does not mean recycle.

(23) Saturated – Soaked to capacity.

(24) Sealed – Closed in a manner to prevent the escape of biomedical waste.

(25) Sharps collection program – A program designed as a non-profit community service to assist the home user in the safe

management of needles and other sharp biomedical waste.

(26) Single-use treatment unit – An individual, self-contained system that can only be used one-time for the treatment of biomedical waste.

(27) Storage – The holding of packaged biomedical waste.

(28) Storage facility – A biomedical waste facility that stores biomedical waste.

(29) Temporary biomedical waste facility – A biomedical waste generating facility that operates at a fixed physical address for no more than 14 consecutive days in conjunction with a single event.

(30) Transfer – The movement of packaged biomedical waste within a biomedical waste facility or between registered transport vehicles.

(31) Transport – The movement of biomedical waste to or from a biomedical waste facility.

(32) Transport container – Any rigid, leak- and puncture-resistant container used to transport biomedical waste.

(33) Transport vehicle – A motor vehicle as defined by section 320.01(1)(a), Florida Statutes, a rail car, watercraft, or aircraft that is capable of holding and transporting biomedical waste.

(34) Treatment unit – A piece of equipment manufactured for the purpose of processing biomedical waste to render it noninfectious.

Rulemaking Authority 381.0098(3) FS. Law Implemented 381.006(8), 381.0098 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, Amended _____.

64E-16.003 General Facility Policies and Procedures

(1) All biomedical waste facilities must:

(a) Manage biomedical waste mixed with hazardous waste in accordance with Chapter 62-730, F.A.C., (June 2023) as incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX.

(b) Manage biomedical waste mixed with radioactive materials in accordance with Chapter 64E-5, F.A.C. After the radioactive component is no longer considered radioactive, the biomedical waste must be managed in accordance with this chapter.

(c) Manage any solid or liquid waste, which is neither hazardous nor radioactive in character, combined with untreated biomedical waste as untreated biomedical waste.

(d) Develop and keep current a site-specific, written operating plan, which must be implemented by the facility to manage biomedical waste, in accordance with section 381.0098, F.S., and this chapter. This plan must be available for review by the department and personnel. The plan must include the following: a description of training for personnel; procedures for segregating,

labeling, packaging, transporting, storing, and treating biomedical waste; and procedures for decontamination. Facilities that treat biomedical waste must also include:

1. The parameters identified during validation testing that provide consistent treatment;

2. The protocol for treating the waste, including a description of treatment containers and placement of the load in the unit;

3. The contingency plan should the facility experience treatment unit downtime that would prevent the treatment of biomedical waste in accordance with Rule 64E-16.010(11); and

4. The response plan in place to be followed in the event the facility is notified or discovers that biomedical waste has left the facility without required treatment.

(e) Provide and document training in proper biomedical waste procedures, in accordance with the facility's operating plan, prior to commencement of duties for new personnel, including temporary personnel and interns, and every 12 months thereafter. Training for treatment facility personnel must also include training in all aspects of the treatment unit operation, including maintenance and contingency procedures.

(f) Maintain paper or electronic biomedical waste management records for no less than three years and make them available for review by the department at the time of inspection. Examples of biomedical waste management records include, transporter pick-up receipts, storage facility receipts, treatment facility receipts, receipts from any facility to which biomedical waste is self-transported, weight logs, purchase and return receipts for mail-in sharps treatment systems, purchase receipts for approved single-use treatment unit, treatment records, and training records.

(g) Decontaminate all surfaces contaminated with spilled or leaked biomedical waste as part of the cleaning process. Facilities must provide the necessary supplies needed to decontaminate the contaminated area, including personal protective equipment (PPE) as required in accordance with subpart Z of 29 CFR 1910.1030(d)(3)(i), (Occupational Exposure to Bloodborne Pathogen Standard), (June 2023) as incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX. This may be achieved by utilizing a prepackaged spill kit. Supplies must be of adequate size for the decontamination and containment of a spill and must include at minimum, absorbent material, disinfectant, red bag or sharps container, gloves, masks, dustpan, and broom or apparatus to pick up sharps.

(2) Biomedical waste in a liquid or semi-liquid form may be disposed into a sewage disposal system, which is approved the Florida Department of Environmental Protection (DEP) to receive such waste.

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

Rulemaking Authority 381.0098(3) FS. Law Implemented 381.006(8), 381.0098 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, Amended _____.

64E-16.004 Containment and Packaging Requirements

(1) Sealed packages of biomedical waste must remain sealed until treatment; except that the department, or an agent designated by the department, may remove any item of biomedical waste from a sealed or unsealed package of biomedical waste for the purpose of inspection or investigation.

(2) Ruptured or leaking packages of biomedical waste must be placed into larger packaging without disturbing the seal of the original ruptured or leaking package.

(3) All packages containing biomedical waste must be visibly identifiable with the international biological hazard symbol and the following phrase: "BIOHAZARD". The labels must be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color, in accordance with subpart Z of 29 CFR, subparagraph 1910.1030(g)(1)(i)(C), Occupational Exposure to Bloodborne Pathogen Standard. The symbol must be at least six inches in diameter on bags or transport containers 19" x 14" or larger, and at least one inch in diameter on all sharps containers and any bags or transport containers smaller than 19" x 14".

(a) Biomedical waste, except sharps, must be discarded at the point of origin into impermeable, red plastic bags. Bags must be sealed at the point of origin prior to transfer.

(b) Each bag must have an impact resistance of at least 165 grams and a tear resistance of at least 480 grams in both the parallel and perpendicular planes with respect to the length of the bag, which must be printed on the red bag or documented by a copy of the results of testing performed by an independent laboratory. Impact resistance must be determined using ASTM D-1709-98 or more current version, "Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method" and tearing resistance must be determined using the ASTM D-1922-00a or more current version, "Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method" as incorporated by reference and may be examined at the Bureau of Environmental Health, 4025 Esplanade Way, Tallahassee, FL 32399-1710.

(c) Sharps must be discarded at the point of origin into single-use or reusable sharps containers and 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 the contents reach three-quarters of the sharps' container height. Portable sharps containers must be closed, in a manner to prevent leakage, when not in use.

(d) Each sharps container must be rigid, leak- and puncture-resistant and designed primarily for the containment of sharps. Permanently mounted sharps container holders must bear the phrase and the symbol described in subsection (3) above when this

information on the sharps container is concealed by the sharps container holder.

(e) Reusable sharps containers must only be emptied with an automated or mechanical delidder and dumping system into a puncture-resistant treatment cart at a treatment facility or directly into a treatment unit and processed. Lids may not be removed manually. Reusable sharps containers and treatment carts must be constructed of smooth, easily cleanable materials. Wheeled racks must be decontaminated after each use. Reusable sharps containers must be cleaned to remove visible contamination and decontaminated after each use with an EPA registered tuberculocidal disinfectant used in accordance with the manufacturer directions or exposure to hot water of at least 180 degrees for a minimum of 15 seconds, and any wastewater disposed in accordance with Rule 62-604.130(1), F.A.C., (June 2023) as incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX.

(f) Biomedical waste must be transported in transport containers; sharps containers that are constructed to prevent the release of biomedical waste into the environment are not required to be packaged in a transport container.

(g) Prior to transport, transport containers must be sealed within the generating facility; except that transport containers stored outdoors must be sealed on the premises of the generating facility.

(h) If reusable, transport containers must be constructed of smooth, easily cleanable, and impermeable materials; must be maintained free of cracks or defects that could damage inner bags or impede disinfection processes; and must meet the criteria listed in paragraph (3)(e) above. If single-use, transport containers such as corrugated and fiberboard containers must not be reused.

(4) When a container used to hold non-sharp biomedical waste is accessible to a patron or visitor of the facility, the exterior of a container must be labeled with a minimum of one-inch in diameter biohazard symbol.

Rulemaking Authority 381.0098(3) FS. Law Implemented 381.006(8), 381.0098 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, Amended _____.

64E-16.005 Labeling Requirements

(1) The exterior of biomedical waste bags and sharps containers must be labeled with the generator's name and address unless treatment occurs at the generating facility. Labeling of bags and sharps containers is not required when they are placed into a larger bag or sharps container that is labeled in accordance with this subsection.

(2) The exterior of the transport container must be labeled with the transporter's name, address, transporter number, and 24-hour telephone number prior to transport. If the registered transporter has multiple locations, the transporter information must reflect the location where the vehicles are registered.

(3) When a transport container is transported by multiple transporters, the labeling on the exterior of the container must reflect

that of the transporter taking possession of the container.

(4) When reusable sharps containers are secured to a wheeled rack, which is specific to a single generator, only the rack is required to be labeled with the generator and transporter information specified in subsections (1) and (2).

Rulemaking Authority 381.0098(3) FS. Law Implemented 381.006(8), 381.0098 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, Amended _____.

64E-16.006 Generator Facility Requirements

(1) All biomedical waste generators must be permitted or determined to be exempt in accordance with this chapter.

(a) Mobile units, such as bloodmobiles, that are part of a permitted or exempted stationary biomedical waste generator facility may operate under the permit or exemption of the stationary facility as long as they return to the stationary facility daily.

(b) A biomedical waste generator that applies for exemption, or an exempted biomedical waste generator, must maintain documentation to prove exemption eligibility, as set forth in Rule 64E-16.011(1)(b). An exempted biomedical waste generator must comply with all requirements of this chapter.

(2) A biomedical waste generator must not contract or arrange for the transport of biomedical waste with a person who is not registered with the department as a biomedical waste transporter.

(a) All biomedical waste must be transported by a department-registered biomedical waste transporter in their own transport vehicle, United States Postal Service-approved mail back service, or the generator of the biomedical waste in accordance with this chapter.

(b) Biomedical waste generators transporting less than 25 pounds of their own generated biomedical waste, in their own transport vehicle, on any single occasion, are exempt from transporter registration, fee, and vehicle marking requirements specified in this chapter; except that biomedical waste generators providing remediation services are not exempt from this requirement and must obtain a transporter registration.

(c) Each vehicle used to transport biomedical waste must contain a spill kit or similar as specified in Rule 64E-16.003(1)(g). The biomedical waste must be packaged in accordance with Rule 64E-16.004.

(3) Prior to completion of service at the clean-up site, a biomedical waste generating facility which provides remediation services must remove all biomedical waste and transport it to their department-permitted biomedical waste generating facility, a department-permitted storage facility, department-permitted treatment facility, or DEP-permitted biomedical waste incineration facility.

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

(a) Indoor storage areas must be restricted from public access; designated in the written operating plan; vermin and insect free; maintained in a sanitary condition; and constructed of easily cleanable, impermeable materials.

(b) Outdoor storage areas, including containers and trailers, must meet the criteria listed in paragraph (4)(a) above, be visibly identified with the international biological hazard symbol, which is at least six-inches in diameter, and restricted by lock. Moveable storage containers must be securely affixed and restricted by lock to prevent theft.

(5) Biomedical waste generators that treat less than 25 pounds of their own generated biomedical waste in a 30-day period are exempt from treatment facility permit and fee requirements.

(6) Health care practitioners must inform their home-user patients verbally and in writing of the recommended method for handling biomedical waste generated by the patient in the home setting. Upon discharge of the patients, health care practitioners who administer in-home services must ensure the removal of all biomedical waste generated while the client is under the care of the healthcare practitioner in accordance with subsection (2) above.

(7) Home-users should segregate and package biomedical waste in a way that minimizes exposure to others.

Rulemaking Authority 381.0098(3) FS. Law Implemented 381.006(8), 381.0098 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, Amended _____.

64E-16.007 Transport Facility Requirements

(1) Any person who transports biomedical waste, must be registered in accordance with section 381.0098(5), F.S.; except biomedical waste generators that meet the requirement specified in Rule 64E-16.006(2)(b). Registration must include all vehicles used to transport biomedical waste, including rental vehicles that are used intermittently as vehicles are taken out of use for routine maintenance. Use of the rental vehicle must include written notification to the department, submission of the written authorization from the rental agency stating awareness of the intended use of the vehicle, and decontamination of the vehicle prior to returning to the rental agency. Vehicles must be inspected by the department prior to use.

(2) Subcontracting or brokering of biomedical waste services is prohibited except as permitted by a federal or state declaration of emergency.

(3) Vehicles may only be registered to a single company or facility.

(4) A biomedical waste transporter must transport biomedical waste in their own registered transport vehicle.

(5) No registered transporter may knowingly accept biomedical waste for transport unless it meets the requirements specified in

Rule 64E-16.004.

(6) At the time of pick-up, a registered transporter must provide the biomedical waste facility with a receipt of pick-up. A transporter providing transport services to a generator, transporter, or storage facility must provide written notification to the generator, transporter, or storage facility that the biomedical waste was received by a department-permitted biomedical waste treatment facility or DEP-permitted biomedical waste incineration facility.

(7) Transport facility records must include:

(a) A copy of an agreement with the permitted storage or permitted treatment facility, or other registered transporter agreeing to receive the transporter's biomedical waste;

(b) Quantity by weight of biomedical waste collected monthly or annually;

(c) Name and physical address of each facility from which the waste was collected;

(d) Name and physical address of each facility where the waste was taken; and

(e) Receipts documenting where all the biomedical waste was stored or treated.

(8) No registered transporter shall compact biomedical waste, open sealed packages of biomedical waste, or allow biomedical waste to leak into the environment.

(9) Transfer of biomedical waste from one registered transport vehicle to another is not allowed unless the transfer occurs on the property of a permitted storage or treatment facility, except as provided in subsection (14) below.

(10) No registered transporter shall knowingly deliver biomedical waste for storage, treatment, or incineration to a facility in Florida that does not have a valid permit issued by the department or the DEP.

(11) The exterior of each transport vehicle must be marked with the business name, transporter number, and 24-hour telephone number. The international biological hazard symbol, which is a minimum 6-inches in diameter, and phrase as described in Rule 64E-16.004(3) must be marked on the exterior portion of the transport vehicle which holds the biomedical waste. Each marking on a transport vehicle must be visibly identifiable and a minimum of 2-inches in height. Each transport vehicle must contain a copy of the biomedical waste transporter registration and operating plan.

(12) All transport vehicles must meet the following requirements:

(a) Vehicles containing biomedical waste must be fully enclosed.

(b) Cargo areas must be designed to allow for the biomedical waste packages to be transported in the upright position to prevent leakage of biomedical waste.

(c) Vehicles must be secured against vandalism and unauthorized entry when unattended, and securely closed and locked during

transit.

(d) Vehicles must be vermin and insect free and must be maintained in a sanitary condition.

(e) Vehicle floors or areas used to hold biomedical waste within the transport vehicle must be constructed of easily cleanable, impermeable materials. 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.

(f) Vehicles must contain a spill kit or similar as specified in Rule 64E-16.003(1)(g).

(13) When there is an accident that results in the spillage of biomedical waste, the registered transporter must notify the department in writing within 24 hours and submit a written follow-up report to the department within 10 days.

(14) When a registered transport vehicle is rendered inoperable during transport, biomedical waste may be transferred to another transport vehicle, including a rental vehicle, without being at a permitted storage or treatment facility.

(a) Use of a rental vehicle, which meets the requirements specified in subsections (11) and (12) above, is permitted providing the rental agency agreement specifies the intended use of the vehicle and the department is notified in writing within 24-hours after the incident that the transporter is using a rental vehicle. Notification to the department must include submission of the written agreement from the rental agency stating awareness of the intended use of the vehicle.

(b) The biomedical waste must be removed and transported to a permitted storage or permitted treatment facility within 24 hours of the incident.

(c) Use of the rental vehicle for a period greater than 24 hours requires registration and inspection of the vehicle prior to use.

(d) Decontaminate the rental vehicle prior to returning to the rental agency.

(15) Biomedical waste transport facilities must annually report to the department the total quantity of biomedical waste transported for the period of July 1 of the previous year through June 30 of the current year, by completing and submitting form DH4109-DCHP-06/2021, Biomedical Waste Transport Facility Annual Report, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####.

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

64E-16.008 Storage Facility Requirements

(1) Any person who stores biomedical waste, including sharps collection programs, must be permitted in accordance with section 381.0098(4)(a), F.S.; except that a permit is not required for:

(a) Generators that store their own generated biomedical waste at their permitted or exempted facility;

(b) Generators under different ownership that share a common storage area at the same physical location or store biomedical waste from other generators under the same ownership and located at a different physical address; or

(c) Transporters that store biomedical waste in a registered transport vehicle for a maximum of 72 hours.

(2) Storage of biomedical waste must not exceed 30 days from the day a department-permitted storage facility receives the biomedical waste. Indoor storage areas must meet the requirements specified in Rule 64E-16.006(4)(a). Outdoor storage areas must meet the requirements specified in Rule 64E-16.006(4)(b).

(3) Upon delivery of biomedical waste to a department-permitted storage facility, a receipt must be provided to the person or biomedical waste facility delivering the biomedical waste. A storage facility must provide written notification to the biomedical waste facility from which they received the biomedical waste that the biomedical waste was received by a department-permitted biomedical waste treatment facility or DEP-permitted biomedical waste incineration facility. The requirements in this subsection do not apply to sharps collection programs.

(4) When using rental storage facilities, including self-storage units or portable storage containers, the department must be provided with a copy of the written agreement from the rental storage facility stating awareness that the storage facility will be used to store biomedical waste. Prior to expiration or termination of the agreement, the self-storage unit or portable storage container must be decontaminated before returning to the rental storage facility.

Rulemaking Authority 381.0098(3) FS. Law Implemented 381.006(8), 381.0098 FS. History–New 6-3-97, Formerly 10D-104.0073, Amended .

64E-16.009 Treatment Process Requirements

All treatment processes used to treat biomedical waste must be permitted in accordance with Rule 64E-16.011(1)(g) and (h). Treatment process standards and procedures are located in the Treatment Process Standards and Approval Manual, (June 2023) as incorporated by reference and available at https://flrules.com/gateway/reference.asp?No=Ref-#####.

Rulemaking Authority 381.0098(3) FS. Law Implemented 381.006(8), 381.0098 FS. History–New 6-3-97, Formerly 10D-104.0074, Amended .

64E-16.010 Treatment Facility Requirements

(1) Any person who treats biomedical waste must be permitted in accordance with section 381.0098(4)(a), F.S.; except biomedical waste generators that meet the requirement specified in Rule 64E-16.006(5).

(2) All biomedical waste treatment facilities must be operated, maintained, and enclosed in a manner that will ensure protection and safety of any person that may come in contact with the facility. Floors must be constructed of easily cleanable, impermeable materials. 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. All treatment facilities must contain a spill kit or similar as specified in Rule 64E-16.003(1)(g).

(3) All pressurized steam treatment units or autoclaves are required to meet the process application requirements of Rule 64E-16.009. Existing in-use steam treatment units are exempt from process approval requirements unless the treatment unit is modified or sold.

(4) Prior to utilizing a treatment unit with a department-approved process, onsite validation testing must be conducted and the results submitted to the department. Department-permitted mobile biomedical waste treatment facilities must conduct onsite validation testing for each type of biomedical waste facility where biomedical waste is treated. A single-use treatment unit with an approved process is not required to undergo onsite validation testing. Onsite validation testing shall:

(a) Be conducted by a person with the knowledge, skills, and experience to conduct such testing;

(b) Be conducted in the presence of an agent of the department;

(c) Be conducted using a minimum of three (3) test repetitions;

(d) Result in a minimum log kill in accordance with Table 1 of this section;

(e) Establish operating parameters, such as temperature, pressure, and treatment time; and

(f) Be repeated when any of the following occurs:

1. Failure of any treatment process operational parameters such as time, temperature, or pressure during validation; or

2. Failure to achieve microbial inactivation of the biological indicators during each treatment cycle during validation;

(5) Revalidation testing must be conducted in accordance with subsection (4) above:

(a) Prior to changing the type of biomedical waste to be treated, including that enclosed in specialized packaging that inhibits the treatment of biomedical waste;

(b) Upon relocation of unit;

(c) Upon any modifications to the treatment process operational parameters;

(d) After repairs are made which may affect the efficacy of the unit;

(e) At least once every 12 months for treatment units that utilize parametric monitoring.

(f) When the treatment device has not been used for at least 90 days.

(6) When a treatment unit fails to operate in accordance with the permitted and acceptable operating parameters (such as, but not limited to, time, temperature, pressure, or chemical concentration) or during routine efficacy testing any biological indicators show growth, the facility must:

(a) Discontinue use of the unit, using emergency shutdown procedures if appropriate, until corrective action has been taken and then repeat the treatment cycle. Repeat validation testing must be performed to verify effective treatment;

(b) Ensure that all biomedical waste that was processed by the unit since the last run when the unit was in compliance is identified as untreated biomedical waste, and maintain documentation showing the biomedical waste was properly retreated by a department-permitted biomedical waste treatment facility or DEP-permitted biomedical waste incineration facility;

(c) Document the failure, including date and specific treatment unit;

(d) Document the facility response, including corrective action; and

(e) Notify the solid waste transporter, the receiving facility, and the department within 72 hours of untreated biomedical waste labeled as "treated biomedical waste" leaving the facility for disposal.

(7) Except for single-use treatment units, quality control must be maintained through routine efficacy testing or parametric monitoring. Routine efficacy testing must be conducted using the approved efficacy testing protocol every 40 hours of operation or once every seven days, whichever occurs first, and achieve a minimum Log kill against the spores found in Table 1. Biological indicators may be incubated onsite and results analyzed by the facility staff, provided a log is maintained recording the date, time, and temperature the incubation began and ended and name of person operating the incubator. Department-permitted mobile treatment facilities must provide the results of routine efficacy testing or parametric monitoring to the biomedical waste facility at time of treatment.

Table 1.

Treatment Process	**Log kill**	**Spores**
Steam under pressure	4	*Bacillus stearothermophilus*
Alternative (such as, but not limited to, dry heat, chemical, or gas)	6	*Bacillus atrophaeus*, *Geobacillus stearothermophilus*, or both organisms as determined during the treatment process approval.

(8) Instruments used to measure the parameters must be calibrated at the frequency recommended by the manufacturer, but not less than once every 6 months, unless the instrument is specifically designed by the manufacturer not to require calibration.

(9) Steam treatment units must be equipped to continuously monitor and record time, temperature, and pressure during the entire length of each treatment cycle.

(10) Treatment of biomedical waste must occur within 30 days of receipt by a treatment facility or within 30 days of generation

within a generating facility. A treatment facility must provide a receipt to the generator or transporter at the time of receiving the biomedical waste.

(11) Each time a treatment unit is used, a record must be maintained. Department-permitted mobile treatment facilities must provide a copy of the record to the biomedical waste facility at the time of treatment. The record must include:

(a) Date, time, start and end times, and operator name;

(b) Actual amount of waste treated;

(c) Type of indicator used; and

(d) Post-treatment confirmation results by either:

1. Recording the temperature, pressure, and length of time the waste was treated; or

2. Recording the levels achieved by parametric monitors.

(12) A copy of the manufacturer's instructions for operating and maintaining the treatment unit must be maintained onsite and available for review by the department.

(13) The treatment unit must be serviced for preventive maintenance in accordance with the manufacturer's specifications. Records of maintenance must be onsite and available for review by the department.

(14) The facility must establish and maintain a contingency agreement with another department-permitted biomedical waste treatment facility or DEP-permitted biomedical waste incinerator should the facility experience treatment unit down time that will prevent treatment in accordance with Rule 64E-16.010(11).

(15) The facility must maintain a record of the disposal facility's contact information including the facility name, permit number, physical location and mailing address, and contact name and phone of the entity receiving the treated biomedical waste.

(16) In addition to the requirements set forth in this section, a mobile treatment facility must meet the requirements specified in Rules 64E-16.007(11) and (12); except the vehicle must be labeled with the permit number rather than the transporter number; assembled with easily cleanable, impermeable floors and walls constructed to prevent leakage of biomedical waste into the environment; and free of biomedical waste when en route on the roadways.

(17) Biomedical waste treatment facilities must annually report to the department the total quantity of biomedical waste treated for the period of July 1 of the previous year through June 30 of the current year by completing and submitting form DH4110-DCHP-06/2021, Biomedical Waste Treatment Facility Annual Report, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####.

(18) Treated biomedical waste must be disposed in accordance with Rule 62-701.520, F.A.C., (June 2023) as incorporated by

reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX.

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

64E-16.011 Permits, Exemptions, Registrations, and Inspections

(1) Each person who plans to generate biomedical waste, operate a biomedical waste storage, transport or treatment facility, or operate a sharps collection program must apply for and receive a permit or registration from the department prior to the commencement of operation. Permits and registrations expire on September 30 each year. The permit or registration must be maintained within the facility and must be made available for review by the department.

(a) Biomedical Waste Generator Permit – Application for an initial permit must be submitted to the department on form DH4089-DHCP-06/2021, Application for Biomedical Waste Generator Facility Permit, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####.

(b) Biomedical Waste Generator Exemption – Application for an exemption must be submitted to the department on form DH8011-DCHP-06/2021, Application for Biomedical Waste Generator Facility Exemption, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####. A biomedical waste generator applying for exemption from permitting must submit to the department documentation from the previous 12 months showing the actual weight of biomedical waste generated in each 30-day period during those 12 months was less than 25 pounds. If within any 30-day period during the previous 12 months an exempted generator produced a total of 25 pounds or more of biomedical waste generated at the main office and any branch offices, a permit must be obtained.

(c) Biomedical Waste Storage Facility Permit – Application for an initial permit must be submitted to the department on form DH4107-DCHP-06/2021, Application for Biomedical Waste Storage Facility Permit, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####.

(d) Biomedical Waste Treatment Facility Permit – Application for an initial permit must be submitted to the department on form DH4111-DCHP-06/2021, Application for Biomedical Waste Treatment Facility Permit, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####. Renewals will not be considered complete without submission of an annual report as specified in subsection 64E-16.010(17) and applicable fee.

(e) Biomedical Waste Sharps Collection Program Permit – Application for an initial permit must be submitted to the department on form DH4108-DCHP-06/2021, Application for Biomedical Waste Sharps Collection Program Permit, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####. Needle collection sites currently operating on

the effective date of this rule must obtain the required permit within 90 days of the effective date.

(f) Biomedical Waste Transport Facility Registration – Application for initial and renewal registration must be submitted to the department on form DH4106-DCHP-06/2021, Application for Biomedical Waste Transport Facility Registration, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####. Renewal applications will not be considered complete without submission of an annual report as specified in Rule 64E-16.007(15) and applicable fee.

(g) Biomedical Waste Treatment Process Efficacy Testing Protocol Permit – Application for permit must be submitted to the department using form DH4149-DCHP-06/2021, Application for Biomedical Waste Treatment Process Efficacy Testing Protocol Permit, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####. Any change in a permitted efficacy testing protocol or treatment process requires that a new application be submitted to the department on form DH 4149.

(h) Biomedical Waste Treatment Process Permit – Application for initial permit must be submitted to the department using form DH4152-DCHP-06/2021, Application for Biomedical Waste Treatment Process Permit, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####.

1. Any change in control, ownership, process, or unit in which the process is utilized requires a new application for process permit be submitted to the department at least 90 days prior to the change. Any change in address or name requires an amended application for process permit be submitted to the department at least 30 days prior to the change.

2. A biomedical waste treatment process permit is valid for three years. Renewal applications must be submitted no later than 90 days prior to expiration of an existing permit on form DH4148-DCHP-06/2021, Application for Biomedical Waste Treatment Process Permit Renewal, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####. Renewal applications must be received by the department within 90 days of the effective date of this rule for currently permitted treatment processes.

(2) Permits, exemptions, and registrations are not transferable from one person to another. In the event of any change of ownership or change in control, a permitted, exempted, or registered facility must notify the department at least 30 days prior to the change by submitting an application for permit, exemption, or registration and applicable fee.

(3) When a facility is leased by the owner to a second party for operation of the facility, the second party must apply to the department for an initial permit prior to the commencement of business. The second party is responsible for the operation and maintenance of the facility.

Rulemaking Authority 381.0098(3) FS. Law Implemented 381.006(8), 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) Public sharps collection programs are not required to pay a fee.

(2) Fee schedule.

(a) Generator, Storage, or Treatment Facility Permit:

1. Initial permit $85.00.

2. Permit renewal received by October 1 $85.00, or after October 1 $105.00.

(b) Transport Facility Registration:

1. Initial registration $85.00.

2. Registration renewal received by October 1 $85.00 or after October 1 $105.00.

3. Each vehicle $10.00.

(c) Treatment Process Efficacy Testing Protocol Permit:

1. Initial process approval $300.00.

2. New approval due to change of process $300.00.

3. New approval due to change $150.00.

(d) Treatment Process Permit:

1. Initial process approval $375.00.

2. New approval due to change of process $375.00.

3. New approval due to change $275.00.

4. Permit renewal received no later than 90 days prior to expiration $175.00 or 90 days after expiration of permit $195.00.

(3) All fees submitted to the department are nonrefundable once the department has begun processing the application.

Rulemaking Authority 381.0098(3) FS. Law Implemented 154.06, 381.006,(8) 381.0098 FS. History–New 12-14-92, Amended 1-23-94, 6-3-97, Formerly 10D-104.0078, Amended 1-12-09 _____.

TREATMENT PROCESS STANDARDS AND APPROVAL MANUAL

INCORPORATED BY REFERENCE IN RULE 64E-16.009, F.A.C., TREATMENT PROCESS REQUIREMENTS

TABLE OF CONTENTS

General

This manual is incorporated by reference in Rule 64E-16.009, Florida Administrative Code (F.A.C.).

This manual specifies standards and procedures for obtaining biomedical waste treatment process approval in accordance with section 381.0098, Florida Statutes, and Chapter 64E-16, F.A.C.

Standards for Biomedical Waste Treatment Processes

(1) Biomedical waste must be treated by a process approved jointly by the Department of Health (Department) and the Florida Department of Environmental Protection (DEP). Any modifications made to an existing approved treatment process, requires a new treatment process approval.

(2) In order to obtain Department approval of a treatment process, applicants must first acquire a Biomedical Waste Treatment Process Efficacy Testing Protocol Permit in accordance with Rule 64E-16.011(1)(g), F.A.C., conduct efficacy testing following the approved efficacy testing protocol using an actual, full-scale, working unit, and then obtain a Biomedical Waste Treatment Process Permit, in accordance with Rule 64E-16.011(1)(h), F.A.C.

(3) Efficacy testing must be conducted utilizing biological indicators. Biological indicators must

(a) Contain the minimum concentration of the organism specified in Table 1;

TABLE 1

Treatment Process	Log kill	Organism

Steam under pressure	4	*Bacillus stearothermophilus*
Alternative (such as, but not limited to, dry heat, chemical, or gas)	6	*Bacillus atrophaeus*, *Geobacillus stearothermophilus*, or both organisms as determined during the treatment process approval.

(b) Be commercially prepared from the same lot or batch and certified by a clinical or commercial laboratory;

(c) Have a D-value (the time in minutes required at a fixed temperature to achieve a 90 percent, or 1 Log, reduction in a specific microbial population) equal to 1.8 minutes unless otherwise approved by the Department;

(d) Have a Z-value (the number of degrees Fahrenheit or Celsius required for a thermal death time curve to change by 1 Log_{10}) equal or greater than 50 degrees Fahrenheit or 10 degrees Celsius;

(e) Be compatible with the treatment process, carrier material, packaging, and, if applicable, culture medium;

(f) Be stored in accordance with the manufacturer's specifications;

(g) Be strategically placed in the most difficult areas to treat in each waste load as approved by the Department. When utilizing more than one organism species, the use of an indicator of each species must be placed together in the same location;

(h) Include laboratory, testing site, and untreated controls to verify organism concentration at the onset of testing, during shipment from the laboratory to the testing site, and when processed in the absence of the process method (such as chemical). Neutralizer controls must be used for chemical processes;

(i) Be wrapped in a paper towel and encased in cotton batting or in another carrier system designed to mimic the thermal resistance in the biomedical waste before placement into the waste load to be treated. Materials used to hold the indicator units must provide effective protection from breakage, be loose in the bulk of the biomedical waste and be easily retrievable at the end of each validation run;

(j) Be wrapped in a thick layer of cotton, wool, or equivalent to prevent direct conduction of heat from the metal when metal containers are used to contain the indicators; and

(k) Be analyzed by an independent laboratory when conducting efficacy testing for treatment process approval, initial validation, or revalidation.

(4) Processes that treat waste utilizing heat or saturated steam must:

(a) Result in the internal temperature of the biomedical waste load reaching a minimum of 250 degrees F (121 degrees C);

(b) Utilize a class 5 chemical indicator placed near the biological indicators; and

(c) Utilize an instrument such as a thermocouple to confirm operating parameters.

(5) All treatment processes must be capable of demonstrating quality control through routine efficacy testing or parametric monitoring in accordance with Rule 64E-16.010(4), F.A.C. Treatment processes utilizing parametric monitoring must continuously monitor and record the operating parameters during the entire length of the treatment cycle in real time, and immediately disable the treatment unit using an automated system should the required parametric levels not be reached.

(6) Treatment systems utilizing a grinding, shredding, or similar method must be managed in accordance with the manufacturer's procedural requirements. If this method takes place prior to treatment, procedures that minimize the chance of exposure to waste handlers must be developed and implemented should the method fail or become jammed.

(7) Unless otherwise approved by the Department, the laboratory used to analyze the results of the validation test must be independent of the facility owner or operator.

(8) For autoclaves, each test must document removal of all air from the chamber using one or more pre-vacuum cycles or, depending on the autoclave, one or more steam pulses.

Biomedical Waste Treatment Process Approval

The approval of a biomedical waste treatment process is conducted jointly by the Department, ensuring the process renders the waste noninfectious, and the DEP, determining the environmental impacts of the process. The process approval is a two-step permit process that is limited to the specific unit models that undergo efficacy testing.

- Step One: Biomedical Waste Treatment Process Efficacy Testing Protocol Permit
- Step Two: Biomedical Waste Treatment Process Permit.

Biomedical Waste Treatment Process Efficacy Testing Protocol Permit

The Biomedical Waste Treatment Process Efficacy Testing Protocol Permit must be obtained prior to conducting efficacy testing to ensure parameters established in the protocol will provide effective treatment of

biomedical waste. To obtain a Biomedical Waste Treatment Process Efficacy Testing Protocol Permit, the following must be submitted in writing to the Department and the DEP:

(1) The name of the technology;

(2) The specific model number(s) undergoing testing;

(3) Schematics and photographs of the treatment unit;

(4) Efficacy testing protocol detailing each step of the testing procedure, including:

(a) Description of the treatment process, including:

1. Treatment method; and

2. Operating parameters used by the process for validation such as time, temperature, pressure, chemical concentration and quantity, and the number of pre-vacuums or steam pulses;

(b) Description of the type(s) of biomedical waste the treatment process is designed to treat;

(c) Maximum capacity of the treatment unit;

(d) Length of treatment cycle;

(e) Description of any containers or carts used to load biomedical waste into the treatment unit, including any item used to line reusable containers or carts;

(f) Biological indicator organism species, format, and certification of purity of organism;

(g) Method for placement of biological indicator organisms within the test load;

(h) Description or schematic of the proposed placement of biological indicator organisms, including:

1. Number of biological indicators to be used;

2. Where they will be strategically placed in each test load ensuring they are located in the most challenging area of the treatment unit. This must also include identification and description of any challenging area of the treatment unit and location of any internal measuring devices; and

3. Explanation of why those placements were selected.

(i) Description of the use of biological indicators as laboratory, field, and untreated controls;

(j) Management of the biological indicator organisms, both pre- and post-treatment, including:

1. Procedures for qualitative or quantitative testing, including protocol for microbial assays if applicable;

2. Documentation of chain of custody;

3. Description of procedure for maintaining integrity of the biological indicator organisms during transport to testing facility and laboratory;

(k) Identify the independent laboratory consultant or third-party vendor performing testing and data, including name, address, telephone number, and contact information;

(l) Description of the treated biomedical waste; and

(m) Documentation that any chemical used to treat biomedical waste is registered as a pesticide with the United States EPA and the Florida Department of Agriculture and Consumer Services (FDACS).

(2) Completed form DH4149-DCHP-06/2021, Application for Biomedical Waste Treatment Process Efficacy Testing Protocol Permit, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####.

Biomedical Waste Treatment Process Permit

To obtain a Biomedical Waste Treatment Process Permit, the following must be submitted in a written format:

(1) Efficacy test results achieving complete inactivation of the biological indicators from testing meeting the following criteria:

(a) Testing conducted following the approved efficacy testing protocol;

(b) Testing conducted using an actual, full-scale, working unit;

(c) Testing conducted using actual biomedical waste reflective of the types of waste the treatment unit treats, including a detailed description of the test loads, which must be of the volume or weight and density equal to the maximum capacity of the treatment unit, including:

1. Weight;

2. Moisture content; and

3. Waste-type composition. Test loads must be composed of all types of materials commonly found in the biomedical waste to be treated (such as tissue, body parts, sharps, plastics, glass, woven materials, blood and blood products, suction canisters that are sealed and solidified, etc.), except surrogate waste may be used in place of body parts;

(d) Testing conducted using a minimum of three test repetitions;

(e) Testing conducted certifying the test efficacy following the method for placement of the biological indicator organisms as described in the protocol and utilizing the specified controls; and

(f) Testing conducted within a 72-hour time frame.

(2) Photo documentation of each step of the testing for each test load, including identification of sample locations within the test load for authenticating the test procedures.

(3) Procedure for performing routine efficacy testing or parametric monitoring utilizing the identified critical process parameters and critical limits that define efficacious treatment for this technology.

(4) Completed form DH4152-DCHP-06/2021, Application for Biomedical Waste Treatment Process Permit, herein incorporated by reference and obtained at https://flrules.com/gateway/reference.asp?No=Ref-#####.