PROGRAM FOR THE MANAGEMENT AND DISPOSAL OF BIOHAZARDOUS WASTE

University of West Florida

Environmental Health and Safety
11000 University Parkway
Pensacola, FL 32514

BIOHAZARDOUS WASTE DISPOSAL
New 4-1-91 Issued, Revised 1994-2017
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Policy:

UWF shall take every precaution against hazards normally associated with handling and disposal of biohazardous materials to avoid human exposure.

Standards:

Chapter 403, Florida Statutes, and Chapter 62-712, Florida Administrative Codes, Rules of the Florida Department of Environmental Protection (FDEP); and Chapter 381, Florida Statutes, and Chapter 64E-16, Florida Administrative Codes, Rules of Florida Department of Health (FDOH).

The DEP regulates these wastes during OFF-SITE transport, storage, treatment and disposal, and on-site incineration. A fine of $2,500 per day per violation is authorized to be levied against violators during an enforcement action.

FDOH regulates the identification, packaging, storage, and treatment of biohazardous waste at the generating facility.

Responsibility:

It shall be the responsibility of the departmental supervisor, instructor, principal investigator, and/or laboratory supervisor to ensure the proper management, storage, and disposal of all biohazardous and medical wastes generated by their respective department.

The instructor, principal investigator, or laboratory supervisor shall ensure that all red bag waste is appropriately steam sterilized (autoclaved) in accordance with specifications outlined in FAC 64E-16 or managed and placed in an appropriate temporary storage location within 24 hours. All sharps shall be collected in appropriately labeled containers, sealed, and placed in red bags when full.

Definitions:

Biohazardous Waste - any solid or liquid waste which may present a threat of infection to humans. The term includes but is not limited to:

Non-liquid human tissue and body parts; autopsy waste; Laboratory and veterinary waste which contains human disease-causing agents; Used disposable sharps; contaminated equipment; Human blood, human blood products, and body fluids; Other materials which represent a significant risk of infections to persons outside the generating facility;

1. Human Pathogens
2. Oncogenic Viruses
3. Animal Cell Cultures
4. Plant Pathogens
5. Infected or potentially infected animals and/or excised tissue
6. Infected or potentially infected human tissue, secretions or blood
7. Recombinant DNA molecules – construction and/or propagation

Sharps - Devices with physical characteristics capable of puncturing, lacerating, or otherwise penetrating the skin. These devices include, but are not limited to, needles, intact or broken glass, intact or broken hard plastic, and scalpels.

Biological Waste - Any solid waste that causes or has the capability of causing disease or infection and includes, but is not limited to, biohazardous waste, diseased or dead animals, and other wastes capable of transmitting pathogens to humans or animals. The terms "biological waste" and "biohazardous waste" are used interchangeably throughout this policy.

Red Bag - A red polyethylene or polypropylene bag designed to meet labeling, color, and impact specifications for the State of Florida as described in FAC 64E-16.004(2)(b).

Sterilization - A process that destroys all microorganisms and their spores. On-site sterilization must be performed in accordance with the requirements of FAC 64E-16.007. Waste that has been treated on-site must be handled and disposed of as "treated" biohazardous waste and may not be disposed of in the normal trash.

Procedures:

1. All biohazardous waste should be decontaminated before disposal if practical. The preferred method of on-site inactivation is steam sterilization. When this method cannot be used, materials should be decontaminated chemically. (Please refer to enclosed disinfectant list.) Departments generating "red-bag" waste that do not have steam sterilization or chemical deactivation capabilities are exempt from this requirement. In most cases, the use of Red Bags and Sharps containers is sufficient.

    a. Biohazardous waste may include ice water from human or animal specimen shipments. Water that may be biohazardous can be disposed of in a laboratory sink.

    b. Biological material should be handled only in specific biology labs or other laboratories where experiments are being carried out.

    c. Styrofoam containers in which potentially infectious biological specimens are received should be handled using appropriate gloves and should be autoclaved prior to disposal. The foam containers should not be re-used or left around the lab.

    d. Liquid and semi-solid biohazardous (biological) materials such as blood, contaminated water, etc. may be poured directly into a sanitary sewer without prior treatment. Some items may require in-sink grinding or shredding in order to be disposed of in this manner.

    e. Limited storage of non-decontaminated waste is restricted to within the generating laboratory or specified departmental area. No biohazardous waste shall be stored longer than 24 hours without being decontaminated, autoclaved, or placed in the temporary storage location in the generating area. Non-liquid biohazardous materials (e.g. bandages, swabs, etc.) may be stored within the generating area, not exceeding 30 days if the material is in a red bag and an appropriately labeled closed container. The storage and management areas should not be readily available to staff, students, and the general public

(i.e. Storage cannot be in hallways, restrooms, classrooms, or other readily available public areas).

2. The transport of non-decontaminated and decontaminated waste outside the laboratory (i.e., to reach an autoclave or waste container) shall be in closed, red polyethylene or polypropylene bags meeting the current specifications of the State of Florida and the University. Sharp objects such as needles and scalpel blades must be packed in approved puncture-proof containers, sealed, and placed in red puncture-resistant bags for transport.

3. Materials being sent to the autoclave or stored for disposal shall be identified as biohazards by red-bagging and labeling with the universal biohazard sign.

Autoclave (heat sensitive) tape should be applied to all bags prior to sterilization. Each bag must be securely tied and labeled with the name of the originating department. Each laboratory will be responsible for transporting its own material to the autoclave and/or to the designated biohazardous waste container. Each Department, laboratory, and Student Health Clinic unit is responsible for the purchase of red bags, puncture-resistant containers and/or disinfectants.

4. Animals deemed biohazardous should be double-bagged (one sealed plastic bag placed inside another sealed plastic bag). If an animal's teeth or claws present the possibility of puncturing the bag, they must be taped. Dead animal(s) should be refrigerated after autoclaving. (Note: Steam sterilization is not very effective - particularly with larger animals.) Animals, not deemed a biohazardous threat, should be disproof sed along with "biohazardous waste" since animal carcasses are not to be the laced in a regular refuge.

5. All biohazardous solid wastes will be transported and disposed of by a transport and disposal contractor licensed by the Florida Department of Environmental Protection for such services.

a. On-site storage of biohazardous waste shall not exceed 30 days. Sharps may be stored in appropriate containers until full. (NOTE: Sharps containers used for other than sharps waste shall be treated as regular biohazardous waste and must be disposed of within 30 days). All laboratory containers will be labeled with the name, department, address, and phone number of the generator. The primary container shall be identified and dated with the start date and the closing date. Building 58/Room 124-B and 960/ have been designated for the temporary on-site storage locations for biohazardous waste. Other rooms may be designated for temporary storage upon approval of the Office of Environmental Health and Safety. After the primary container has been sealed, the box shall be identified with the following:

b. Additional work practices for infectious materials:

i. Hands should be washed after caring for infected persons, animals, and/or material, after removing gloves, or immediately after possible contact with body fluids.

ii. Contaminated equipment shall be bagged, labeled, cleaned, and disinfected (e.g., utensils and trays).

iii. Use a convenient location for puncture-resistant containers to dispose of equipment such as needles, syringes, scalpel blades, and other sharp items. Needles should not be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand.

iv. Spills (e.g., body fluids) must be cleaned immediately and the area chemically disinfected.

v. The use of personal protective equipment such as gown gloves and eye-covering should be worn when contamination of skin or clothing is likely or has occurred. Laboratory personnel shall wear gloves when handling red bags.

c. **Training**

i. Biomedical waste training is required annually by paragraph 64E-16.003(2) (a), F.A.C. for all personnel that handles biomedical waste. EH&S provides biomedical waste training through the EH&S Biomedical Waste Training online, classroom-based, or Canvas (e-learning). The main components of the training must cover:

- Definition and identification of biomedical waste
- Segregation
- Storage
- Labeling
- Transport
- Spill Clean-up procedures
- Contingency Plan for Emergency Transport
- Procedure for containment
- Treatment method

ii. Environmental Health & Safety (EH&S) maintains records of employee training. Training records must be kept for participants in all training sessions for a minimum of three (3) years and must be available for review by Department of Health (DOH) inspectors. UWF EH&S maintains digital records of training.

6. Any individuals who have contact with human blood or body fluids as a condition of their employment, must be included in and comply with the requirements of the Bloodborne Pathogen Standard, 29 CFR 1910.1030 as adopted by the State of Florida and be included in the University of West Florida's Bloodborne Pathogen Program. Employees of the University who handle biohazardous waste, as a condition of their employment, shall be offered the Hepatitis B vaccine series.

7. Individuals who are injured by a "sharp" (medical instrument) outside of a health facility setting should be referred to the Student Health Clinic or Office of Human Resources to determination of their Tetanus and Hepatitis B immune status. Post-exposure prophylaxis for Hepatitis B should be considered where perceptible evidence of blood or body fluids exists in the sharp (e.g. broken blood vacuum collection tubes) and parenteral exposure has occurred.

8. Any questions regarding the interpretation of this policy should be directed to members of the Biohazardous Materials Review sub-committee or the Director of Environmental Health and Safety. (See attached list.)

DISINFECTANTS

Chlorine: This halogen is a universal decontaminant active against all microorganisms, including bacterial spores. Chlorine combines with protein and rapidly decreases in concentration in its presence. Free, available chlorine is the active element. It is a strong oxidizing agent, corrosive to metals. Chlorine solutions will gradually lose strength so fresh solutions must be prepared frequently.

Sodium hypochlorite is usually used as a base for chlorine decontaminants. An excellent decontaminant can be prepared from household or laundry bleach. These bleaches usually contain 5.25% available chlorine or 52,500 ppm If diluted from 1 to 100, the solution will contain 525 ppm of available chlorine, and if a nonionic detergent such as Naccanol is added in a concentration of about 0.7%, a very good decontaminant is created. These are recommended for certain disinfecting procedures provided the available chlorine needed is considered. Low concentrations of available chlorine (50 to 500 ppm) are active against vegetative bacteria and most viruses. For bacterial spores, concentrations of 2500 ppm chlorine are needed.

Iodine: The characteristics of chlorine and iodine are similar. One of the most popular groups of decontaminants used in the oncologic laboratory is the iodophor, and Wescodyne is perhaps the most popular. The range of dilution of Wescodyne recommended by the manufacturer is 1 oz. in 5 gal. of water giving 25 ppm of available iodine to 3 oz. in 5 gals. giving 75 ppm at 75 ppm, the concentration of free iodine is .0075%. This small amount can be rapidly taken up by any extraneous protein present. Clean surfaces or clear water can be effectively treated by 75 ppm available iodine, but difficulties may be experienced if any appreciable amount of protein is present. For bacterial spores, a dilution of 1 to 40 is recommended by the manufacturer giving 750 ppm for washing the hands, it is recommended that Wescodyne be diluted 1 to 10 or 10% in 50% ethyl alcohol (a reasonably good decontaminant itself) which will give 1,600 ppm of available iodine, at which concentration relatively rapid inactivation of any microorganisms will occur. Iodophor has a built-in indicator. If the solution is brown or yellow, it is still active. Iodophor is relatively harmless to man. Iodophor can be readily inactivated and iodophor stains can be readily removed with solutions of Na 2S 2O3 (sodium thiosulfate).

Formaldehyde-Alcohol: Solutions of 8% formalin in 70% alcohol are considered very good for disinfection purposes because of their effectiveness against vegetative bacteria, spores, and viruses. For

many application,s this is the disinfectant of choice. (NOTE: To be used only where absolutely necessary due to health hazards associated with formaldehyde.)

Alcohols: In concentrations of 70 to 95%, alcoholic solutions are good general-use disinfectants, but they exhibit no activity against bacterial spores.

ADDITIONAL RESOURCES

Additional information may be obtained from the following sources:

1. CHAPTER 62-712 BIOMEDICAL AND BIOLOGICAL WASTE MANAGEMENT
2. Biosafety in the Laboratory: Prudent Practices for Handling and Disposal of Infectious Materials, National Academy Press, Washington, D.C. (1989).
3. Centers for Disease Control Office of Biosafety Atlanta, GA 30333 Phone: (404) 329-3883
4. National Institutes of Health Division of Safety Bethesda, MD 20892 (301) 496-3883
5. National Technical Information Service Publication # PB86-199130 Springfield, VA 22161

MEMBERS OF THE UWF BIOHAZARDOUS MATERIALS REVIEW SUB-COMMITTEE January 31, 2017

1 Director Environmental Health and Safety
2 Laboratory Coordinator Department of Chemistry
3 Program Director Medical Technology
4 Laboratory/Scientific Stores Manager Department of Chemistry
5 Director, Student Health Center

EMERGENCY CONTINGENCY PLAN

If the primary transporter is unable to remove waste from the Facility/Site, another registered biomedical waste transporter will be selected from the Florida Department of Health s Registered Biomedical Waste Transporter list.

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 – Is 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 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 that 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 that 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 that 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, 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, by this chapter. This plan shall be available for review by the department and facility personnel. The plan shall include the following: a description of personnel training; procedures for segregating, labeling, packaging, transporting, storing, and treating biomedical waste; procedures for decontaminating biomedical waste spills; and a contingency plan for emergencies. Facilities that 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 its designee shall train new personnel who handle biomedical waste as part of their work responsibilities. This training shall be provided for the commencement of duties related to biomedical waste handling. Refresher training shall be completed annually by all personnel who handle

the 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 before 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. The use of these generator-specific labels satisfies the requirements of paragraphs 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, 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 the 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., before 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 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 paragraphs 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 by 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 every 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 on site 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 the 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, 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 – anyone

a. Mycobacterium bovis
b. Mycobacterium fortuitum

3. Fungus – anyone

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 the 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 tap water. 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 presents 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, 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 are 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 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 this chapter, grinding shall also mean shredding or hammermilling.

(c) If grinding takes place before 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 before placing the unit into service.
(f) Inspection of the unit, including treatment and maintenance records, will occur during the annual inspection for the hospital's biomedical waste permit.
Rulemaking Authority 381.006, 381.0098 FS. Law Implemented 381.006, 381.0098, 395.002(13), 395.1011 FS.
History–New 6-19-89, Amended 12-14-92, 1-23-94, 8-20-95, 6-3-97, Formerly 10D-104.007.

64E-16.008 Biomedical Waste Transport.
(1) No registered transporter may knowingly accept biomedical waste for transport unless it has been properly segregated, packaged, and labeled.
(2) Each registered transporter shall provide the generator with a receipt of pick-up.
(3) During transport, no registered transporter shall compact biomedical waste or allow it to leak into the environment.
(4) Transfer of biomedical waste from one transport vehicle to another is not allowed unless the transfer occurs at a permitted storage or treatment facility, except as provided in paragraph 64E-16.008(10)(a), F.A.C. Intermodal transfers of biomedical waste are allowed provided transport shipping seals remain intact.
(5) Any registered transporter who unknowingly fails to comply with subsection (3) or (4), of this rule, because such biomedical waste has not been properly segregated or separated from other solid wastes by the generating facility is not guilty of a violation under this rule.
(6) No registered transporter shall knowingly deliver biomedical waste for storage or treatment to a facility that 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, under Section 381.0098, F.S., and by 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 that 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 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, that produces or treats less than 25 pounds of biomedical waste 30-dayperiod periods every 30 days, 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 to before

December 31, 1995, or for which an operating 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 a permit shall be submitted to the department. A permitted generator may work at a branch office for no more than six hours on any day-day day-day seven-day-day seven-day periods 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.