

## Chapter 64E-16, Florida Administrative Code

### Biomedical Waste

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

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#### **64E-16.001 Scope of Chapter Rules.**

(1) These rules prescribe minimum standards relating to the management of biomedical waste.

(a) Minimum standards are established for permitting biomedical waste generator facilities, storage facilities, and treatment facilities, and for registration of biomedical waste transport facilities. Such requirements are established to ensure that the waste is properly handled by all facilities that generate, transport, store, or treat biomedical waste.

(b) These rules do not apply to:

1. Incineration of biomedical waste.

2. Linen that is to be laundered and re-used.

3. Contaminated, single-use medical devices that are intended to be re-processed, provided the devices are placed in packaging separate from biomedical waste with written designation for reprocessing.

4. Discarded prescription drugs which are managed in accordance with section 64F-12.023, Florida Administrative Code.

5. 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.

6. 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.

7. Farm operations and agricultural businesses.  
Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 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.**

For the purpose of these rules, the following words and phrases shall have the meanings indicated:

(1) ASTM International, 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. The term includes, but is not limited to, nonliquid human tissue and body parts; laboratory and veterinary wastes which contain human disease-causing agents; human blood, blood products, and body fluids; and discarded sharps. In instances where contamination of a sharp cannot be determined, it shall be regulated as biomedical waste. Also included are the following items, which in the opinion of the department represent a significant risk of infection to persons outside the generating facility:

(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.

(3) Biomedical waste facility - Any person who generates, stores, transports, or treats biomedical waste at a given physical address.

(4) Body fluids - Those fluids which have the potential to harbor pathogens such as human immunodeficiency virus and hepatitis B and C viruses, including blood, blood products, lymph, semen, vaginal secretions, and 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 biomedical waste from an inanimate surface with the use of a United States Environmental Protection Agency registered tuberculocidal disinfectant in accordance with the manufacturer's instructions.

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

(8) Hazardous waste - Those wastes defined in Chapter 62-730, F.A.C.

(9) Health care provider - Any person who provides medical care, nursing care, dental care, psychiatric services, or personal services.

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

(11) Indicator - A device that is used to verify treatment conditions.

(12) Label - A means by which the party responsible for a package of biomedical waste is identified.

(13) Leak resistant - Prevents liquid from escaping into the environment.

(14) Mobile biomedical waste facility - A biomedical waste facility that is capable of moving from one physical address to another physical address.

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

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

(17) Personal service - Direct physical assistance with or supervision of the activities of daily living and the

self-administration of medication and other similar services.

(18) Point of origin - The room or area where biomedical waste is generated.

(19) Public needle 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.

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

(21) Receipt – Written documentation which specifies the type of biomedical waste; amount of biomedical waste; name of transporter, storage facility, or treatment facility; name and physical address of generator; and date of pick up, delivery, or treatment.

(22) Recycling – Any process by which materials which would otherwise become solid waste are segregated, processed, and returned to use in the form of raw materials or products created from the raw materials. **For the purpose of this chapter, this does not mean reuse.**

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

(24) Saturated - Soaked to capacity.

(25) Sealed – Fastened in a manner to prevent the escape of biomedical waste.

(26) Storage -The holding of packaged biomedical waste.

(27) Storage facility - A facility that stores biomedical waste.

(28) Temporary biomedical waste facility – A biomedical waste facility that operates at a fixed physical address for a period of time of not more than 14 consecutive days in conjunction with a single event or celebration.

(29) Transfer - The movement of packaged biomedical waste within a facility or from one transport vehicle to another.

(30) Transport - The movement of biomedical waste to or from a facility.

(31) Transport container - Any rigid container used to transport biomedical waste.

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

(33) 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.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 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 shall:

(a) Comply with local building and zoning codes.

(b) Manage biomedical waste mixed with hazardous waste in accordance with the rules of the Department of Environmental Protection.

(c) Manage biomedical waste mixed with radioactive materials in a manner that does not violate the provisions of Chapter 64E-5, F.A.C., Control of Ionizing Radiation Hazards. After the radioactive component is no longer considered radioactive, the biomedical waste shall be managed in accordance with these rules.

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

(e) Develop a written operating plan, which must be implemented by the facility to manage biomedical waste, in accordance with section 381.0098, F.S., and these rules. 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; and procedures for decontamination. Plans shall be site specific for each location at which a facility provides services. Facilities which treat biomedical waste shall include a treatment contingency plan should the facility experience treatment unit down time which would prevent the treatment of biomedical waste in accordance with subsection 64E-16.010(9). Written operating plans for treatment facilities shall also include items referenced in subsection 64E-16.010(7). Plans shall be updated when regulations, facility policies, or procedures change.

(f) Provide and document training in proper biomedical waste procedures, in accordance with the facility's operating plan, for new personnel, including temporary personnel and interns, who handle biomedical waste as part of their work responsibilities. 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 for treatment facility personnel shall also include that which is referenced in subsection 64E-16.010(8).

(g) Maintain paper or electronic biomedical waste management records for biomedical waste facilities for three years. Records shall be available for review by the department at the time of inspection for the previous 12-month period for permitted or registered facilities and the previous three-year period for exempted facilities. 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 processes, treatment records, training records, and as other.

(2) Biomedical waste in a liquid or semi-liquid form may be disposed into a disposal system, which is approved by the department or the Department of Environmental Protection 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 381.006, 381.0098 FS. Law Implemented 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 Packaging.**

(1) When sealed, packages of biomedical waste shall remain sealed until treatment, except that the department, or an agent of the department, may remove any item of biomedical waste from a sealed or unsealed package of biomedical waste for the purpose of investigation.

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

(3) 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”, “REGULATED MEDICAL WASTE”, or “INFECTIOUS SUBSTANCE.” The symbol shall be red, orange, or black and the background color shall contrast with that of the symbol; or the symbol and background color must comply with the requirements cited in subpart Z of 29 CFR sub-subparagraph 1910.1030(g)(1)(i)(C), Occupational Exposure to Bloodborne Pathogen Standard.



##### (a) Bags.

1. Biomedical waste, except sharps, shall be discarded at the point of origin into impermeable, red plastic bags. Bags shall be sealed at the point of origin.

2. Each bag shall meet the following physical requirements:

a. The international biological hazard symbol shall be at least six inches in diameter on bags 19" x 14" or larger, and at least one inch in diameter on bags smaller than 19" x 14".

b. The impact resistance shall be at least 165 grams and the tear resistance shall be at least 480 grams in both the parallel and perpendicular planes with respect to the length of the bag. Impact resistance shall be determined using the current version of ASTM D1709, Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method, and tearing resistance shall be determined using the current version of ASTM D-1922, Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method, here incorporated by reference and which can be obtained from the Bureau of Community of Environmental Health, 4052 Bald Cypress Way, Bin A08, Tallahassee, FL 32399-1710. Impact and tearing resistance for these construction standards shall be documented by a copy of the results of testing performed by an independent laboratory.

c. The total sum concentration of lead, mercury, hexavalent chromium, and cadmium shall be no greater than 100 parts per million in any bag.

(b) Sharps containers.

1. Sharps shall be discarded at the point of origin into single use or reusable sharps 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 the contents reach three quarters of the sharps container height.

2. Each sharps container shall meet the following physical requirements:

a. Be rigid, leak and puncture resistant.

b. Designed primarily for the containment of sharps.

c. Have at least a one inch in diameter international biological hazard symbol.

d. Manufactured meeting the requirements for metals described in subsubparagraph (3)(a)2.c. above.

3. Permanently mounted sharps container holders shall bear the phrase and the international biological hazard symbol described in subsection (3) above, when this information on the sharps container is concealed by the sharps container holder.

4. Reusable sharps containers shall only be emptied into a puncture resistant treatment cart or directly into a

treatment unit. Reusable sharps containers and treatment carts shall be constructed of smooth, easily cleanable materials. Reusable sharps containers shall be decontaminated after each use.

(c) Transport Containers.

1. Biomedical waste shall be transported only in transport containers except that 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.

2. Prior to transport, transport containers shall be sealed within the generating facility, except outdoor storage containers shall be sealed at the generating facility.

3. Each transport container shall meet the following physical requirements:

a. Be rigid, leak-resistant and puncture-resistant.

b. Have at least a six inches in diameter international biological hazard symbol on transport containers 19" x 14" or larger, and at least one inch in diameter on transport containers less than 19" x 14".

4. If reusable, transport containers shall be constructed of smooth, non-absorbent, easily cleanable materials and shall be decontaminated after each use.

5. If single-use, transport containers may be recycled provided they are not visibly contaminated.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 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-104.004, Amended \_\_\_\_\_.

**64E-16.005 Labeling.**

(1) The exterior of biomedical waste bags and sharps containers shall be labeled with the generator's name and address unless treatment occurs at the generating facility. If a bag or sharps container is placed into a larger bag prior to transport, the label for the exterior larger bag shall comply with this subsection. Under these circumstances, inner bags and inner sharps containers are not required to be labeled.

(2) Transport containers shall be labeled with the contracted transporter's name, address, registration number, and 24-hour telephone number that provides call-back from the transporter within 30 minutes during nonbusiness hours.

(3) When reusable sharps containers are secured to a rack for transport, only the rack is required to be labeled with the generator and transporter information specified in subsections (1) and (2) above.

(4) 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 subsection (1) of these rules.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 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 obtain a permit or exemption from the department.

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

(b) A biomedical waste generator who produces less than 25 pounds of biomedical waste in each 30-day period during the previous 12 months shall be exempted from permit and fee requirements of this chapter but shall comply with all other requirements. A biomedical waste generator choosing to apply for exemption or an exempted biomedical waste generator shall maintain documentation to prove exemption eligibility, as set forth in subparagraph 64E-16.013(1)(a)2.

(c) A permitted or exempted generator may work at a branch office for no more than six hours in any seven day period without applying for an additional permit or exemption. These generators must notify the county health department(s) having jurisdiction over both the main and branch office(s) of the address and operating hours of the branch office within 30 days of commencement of operation at the branch office.

(2) All biomedical waste generated in Florida must be transported by a department registered biomedical waste transporter, United States Postal Service approved mail back service, or the generator of the biomedical waste in accordance with these rules.

(3) Biomedical waste generators transporting less than 25 pounds of their own generated biomedical waste, in their own transport vehicle, on any single occasion, are exempted from transporter registration, fee, and vehicle marking requirements of these rules.

(4) Storage of biomedical waste shall not exceed 30 days at the generating facility. The 30-day period shall commence 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 shall be:

1. Restricted from public access;

2. Designated in the written operating plan;
3. Vermin and insect free;
4. Maintained in a sanitary condition; and
5. Constructed of smooth, easily cleanable materials that are impervious to liquids.

(b) Outdoor storage areas, including containers and trailers shall, in addition to the criteria listed in paragraph

4(a) above, be:

1. Visibly identified with a minimum six inches in diameter international biological hazard symbol as described in subsection 64E-16.004(3), and

2. Restricted by lock.

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

(6) Health care providers shall 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. Health care providers, who administer in-home services, shall remove or have removed by a registered biomedical waste transporter or use of a United States Postal Service approved mail-back service, all biomedical waste generated while the client is a patient of the healthcare provider.

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

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 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 shall obtain a biomedical waste transport facility registration; except biomedical waste generators that meet the requirement specified in subsection 64E-16.006(3), are exempted from biomedical waste transporter registration and fee.

(2) No registered transporter may knowingly accept biomedical waste for transport unless it has been properly segregated, packaged, labeled, and sealed.

(3) At the time of pick-up, a registered transporter shall provide the generator with a receipt of pick-up.

Registered transporters that transport biomedical waste to a department permitted biomedical waste treatment facility or DEP permitted biomedical waste incineration facility shall provide generators with written documentation that the waste was received by a department permitted biomedical waste treatment facility or DEP permitted biomedical waste incineration facility.

(4) Transport facility records must include:

(a) Approximate quantity by weight collected in a month;

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

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

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

(5) During transport, no registered transporter shall compact biomedical waste or allow it to leak into the environment.

(6) Transfer of biomedical waste from one registered transport vehicle to another is not allowed unless the transfer occurs at a permitted storage or treatment facility, except as provided in paragraph 64E-16.007(12)(a).

(7) Any registered transporter who unknowingly fails to comply with subsections (5) or (6) 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.

(8) No registered transporter shall knowingly deliver biomedical waste for storage, treatment, or incineration to a facility which does not have a valid permit issued by the department or the Department of Environmental Protection.

(9) Each transport vehicle transporting biomedical waste shall be marked on the exterior of the vehicle with the following:

(a) Business name;

(b) Registration number;

(c) 24-hour telephone number which provides call-back from the transporter within 30 minutes during nonbusiness hours; and

(d) The phrase and a minimum 6-inch in diameter international biological hazard symbol as described in subsection 64E-16.004(3).

(10) All transport vehicles containing biomedical waste shall be fully enclosed. They shall be secured against

vandalism and unauthorized entry when unattended. Vehicles shall be vermin and insect free and shall be maintained in a sanitary condition. Walls and floors shall be constructed of smooth, easily cleanable materials that are impervious to liquids.

(11) 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.

(12) In a situation where a registered transport vehicle is rendered inoperable during transport, the following is allowed:

(a) Biomedical waste may be transferred to another transport vehicle, including a rental vehicle, without being at a storage or treatment facility.

(b) Use of a rental vehicle is permitted providing:

1. The rental agency is notified of the intended use of the vehicle;

2. The department is notified on the first working day after the incident that the transporter is using a rental vehicle. Notification to the department shall include submission of the written authorization from the rental agency stating awareness of the intended use of the vehicle; and

3. The vehicle is decontaminated before return to the rental agency.

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

(13) Biomedical waste transport facilities shall submit the following information on form DH 4109, Biomedical Waste Transport Facility Annual Report, herein incorporated by reference and which can be obtained from the environmental health section of the county health department, which has jurisdiction for the biomedical waste program in the county where the transport facility is located, or from the internet at <http://www.doh.state.fl.us/Environment/community/biomedical/index.html>

(a) The total quantity of biomedical waste transported from July 1 of the previous year through June 30 of the current year, including that which was:

1. Collected and treated or incinerated in Florida;

2. Collected out of state and treated or incinerated in Florida; and

3. Collected in Florida and treated or incinerated out of state.

(b) The name of any state where biomedical waste was collected for treatment in Florida; and

(c) The name and location of any treatment or incineration facility where Florida generated biomedical waste was taken.

Rulemaking Authority: 381.006, 381.0098 F.S. Law Implemented 381.0098 FS. History-New, 6-3-97, Formerly 10D-104.007, Amended \_\_\_\_\_.

**64E-16.008 Storage Facility Requirements.**

(1) A storage permit is required for a facility that stores biomedical waste, except that a permit is not required for:

(a) Generators that store their own generated biomedical waste;

(b) Generators under different ownership that share a common storage area at the same physical location;

(c) Generators that store biomedical waste from other generators under the same ownership and located at a different physical address; or

(d) Transporters that store biomedical waste in a department registered transport vehicle for less than 72 hours.

(2) Storage of biomedical waste shall not exceed 30 days from the day a department permitted storage facility receives the biomedical waste.

(a) Indoor storage areas shall meet the requirements specified in paragraph 64E-16.006(4)(a).

(b) Outdoor storage areas shall meet the requirements specified in paragraph 64E-16.006(4)(b).

(3) Upon delivery of biomedical waste to a department permitted storage facility, a receipt shall be provided to the biomedical waste facility delivering the biomedical waste.

(4) A department permitted storage facility that contracts with a registered transporter to transport biomedical waste to a treatment facility shall provide the transporter with copies of receipts from the generator.

Rulemaking Authority: 381.06, 381.0098 F.S. Law Implemented 381.0098 FS. History-New, 6-3-97, Formerly 10D-104.0073, Amended \_\_\_\_\_.

**64E-16.009 Treatment Process Requirements.**

(1) Biomedical waste shall be treated by a process approved by the department.

(2) In order to achieve department approval of a treatment process, applicants must first, obtain a Biomedical Waste Treatment Process Efficacy Testing Protocol Permit, conduct efficacy testing, and then obtain a Biomedical

Waste Treatment Process Permit.

(a) Applicants seeking a Biomedical Waste Treatment Process Efficacy Testing Protocol Permit shall submit DH form (# to be assigned), Application for Biomedical Waste Treatment Process Efficacy Testing Protocol Permit, herein incorporated by reference, and the efficacy testing protocol, which details each step of the testing procedure and includes:

1. Detailed description of the test loads including the weight, moisture content, and 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, sharps, plastics, glass, woven materials, blood and blood products, suction canisters that are sealed and gelled, etc., and must be of the volume or weight and density equal to the maximum capacity of the treatment unit;

2. Biological indicator organism species and format;

3. Method for placement of biological indicator organisms within the test load;

4. Description of where biological indicator organisms will be strategically placed in each test load with an explanation of why those placements were selected;

5. Management of the biological indicator organisms, both pre- and post-treatment;

6. Description of how the treatment process works;

7. Maximum capacity of the treatment unit; and

8. Documentation that any chemical used to treat biomedical waste is registered with the United States Environmental Protection Agency and the Florida Department of Agriculture and Consumer Services.

(b) Upon department approval of efficacy testing protocol, the applicant may begin efficacy testing. Efficacy testing shall be conducted:

1. Following the approved efficacy testing protocol;

2. Using an actual, full-scale, working unit;

3. Using a minimum of three (3) test repetitions; and

4. Measuring and qualifying the test efficacy as described in subsection 64E-16.009(3).

(c) Upon completion of efficacy testing, the applicant shall submit:

1. DH form (# to be assigned), Application for Biomedical Waste Treatment Process Permit, herein incorporated by reference;

2. Efficacy testing results;

3. The procedure for performing routine efficacy testing or parametric monitoring; and

4. Identification of critical process parameters and critical limits that define efficacious treatment.

(3) All testing shall result in a minimum log 6 kill against a *Mycobacterium* species and a minimum log 4 kill against *Bacillus atropheus* or *Geobacillus stearothermophilus*. Results shall be verified by an independent laboratory.

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

(5) All materials incorporated herein by reference may be obtained from the Bureau of Community of Environmental Health, 4052 Bald Cypress Way, Bin A08, Tallahassee, FL 32399-1710 or from the internet at <http://www.doh.state.fl.us/Environment/community/biomedical/index.html> Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.0098, FS. History—New 6-19-89, Amended 12-14-92, 1-23-94, 8-20-95, 6-3-97, Formerly 10D-104.013, Amended .

#### **64E-16.010 Treatment Facility Requirements.**

(1) Any person who treats biomedical waste shall obtain a biomedical waste treatment facility permit; except biomedical waste generators that meet the requirement specified in subsection 64E-16.006(5) are exempted from a biomedical waste treatment facility permit and fee.

(2) Steam treatment units without an approved process, which are currently in use at permitted treatment or generator facilities, are exempted from process approval requirements.

(3) Prior to utilizing a treatment unit with an approved process, onsite validation testing shall be conducted and the results submitted to the county health department which has jurisdiction for the biomedical waste program in the county where the treatment facility is located. Department permitted mobile biomedical waste treatment facilities shall conduct onsite validation testing at each 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 using the approved efficacy testing protocol in paragraph 64E-16.009(2)(a);

(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 4 kill against *Bacillus atropheus* or *Geobacillus stearothermophilus*.

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

(4) When required by the department, treatment units currently in operation shall undergo revalidation testing in order to establish new operating parameters.

(a) Revalidation testing shall be conducted:

1. Prior to changing the type of biomedical waste to be treated;

2. Prior to changing the unit operating equipment;

3. After repairs are made which may effect the efficacy of the unit; or

4. At least once every 6 months for treatment units that utilize parametric monitoring.

(b) Revalidation testing shall be conducted in accordance with paragraphs (3)(a), (c), and (d) above.

(5) Except for single-use treatment units, quality control shall be maintained through routine efficacy testing or parametric monitoring. Department permitted mobile treatment facilities shall provide the results of routine efficacy testing or parametric monitoring to the biomedical waste facility at time of treatment.

(a) Routine efficacy testing shall be conducted once every seven days for commercial permitted treatment facilities or once every 40 hours of operation for generators who treat their own waste, in accordance with paragraphs (3)(a) and (d) above.

(b) Treatment units utilizing parametric monitoring shall operate on parameters determined during validation testing as required per paragraph (3)(e) above.

1. Operating parameters shall be revalidated in accordance with subsection (4) above.

2. Instruments used to measure the parameters shall 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.

(6) Steam treatment units shall:

(a) Be equipped to continuously monitor and record time, temperature and pressure during the entire length of each treatment cycle; or

(b) Utilize an indicator that indicates exposure to steam and temperature. The indicator shall be specific to the treatment unit's operating temperature. The indicator shall be placed on a non-heat conducting probe at the center of



each treatment container in the load to confirm treatment. Waste shall not be considered treated if the indicator does not document exposure to steam and the required temperature.

(7) The written operating plan shall specify, at a minimum, the parameters determined from validation testing that provide consistent treatment, such as exposure time, temperature, and pressure. The protocol for treating the waste, including a description of waste containers and placement of the load in the unit, shall be specified.

(8) Personnel operating the treatment unit must be trained in all aspects of its operation, including maintenance and contingency procedures.

(9) Treatment shall occur within 30 days of delivery of biomedical waste by a transporter or generator to a permitted treatment facility or within 30 days of generation within a generating facility.

(10) Upon delivery of biomedical waste to a treatment facility, a receipt shall be provided to the generator or transporter delivering the biomedical waste. At the time of treatment, a permitted mobile treatment facility shall provide the biomedical waste facility with a receipt of treatment.

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

- (a) The date, time, and operator name;
- (b) The type, source, and approximate amount of waste treated;
- (c) The post-treatment confirmation results by either:
  1. Recording the temperature, pressure, and length of time the waste was treated;
  2. Maintaining the temperature and pressure monitoring indicators; or
  3. Recording the levels achieved by parametric monitors.

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

(13) The 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 by the department.

(14) The facility shall establish and maintain a contingency agreement with another department permitted biomedical waste treatment facility, Department of Environmental Protection permitted biomedical waste incinerator, or department registered transporter should the facility experience treatment unit down time that will

prevent treatment in accordance with subsection 64E-16.010(9) above.

(15) In addition to the requirements set forth in this section, a mobile biomedical waste treatment facility shall be:

(a) Secured against vandalism and unauthorized entry when unattended;

(b) Marked on the exterior of the vehicle with the business name, permit number, 24-hour telephone number which provides call-back from the treatment facility within 30 minutes during nonbusiness hours, and placards showing the phrase and a minimum 6-inch in diameter international biological hazard symbol as described in subsection 64E-16.004(3);

(c) Maintained in a sanitary condition and vermin and insect free;

(d) Assembled with smooth, easily cleanable floors and walls that are impervious to liquids;

(e) Constructed to prevent leakage of biomedical waste into the environment; and

(f) Free of biomedical waste when en route on the roadways.

(16) Biomedical waste treatment facilities shall submit the following information on form DH 4110, 1/10, Biomedical Waste Treatment Facility Annual Report, herein incorporated by reference and which can be obtained from the environmental health section of the county health department, which has jurisdiction for the biomedical waste program in the county where the treatment facility is located, or from the internet at <http://www.doh.state.fl.us/Environment/community/biomedical/index.html>:

(a) Total quantity of biomedical waste treated from July 1 of the previous year through June 30 of the current year;

(b) Total quantity of biomedical waste treated which was generated out-of-state from July 1 of the previous year through June 30 of the current year; and

(c) The names of any states where biomedical waste was collected for treatment in Florida.

(17) Treated biomedical waste shall be labeled with the phrase "Treated Biomedical Waste" in accordance with Section 62-701.520, Florida Administrative Code.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.0098 FS. History-New 12-14-92, Amended 1-23-94, 8-29-95, 6-3-97, Formerly 10D-104.0075, Amended \_\_\_\_\_.

#### **64E-16.011 Inspections.**

Department personnel shall inspect registered transport facilities, permitted generator facilities, storage

facilities, and treatment facilities at least once a year. Facilities exempted from the registration and fee requirements under subsection 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 section 381.0098, F.S., or these rules. Results of each inspection shall be recorded on DH Form 4085, 1/05, Biomedical Waste Generator/Transporter/Storage/Treatment Inspection Report, herein incorporated by reference and which can be obtained from the environmental health section of the county health department having jurisdiction.  
Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.0098 FS. History-New 12-14-92, Amended 1-23-94, 8-20-95, 6-3-97, Formerly 10D-104.0076, 11-5-02, Amended \_\_\_\_\_.

**64E-16.012 Transport Facility Registration.**

(1) Biomedical waste transporters shall be registered with the department annually.

(a) Each person who plans to construct, purchase, change control, reopen, or operate a biomedical waste transport facility shall apply for and receive a registration from the department prior to the commencement of operation.

(b) Application for initial and renewal registration shall be submitted to the department on form DH 4106, 1/10, Application for Biomedical Waste Transport Facility Registration, which is incorporated herein by reference and which can be obtained from the environmental health section of the county health department, which has jurisdiction for the biomedical waste program in the county where the transport facility is located, or from the internet at <http://www.doh.state.fl.us/Environment/community/biomedical/index.html>.

(c) Biomedical waste generators that meet the requirements specified in subsection 64E-16.006(3) are exempted from registration.

(2) Biomedical waste transport facility registrations shall expire on September 30 each year. Renewal applications will not be considered complete without submission of an annual report as specified in subsection 64E-16.007(13).

(3) Biomedical waste transport facility registrations shall not be transferable from one person to another.

(4) In the event of an address change, biomedical waste transport facilities shall notify the department at least 30 days prior to the change by submitting an amended application form DH 4106.

Rulemaking Authority 381.0098 FS. Law Implemented 381.0098 FS. History-New, 6-3-97, Formerly 10D-104.0078, 1-12-09, Amended \_\_\_\_\_.

**64E-16.013 Permits and Exemptions.**

(1) All biomedical waste generator, storage, and treatment facility permits shall be obtained from the department annually.

(a) Each person who plans to construct, purchase, change control, reopen, or operate a biomedical waste generator, storage, or treatment facility shall apply for and receive a permit from the department prior to the commencement of operation.

1. Biomedical waste generator permit - Application for an initial permit shall be submitted to the department on form DH 4089, 1/10, Application for Biomedical Waste Generator Facility Permit, herein incorporated by reference.

2. Biomedical waste generator exemption – Application for an exemption shall be submitted to the department on form DH (# to be assigned) 1/10, Application for Biomedical Waste Generator Facility Exemption, herein incorporated by reference. A biomedical waste generator applying for exemption from permitting shall submit to the department documentation from the previous 12 months showing the biomedical waste generated in each 30-day period during those 12 months was less than 25 pounds. Documentation must include the weight of the biomedical waste generated in each 30-day period for the previous 12 months and may be in the form of a monthly log or receipts. 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 at the main office and any branch offices, a permit must be obtained.

3. Biomedical waste storage facility permit – Application for an initial permit shall be submitted to the department on form DH 4107, 1/10, Application for Biomedical Waste Storage Facility Permit, herein incorporated by reference.

4. Biomedical waste treatment facility permit – Application for an initial permit shall be submitted to the department on form DH 4111, 1/10, Application for Biomedical Waste Treatment Facility Permit, herein incorporated by reference. Permits shall be renewed with the submission of an annual report as specified in subsection 64E-16.010(15).

5. Biomedical waste needle collection program permit – Application for an initial permit shall be submitted to the department on form DH 4108, 1/10, Application for Biomedical Waste Needle Collection Program Permit, herein incorporated by reference. Persons engaged in a needle collection program with single or multiple facility locations may operate under a single permit provided:

a. The needle 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.

(b) Permits and exemptions shall not be transferable from one person to another. In the event of an address or name change, permitted or exempted facilities shall notify the department at least 30 days prior to the change by submitting an amended application for permit or exemption.

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

(d) Biomedical waste generator, storage, and treatment permits shall expire on September 30 each year, except that permits for temporary biomedical waste facilities shall be valid for a period of time not to exceed 14 consecutive days. The permit, or a copy thereof, shall be maintained within the facility and shall be made available for review by department personnel.

(2) Biomedical waste treatment process efficacy testing protocol permit – Application for permit shall be submitted to the department using DH form (# to be assigned), 1/10, Application for Biomedical Waste Treatment Process Efficacy Testing Protocol Permit, herein incorporated by reference. Any change in a permitted efficacy testing protocol or treatment process requires that a new application for efficacy testing protocol permit be submitted to the department on form DH (# to be assigned).

(3) Biomedical waste treatment process permit – Application for initial permit shall be submitted to the department using DH form (# to be assigned), 1/10, Application for Biomedical Waste Treatment Process Permit, herein incorporated by reference.

(a) Any change in control, ownership, process, or unit in which the process is utilized requires that a new application for process permit be submitted to the department at least 90 days prior to the change.

(b) Any change in address or name requires that an amended application for process permit be submitted to the department at least 30 days prior to the change.

(c) Approval shall be valid for three years.

(d) Renewal applications shall be submitted on DH form (# to be assigned), 1/10, Application for Biomedical Waste Treatment Process Permit Renewal, herein incorporated by reference, no later than 90 calendar days prior to expiration of an existing approval.

(4) All materials incorporated herein may be obtained from the environmental health section of the county health department, which has jurisdiction for the biomedical waste program in the county where the facility is located, or from the internet at <http://www.doh.state.fl.us/Environment/community/biomedical/index.html>. Rulemaking Authority 381.0006, 381.0098 FS. Law Implemented 381.0098, FS. History-New 6-19-89, Amended 12-14-92, 1-23-94, 6-3-97, 10D-104.008, 11-5-02, Amended \_\_\_\_\_.

**64E-16.014 Fees.**

(1) Public needle collection programs, state-owned and operated biomedical waste facilities, exempted generators, and generators who transport or treat their own biomedical waste in accordance with section 64E-16.006 are not required to pay a fee.

(2) Fee schedule.

Generator Facility Permit:

Initial permit \$85.00

Permit renewal received by October 1 \$85.00 or after October 1 \$105.00

Transport Facility Registration (one vehicle):

Initial registration \$85.00

Registration renewal received by October 1 \$85.00 or after October 1 \$105.00

Additional Vehicle \$10.00

Storage Facility Permit:

Initial permit \$85.00

Permit renewal received by October 1 \$85.00 or after October 1 \$105.00

Treatment Facility Permit:

Initial permit \$150.00

Permit due to change of process or type of waste treated \$150.00

Permit renewal received by October 1 \$85.00 or after October 1 \$105.00

Biomedical Waste Treatment Process Efficacy Testing Protocol Permit \$200.00

Biomedical Waste Treatment Process Permit:

Initial permit \$400.00

Permit renewal received by October 1 \$85.00 or after October 1 \$105.00

Permit due to change of process \$400.00

Change of owner or control permit \$85.00

No fee shall exceed the maximum amount established by the statute. All fees submitted to the department are nonrefundable, once the department has begun processing the application.

Rulemaking Authority: 381.006, 381.0098 FS. Law Implemented 154.06, 381.0098 FS. History-New \_\_\_\_\_.

**64E-16.015 Enforcement and Penalties.**

~~(1) According to section 381.0025, F.S., any person who generates, transfers, treats, stores, transports or disposes of biomedical waste in violation of this chapter; or who interferes with, hinders, or opposes any employee of the department in the discharge of his or her duties, or who impersonates an employee of the department, is chargeable with a misdemeanor of the second degree, punishable as provided in sections 775.082 and 775.083, F.S.~~

(1) (2) Any registered, permitted, or exempted biomedical waste facility is subject to having their biomedical waste facility registration or permit 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 facility:

- (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.

~~(2) (3) For violation of any provision of Chapter 64E-16, F.A.C., the department shall deny, suspend or revoke any biomedical waste permit or impose an administrative fine of up to \$2500 per day for each violation of this chapter or pursue other enforcement action authorized by law.~~ In determining the type and degree of enforcement

action necessary, the department shall take into consideration the following:

(a) The gravity of the violation, including the probability that death or serious physical harm to any person may result or has resulted, the severity of the actual or potential harm, and the extent to which the provisions of the applicable statutes or rules were violated.

(b) Actions taken by the owner or operator to correct violations.

(c) Any previous violations.

Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.0098 FS. History-New \_\_\_\_\_.



<b>DH use only:</b> Check No. _____ Check Amount _____
Date Received _____ Receipt No. _____
Facility Permit No. _____ Date Issued _____
Amended Application Only _____ Date Received _____

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Application for Biomedical Waste Generator Facility Permit**  
Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

Instructions: Do not leave any item blank. Enter NA for non-applicable items. For initial permit, submit completed application along with the \$85.00 fee to the county health department which has jurisdiction for the biomedical waste program in the county where the facility to be permitted is located. State-owned and operated facilities are exempted from the permit fee. To select the county, type the following link into browser: [http://www.myfloridaeh.com/community/biomedical/county\\_coordinators.htm](http://www.myfloridaeh.com/community/biomedical/county_coordinators.htm)

1. Application Type: Initial Permit \_\_\_\_\_ Amended Permit \_\_\_\_\_
2. Application for (Check one): Fixed Facility \_\_\_\_\_ Temporary Facility \_\_\_\_\_ Mobile Facility \_\_\_\_\_  
(Applicant must be a legal entity, i.e.: individual, partnership, corporation, association, or public body)
3. Facility Name: \_\_\_\_\_
4. Facility Address: \_\_\_\_\_  
Street City State Zip Code
5. Contact Person: \_\_\_\_\_ Telephone: ( ) \_\_\_\_\_
6. Facility Email Address: \_\_\_\_\_
7. Name of Facility Owner: \_\_\_\_\_
8. Mailing Address of Facility Owner: \_\_\_\_\_  
Street City State Zip Code
9. Business Phone: ( ) \_\_\_\_\_ 24-Hour Emergency Phone: ( ) \_\_\_\_\_
10. Type of Waste Generated: \_\_\_\_\_ Sharps \_\_\_\_\_ Non-sharps
11. Method of Removal: (Check One)
  1. By applicant, to where: \_\_\_\_\_
  2. By transporter, company name: \_\_\_\_\_ 4-digit registration number: \_\_\_\_\_
  3. By mail-back, company name: \_\_\_\_\_
12. Branch Offices: \_\_\_\_\_ Yes \_\_\_\_\_ No  
If yes, attach sheet with complete name, address, and phone number of branch office(s) and submit to county health department(s) having jurisdiction over both main and branch offices.

Check Type of Facility:

<input type="checkbox"/> Abortion Clinic	<input type="checkbox"/> Funeral Home	<input type="checkbox"/> Podiatrist	<input type="checkbox"/> Trauma Scene Clean-up
<input type="checkbox"/> Acupuncture	<input type="checkbox"/> Home Health	<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Veterinarian
<input type="checkbox"/> Blood Bank	<input type="checkbox"/> Hospital	<input type="checkbox"/> Residential Facility	<input type="checkbox"/> Tattoo and Body Piercing
<input type="checkbox"/> Clinical Laboratory	<input type="checkbox"/> Medical Doctor	<input type="checkbox"/> State Owned/Operated Facility	<input type="checkbox"/> Tattoo Only
<input type="checkbox"/> Dentist	<input type="checkbox"/> Nursing Home	<input type="checkbox"/> Surgical Center/Walk-in Clinic	<input type="checkbox"/> Body Piercing Only
<input type="checkbox"/> Dialysis Clinic	<input type="checkbox"/> Osteopath	<input type="checkbox"/> Other (specify)	

The undersigned owner/owner's representative hereby agrees to operate the biomedical waste generating facility described in this application in accordance with the requirements of Section 381.0098, Florida Statutes, and Chapter 64E-16, F.A.C. The information contained in this application, which serves as a basis for permitting or exemption, is true and correct. I understand that any misrepresentation of the facts in this application, or failure to comply with sanitary standards, is grounds for denial, administrative fine, or revocation of the biomedical waste permit or exemption. Biomedical waste shall be handled within the facility in accordance with the generator's written operating plan. Operating plan must be in compliance with 64E-16, F.A.C.

\_\_\_\_\_  
Signature of Authorized Representative                      Name of Authorized Representative (print or type)                      Date





DH use only: Check No. _____ Check Amount _____	
Date Received _____	Receipt No. _____
Facility Permit No. _____	Date Issued _____
Amended Application Only _____	Date Received _____

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Application for Biomedical Waste Generator Facility Exemption**  
Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

**FOR CURRENTLY PERMITTED GENERATORS ONLY: A currently permitted biomedical waste generator, that produces less than 25 pounds of biomedical waste in each 30 day period, may claim an exemption from the fee and permitting requirements only of Chapter 64E-16, F.A.C. A currently permitted biomedical waste generator applying for exemption from permitting must submit documentation from the previous 12 months showing the biomedical waste generated in each 30 day period during those 12 months was less than 25 lbs. Documentation must include the amount of waste generated in each 30 day period for the previous 12 months and may be in the form of a monthly log or receipts.**

Instructions: Do not leave any item blank. Enter NA for non-applicable items. Submit completed application along with the required documentation to the county health department which has jurisdiction for the biomedical waste program in the county where the facility to be permitted is located. State-owned and operated facilities are exempted from the permit fee. To select the county, type the following link into browser: [http://www.myfloridaeh.com/community/biomedical/county\\_coordinators.htm](http://www.myfloridaeh.com/community/biomedical/county_coordinators.htm)

- Application Type: Initial Exemption \_\_\_\_\_ Amended Exemption \_\_\_\_\_
- Application for (Check one): Fixed Facility \_\_\_\_\_ Mobile Facility \_\_\_\_\_  
(Applicant must be a legal entity, i.e.: individual, partnership, corporation, association, or public body)
- Facility Name: \_\_\_\_\_
- Facility Address: \_\_\_\_\_  
Street City State Zip Code
- Contact Person: \_\_\_\_\_ Telephone: ( ) \_\_\_\_\_
- Facility Email Address: \_\_\_\_\_
- Name of Facility Owner: \_\_\_\_\_
- Mailing Address of Facility Owner: \_\_\_\_\_  
Street City State Zip Code
- Business Phone: ( ) \_\_\_\_\_ 24-Hour Emergency Phone: ( ) \_\_\_\_\_
- Type of Waste Generated: \_\_\_\_\_ Sharps \_\_\_\_\_ Non-sharps
- Method of Removal: \_\_\_\_\_ 1. By applicant, to where: \_\_\_\_\_  
(Check One)  
\_\_\_\_\_ 2. By transporter, company name: \_\_\_\_\_ 4-digit registration number: \_\_\_\_\_  
\_\_\_\_\_ 3. By mail-back, company name: \_\_\_\_\_
- Maximum weight of biomedical waste generated during any 30-day period: \_\_\_\_\_ lbs.
- Branch Offices: \_\_\_\_\_ Yes \_\_\_\_\_ No If yes, attach sheet with complete name, address, and phone number of branch office(s) and submit to county health department(s) having jurisdiction over both main and branch offices.

Check Type of Facility:

<input type="checkbox"/> Abortion Clinic	<input type="checkbox"/> Funeral Home	<input type="checkbox"/> Podiatrist	<input type="checkbox"/> Trauma Scene Clean-up
<input type="checkbox"/> Acupuncture	<input type="checkbox"/> Home Health	<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Veterinarian
<input type="checkbox"/> Blood Bank	<input type="checkbox"/> Hospital	<input type="checkbox"/> Residential Facility	<input type="checkbox"/> Tattoo and Body Piercing
<input type="checkbox"/> Clinical Laboratory	<input type="checkbox"/> Medical Doctor	<input type="checkbox"/> State Owned/Operated Facility	<input type="checkbox"/> Tattoo Only
<input type="checkbox"/> Dentist	<input type="checkbox"/> Nursing Home	<input type="checkbox"/> Surgical Center/Walk-in Clinic	<input type="checkbox"/> Body Piercing Only
<input type="checkbox"/> Dialysis Clinic	<input type="checkbox"/> Osteopath	<input type="checkbox"/> Other (specify)	

The undersigned owner/owner's representative hereby agrees to operate the biomedical waste generating facility described in this application in accordance with the requirements of Section 381.0098, Florida Statutes, and Chapter 64E-16, F.A.C. The information contained in this application, which serves as a basis for permitting or exemption, is true and correct. I understand that any misrepresentation of the facts in this application, or failure to comply with sanitary standards, is grounds for denial, administrative fine, or revocation of the biomedical waste permit or exemption. Biomedical waste shall be handled within the facility in accordance with the generator's written operating plan. Operating plan must be in compliance with 64E-16, F.A.C.

\_\_\_\_\_  
Signature of Authorized Representative                      Name of Authorized Representative (print or type)                      Date



**DH use only:** Check No. \_\_\_\_\_ Check Amount \_\_\_\_\_  
Date Received \_\_\_\_\_ Receipt No. \_\_\_\_\_  
Facility Permit No. \_\_\_\_\_ Date Issued \_\_\_\_\_  
Amended Application Only \_\_\_\_\_ Date Received \_\_\_\_\_

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Application for Biomedical Waste Transport Facility Registration**  
Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

Instructions: Do not leave any item blank. Enter NA for non-applicable items. Initial transporter registration is required for a new facility or a facility that changes ownership or control. The initial registration fee is \$85.00 (one vehicle). Each additional vehicle is \$10.00. Registrations expire September 30 of each year. The registration fee for renewal applications received by October 1 is \$85.00 (one vehicle). Each additional vehicle is \$10.00. The registration fee for renewal applications received after October 1 is \$105.00 (one vehicle). Each additional vehicle is \$10.00. For registration, submit completed application along with the fee to the county health department which has jurisdiction for the biomedical waste program in the county where the vehicles will be kept. State-owned and operated facilities are exempted from the permit fee. Registrations are not transferable from one person to another. To select the county, type the following link into browser: [http://www.myfloridaeh.com/community/biomedical/county\\_coordinators.htm](http://www.myfloridaeh.com/community/biomedical/county_coordinators.htm)

1. Application Type (Choose One): \_\_\_\_\_ Initial Registration \_\_\_\_\_ Renewal Registration \_\_\_\_\_ Amended Registration  
(Applicant must be a legal entity, i.e.: individual, partnership, corporation, association, or public body)
2. Facility Name: \_\_\_\_\_
3. Facility Address: \_\_\_\_\_  
Street City State Zip Code
4. Contact Person: \_\_\_\_\_ Telephone: ( ) \_\_\_\_\_
5. Facility Email Address: \_\_\_\_\_
6. Name of Facility Owner: \_\_\_\_\_
7. Mailing Address of Facility Owner: \_\_\_\_\_  
Street City State Zip Code
8. Business Phone: ( ) \_\_\_\_\_
9. 24-Hour Emergency Phone: ( ) \_\_\_\_\_
10. Federal Employer Identification Number of transporter: \_\_\_\_\_
11. Anticipated counties to be served:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

12. List all known facilities where you will be taking biomedical waste for treatment or further storage (attach additional sheets if necessary):

STORAGE	TREATMENT

13. Submit the following information for each cargo carrying body. (Attach additional sheets, if necessary):

YEAR	MAKE	MODEL	TAG NUMBER	VEHICLE IDENTIFICATION NUMBER

14. For Renewals Only: Please attach copy of the Biomedical Waste Transporter Annual Report DH 4109.

The undersigned owner/owner's representative hereby agrees to operate the biomedical waste transporter facility described in this application in accordance with the requirements of Section 381.0098, Florida Statutes, and Chapter 64E-16, F.A.C. The information contained in this application, which serves as a basis for registration, is true and correct. I understand that any misrepresentation of the facts in this application, or failure to comply with sanitary standards, is grounds for denial, administrative fine, or revocation of the biomedical waste registration. Biomedical waste shall be handled in accordance with the transporter's written operating plan. Operating plan must be in compliance with 64E-16, F.A.C.

\_\_\_\_\_  
 Signature of Authorized Representative      Name of Authorized Representative (print or type)      Date



STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Biomedical Waste Transport Facility Annual Report**

Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

Pursuant to Chapter 64E-16, Florida Administrative Code, a registered transporter seeking renewal shall submit this form together with Form DH 4106, Application for Biomedical Waste Transporter Registration, to the county health department that issues the transporter's biomedical waste transporter registration. Registrations expire September 30 of each year. To select the county, type the following link into browser:

[http://www.myfloridaeh.com/community/biomedical/county\\_coordinators.htm](http://www.myfloridaeh.com/community/biomedical/county_coordinators.htm)

1. Business name of transporter: \_\_\_\_\_
2. Transporter 4-digit registration number: \_\_\_\_\_
3. Quantity of biomedical waste transported from July 1 of last year through June 30 of this year:

**SPECIFY POUNDS OR TONS**

- (a) Collected and treated or incinerated in Florida \_\_\_\_\_ lbs. \_\_\_\_\_ tons
- (b) Collected out of state and treated or incinerated in Florida \_\_\_\_\_ lbs. \_\_\_\_\_ tons
- (c) Collected in Florida and treated or incinerated out of state \_\_\_\_\_ lbs. \_\_\_\_\_ tons
- (d) **TOTAL** \_\_\_\_\_ lbs. \_\_\_\_\_ tons

4. Provide the name of the state(s) where biomedical waste was collected for treatment in Florida:  
\_\_\_\_\_  
\_\_\_\_\_

5. List the facilities and their location (both in state and out-of-state) where Florida biomedical waste was treated:

**FACILITY**

**STATE**

FACILITY	STATE
_____	_____
_____	_____

The information contained in this application is true and correct. I understand that failure to comply with these requirements or any misrepresentation of facts in this application is grounds for denial, suspension, or revocation of a permit, and/or an administrative fine.

\_\_\_\_\_  
Signature of Authorized Representative      Name of Authorized Representative (print or type)      Date



<b>DH use only:</b> Check No. _____	Check Amount _____
Date Received _____	Receipt No. _____
Facility Permit No. _____	Date Issued _____
Amended Application Only _____	Date Received _____

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Application for Biomedical Waste Storage Facility Permit**  
Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

Instructions: Do not leave any item blank. Enter NA for non-applicable items. For initial permit, submit completed application with attachment and \$85.00 fee to the county health department which has jurisdiction for the biomedical waste program in the county where the facility to be permitted is located. State-owned and operated facilities are exempted from the permit fee. Permits are not transferable from one person to another. To select the county, type the following link into browser: [http://www.myfloridaeh.com/community/biomedical/county\\_coordinators.htm](http://www.myfloridaeh.com/community/biomedical/county_coordinators.htm)

1. Application Type (Choose One): \_\_\_\_\_ Initial Permit \_\_\_\_\_ Amended Permit  
(Applicant must be a legal entity, i.e.: individual, partnership, corporation, association, or public body)
2. Facility Name: \_\_\_\_\_
3. Facility Address: \_\_\_\_\_  

Street	City	State	Zip Code
--------	------	-------	----------
4. Contact Person: \_\_\_\_\_ Telephone: ( ) \_\_\_\_\_
5. Facility Email Address: \_\_\_\_\_
6. Name of Facility Owner: \_\_\_\_\_
7. Mailing Address of Facility Owner: \_\_\_\_\_  

Street	City	State	Zip Code
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8. Business Phone: ( ) \_\_\_\_\_
9. 24-Hour Emergency Phone: ( ) \_\_\_\_\_
10. Date of beginning operation: \_\_\_\_\_
11. List where the biomedical waste will be treated or taken for further storage:  
 \_\_\_\_\_  
 \_\_\_\_\_
12. **Attachment:** Attach a schematic of the general layout of the facility and a description of the operation of the facility.

The undersigned owner/owner's representative hereby agrees to operate the biomedical waste generating facility described in this application in accordance with the requirements of Section 381.0098, Florida Statutes, and Chapter 64E-16, F.A.C. The information contained in this application, which serves as a basis for permitting or exemption, is true and correct. I understand that any misrepresentation of the facts in this application, or failure to comply with sanitary standards, is grounds for denial, administrative fine, or revocation of the biomedical waste permit or exemption. Biomedical waste shall be handled within the facility in accordance with the generator's written operating plan. Operating plan must be in compliance with 64E-16, F.A.C.

\_\_\_\_\_  
Signature of Authorized Representative                      Name of Authorized Representative (print or type)                      Date



<b>DH use only:</b> Check No. _____	Check Amount _____
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Facility Permit No. _____	Date Issued _____
Amended Application Only _____	Date Received _____

STATE OF FLORIDA  
DEPARTMENT OF HEALTH

**Application for Biomedical Waste Treatment Process Efficacy Testing Protocol Permit**

Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

Instructions: Do not leave any item blank. Enter NA for non-applicable items. Submit completed application along with the \$200.00 fee and attachments to the Florida Department of Health, Bureau of Community Environmental Health, 4052 Bald Cypress Way, Bin A08, Tallahassee, FL, 32399-1710.

1. Name of Applicant: \_\_\_\_\_
2. Mailing Address of Applicant: \_\_\_\_\_  

Street	City	State	Zip Code
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3. Contact Person: \_\_\_\_\_ Telephone: (    ) \_\_\_\_\_
4. Name of Process: \_\_\_\_\_
5. Description of Treatment Process: \_\_\_\_\_
6. **Attachment:** Efficacy test protocol.

Efficacy testing protocol should detail each step of the testing procedure and shall include:

1. Detailed description of the test loads including weight, moisture content, and 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, sharps, plastics, glass, woven materials, blood and blood products, suction canisters that are sealed and gelled, etc.), and must be of the volume or weight and density equal to the maximum capacity of the treatment unit;
2. Biological indicator organism species and format;
3. Method for placement of the biological indicator organisms within the test load;
4. Description of where biological indicator organisms will be strategically placed in each test load and explanation why those placements were selected;
5. Management of the biological indicator organisms, both pre- and post-treatment;
6. Description of how the treatment process works;
7. Maximum capacity of the treatment unit; and
8. Documentation that any chemical used to treat biomedical waste is registered with the United States Environmental Protection Agency and the Florida Department of Agriculture and Consumer Services.

I understand that approval shall be limited to the type composition, operating parameters, and conditions specified in the efficacy testing data submitted to the department. Any change to the process or unit that might affect efficacy will require a new approval.

The information contained in this application is true and correct. I understand that failure to comply with these requirements or any misrepresentation of facts in this application is grounds for denial, suspension, or revocation of a permit, and/or an administrative fine.

Signature of Authorized Representative	Name of Authorized Representative (print or type)	Date
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<b>DH use only:</b> Check No. _____	Check Amount _____
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Facility Permit No. _____	Date Issued _____
Amended Application Only _____	Date Received _____

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Application for Biomedical Waste Treatment Process Permit**  
Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

Instructions: Do not leave any item blank. Enter NA for non-applicable items. Submit completed application along with the required fee and attachments to the Florida Department of Health, Bureau of Community Environmental Health, 4052 Bald Cypress Way, Bin A08, Tallahassee, FL, 32399-1710. Permits are not transferable from one person to another.

1. Application for (Check one only):
  - a)  Initial process approval (Complete lines 1 through 8 and submit \$400 fee.)
  - b)  New approval due to change of process (Complete lines 1 through 8 and submit \$400 fee.)
  - c)  New approval due to change (Complete lines 1 through 5 and submit \$85.00 fee.)  
 Ownership  Control
2. Name of Process: \_\_\_\_\_
3. Name of Process Owner: \_\_\_\_\_
4. Mailing Address of Process Owner: \_\_\_\_\_  

	Street	City	State	Zip Code
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5. Contact Person: \_\_\_\_\_ Telephone: (    ) \_\_\_\_\_
6. Type of Treatment Process: \_\_\_\_\_
7. Maximum Treatment Capacity: \_\_\_\_\_ pounds/hour
8. **Attachment 1.** Documentation of efficacy testing protocol approval.
9. **Attachment 2.** Efficacy test results, including:
  - a) Identification of the location and dates of the testing;
  - b) Raw data from a minimum of three (3) test repetitions; and
  - c) Certification of the biological indicator organism, including preparation procedure and pre- and post-treatment confirmation of organism population by an independent laboratory;
10. **Attachment 3.** Procedure for monitoring quality control through routine efficacy testing or parametric monitoring.
11. **Attachment 4.** Identification of critical process parameters and critical limits that define efficacious treatment.

I understand that approval shall be limited to the type composition, operating parameters, and conditions specified in the efficacy testing data submitted to the department. Any change to the process or unit that might affect efficacy will require a new approval.

The information contained in this application is true and correct. I understand that failure to comply with these requirements or any misrepresentation of facts in this application is grounds for denial, suspension, or revocation of a permit, and/or an administrative fine.

Signature of Authorized Representative	Name of Authorized Representative (print or type)	Date
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<b>DH use only:</b> Check No. _____	Check Amount _____
Date Received _____	Receipt No. _____
Facility Permit No. _____	Date Issued _____
Amended Application Only _____	Date Received _____

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Application for Biomedical Waste Treatment Process Permit Renewal**  
Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

Instructions: Do not leave any item blank. Enter NA for non-applicable items. Submit completed application along with the required fee of \$85 and attachment to: Bureau of Community Environmental Health, 4052 Bald Cypress Way, Bin A08, Tallahassee, FL , 32399-1710.

1. Has process changed during the last 3 years? \_\_\_Yes\* \_\_\_ No  
\*If yes, Application for a Biomedical Waste Treatment Process Approval must be submitted for new approval.
2. Name of Process: \_\_\_\_\_
3. Name of Process Owner: \_\_\_\_\_
4. Mailing Address of Process Owner: \_\_\_\_\_  

Street	City	State	Zip Code
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5. Contact Person: \_\_\_\_\_ Telephone: (    ) \_\_\_\_\_
- 6..Type of Treatment Process: \_\_\_\_\_
7. Maximum Treatment Capacity: \_\_\_\_\_ pounds/hour \_\_\_\_\_ tons/day
8. **Attachment:** Attach a list of the sites using the process in Florida.

I understand that renewal shall be limited to the type composition, operating parameters, and conditions specified in the efficacy testing data submitted to the department. Any change to the process or unit that might affect efficacy will require a new approval.

The information contained in this application is true and correct. I understand that failure to comply with these requirements or any misrepresentation of facts in this application is grounds for denial, suspension, or revocation of a permit, and/or an administrative fine.

Signature of Authorized Representative	Name of Authorized Representative (print or type)	Date
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<b>DH use only:</b> Check No. _____ Check Amount _____
Date Received _____ Receipt No. _____
Facility Permit No. _____ Date Issued _____
Amended Application Only _____ Date Received _____

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Application for Biomedical Waste Treatment Facility Permit**  
Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

Instructions: Do not leave any item blank. Enter NA for non-applicable items. Submit completed application along with the required fee and attachments to the county health department which has jurisdiction for the biomedical waste program in the county where the treatment facility is located. State-owned and operated facilities are exempted from the permit fee. Permits are not transferable from one person to another. To select the county, type the following link into browser: [http://www.myfloridaeh.com/community/biomedical/county\\_coordinators.htm](http://www.myfloridaeh.com/community/biomedical/county_coordinators.htm)

1. Application for (Check one):

- a)  Initial treatment facility permit Fee: \$150.00
- b)  Change of operating equipment or type of biomedical waste treated Fee: \$150.00
- c)  Amended application (No fee)

2. Facility Type:  Fixed Facility  Mobile Facility  Vehicle Identification Number  
(for mobile only)

3. Name of Facility: \_\_\_\_\_

4. Facility Address: \_\_\_\_\_  
Street City State Zip Code

5. Contact Person: \_\_\_\_\_ Telephone ( ) \_\_\_\_\_

6. Facility Email Address: \_\_\_\_\_

7. Name of Facility Owner: \_\_\_\_\_

8. Mailing Address of Facility Owner: \_\_\_\_\_  
Street  
City State Zip Code

9. Telephone of Facility Owner: ( ) \_\_\_\_\_

10. 24-Hour Emergency Phone: ( ) \_\_\_\_\_

11. Type of Treatment Process:  Steam  Chemical  Other

If other, explain \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

12. Treatment Process Unit Name and Model: \_\_\_\_\_

13. Maximum Treatment Capacity \_\_\_\_\_ pounds/hour \_\_\_\_\_ tons/day

14. Days of Treatment Facility Operation: \_\_\_\_\_

15. Hours of Treatment Facility Operation: \_\_\_\_\_

16. Date Validation Testing is to be Conducted:

17. **Attachment.** For initial permit only:

- a) Documentation of process approval;
- b) Efficacy testing protocol;
- c) Schematic of the general layout of the facility; and
- d) Description of the operation of the facility.

I agree to operate the biomedical waste treatment facility described in this application in accordance with the requirements of section 381.0098, Florida Statutes, and Chapter 64E-16, F.A.C.

The information contained in this application is true and correct. I understand that failure to comply with these requirements or any misrepresentation of facts in this application is grounds for denial, suspension, or revocation of a permit, and/or an administrative fine.

\_\_\_\_\_  
Signature of Authorized  
Representative

\_\_\_\_\_  
Name of Authorized Representative  
(print or type)

\_\_\_\_\_  
Date



STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Biomedical Waste Treatment Facility Annual Report**  
Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

The owner(s) or operator(s) of a biomedical waste treatment facility shall document on this form the quantity of biomedical waste treated annually and submit to the Biomedical Waste Coordinator in the County Health Department that has jurisdiction for carrying out the Biomedical Waste Program in the county where the treatment facility is located. To select the county, type the following link into browser:  
[http://www.myfloridaeh.com/community/biomedical/county\\_coordinators.htm](http://www.myfloridaeh.com/community/biomedical/county_coordinators.htm)

1. Name of Facility: \_\_\_\_\_
2. Facility Permit Number: \_\_\_\_\_
3. Total quantity of biomedical waste treated at this facility from July 1 of last year through June 30 of this year:

<u>Specify Type of Treatment</u>	<u>Quantity</u>	<u>Circle One</u>
(a) _____	_____	lbs.    tons
(b) _____	_____	lbs.    tons
(c) _____	_____	lbs.    tons
(d) _____	_____	lbs.    tons

4. Total quantity of biomedical waste treated which was generated out-of-state from July 1 of last year through June 30 of this year:

\_\_\_\_\_ lbs.    tons

5. Provide the name(s) of the state(s) where biomedical waste was collected for treatment in Florida:  
\_\_\_\_\_  
\_\_\_\_\_

The information contained in this application is true and correct. I understand that failure to comply with these requirements or any misrepresentation of facts in this application is grounds for denial, suspension, or revocation of a permit, and/or an administrative fine.

\_\_\_\_\_  
Signature of Authorized Representative                      Name of Authorized Representative (print or type)                      Date



<b>DH use only:</b> Date Received _____	
Facility Permit No. _____	Date Issued _____
Amended Application Only _____	Date Received _____

STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
**Application for Biomedical Waste Needle Collection Program Permit**  
Authority 381.0098 F.S. and Chapter 64E-16, F.A.C.

Instructions: Do not leave any item blank. Enter NA for non-applicable items. Submit completed application to the county health department which has jurisdiction for the biomedical waste program in the county where the facility to be permitted is located. Permits are not transferable from one person to another. To select the county, type the following link into browser: [http://www.myfloridaeh.com/community/biomedical/county\\_coordinators.htm](http://www.myfloridaeh.com/community/biomedical/county_coordinators.htm)

1. Application Type (Choose One): \_\_\_\_\_ Initial Permit \_\_\_\_\_ Amended Permit  
(Applicant must be a legal entity, i.e.: individual, partnership, corporation, association, or public body)
2. Facility Name: \_\_\_\_\_
3. Facility Address: \_\_\_\_\_  

Street	City	State	Zip Code
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4. Facility Email Address: \_\_\_\_\_
5. Contact Person: \_\_\_\_\_ Telephone: (\_\_\_\_) \_\_\_\_\_
6. Contact Mailing Address: \_\_\_\_\_  

Street	City	State	Zip Code
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7. Business Phone: (\_\_\_\_) \_\_\_\_\_
8. 24-Hour Emergency Phone: \_\_\_\_\_
9. Beginning date of program: \_\_\_\_\_
10. **Attachment 1.** List all collection facilities intended for coverage under this permit, including the street address and city, state, zip code and phone number.
11. **Attachment 2.** Describe how the program will function or operate, including where the biomedical waste will be stored and treated.

The undersigned owner/owner's representative hereby agrees to operate the biomedical waste needle collection program described in this application in accordance with the requirements of Section 381.0098, Florida Statutes, and Chapter 64E-16, F.A.C. The information contained in this application, which serves as a basis for permitting, is true and correct. I understand that any misrepresentation of the facts in this application, or failure to comply with sanitary standards, is grounds for denial, administrative fine, or revocation of the biomedical waste needle collection program permit. Biomedical waste shall be handled within the facility in accordance with the facility's written operating plan. Operating plan must be in compliance with 64E-16, F.A.C.

\_\_\_\_\_  
Signature of Authorized Representative                      Name of Authorized Representative (print or type)                      Date