CHAPTER 64E-16
BIOMEDICAL WASTE

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.

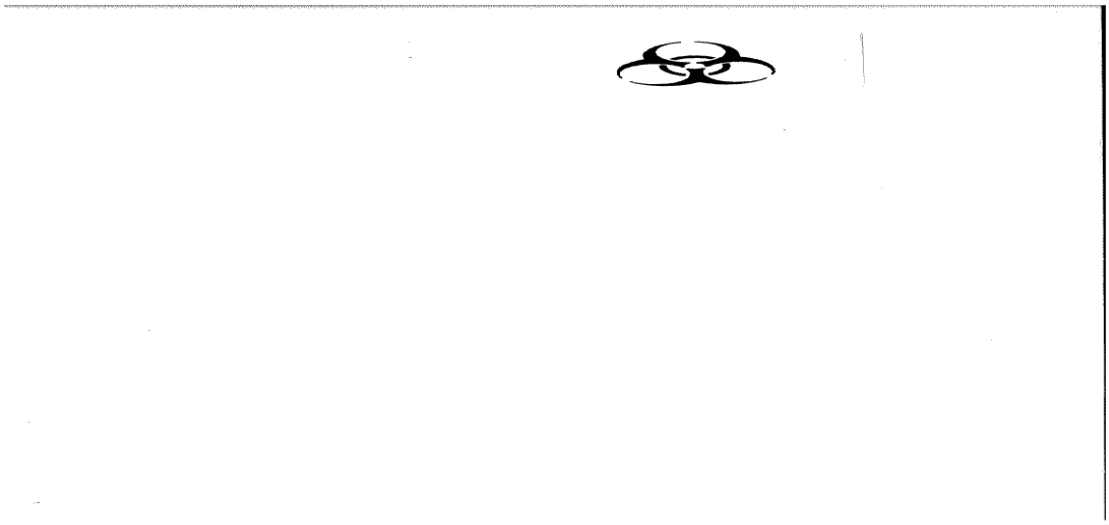
(d) Outdoor storage areas, including containers and trailers, shall, in addition to the above criteria, be conspicuously marked with the international biological hazard symbol as described in paragraph 64E-16.004(2)(b), F.A.C., and shall be secured against

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" × 14" or larger, and at least one inch in diameter on bags smaller than 19" × 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" × 14" or larger, and at least one inch in diameter on outer containers less than 19" × 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 subsections (3) or (4) of this section 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:	
(application received by October 1)	$85.00
(application received after October 1)	$105.00
Treatment Permit:	
(application received by October 1)	$85.00
(application received after October 1)	$105.00
Storage Permit:	
(application received by October 1)	$85.00
(application received after October 1)	$105.00
Transporter Registration (one vehicle):	
(application received by October 1)	$85.00
(application received after October 1)	$105.00
Additional Vehicle	$10.00

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.