



BIOLOGICAL WASTE PROGRAM

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**FLORIDA ATLANTIC UNIVERSITY
BIOLOGICAL WASTE PROGRAM**

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PURPOSE AND SCOPE

To establish minimum sanitary practices relating to the segregation, handling, labeling, storage, treatment, and disposal of biological and biomedical waste, as established by [Chapter 64E-16, Florida Administrative Code \(FAC\)](#), to minimize exposure of employees, patients, and the public to infectious agents or other potentially infectious materials.

This program applies to all facilities at Florida Atlantic University that generate biological waste in research, clinical and athletic programs.

DEFINITIONS

The following terms are used in this program:

AUTOCLAVE – Apparatus that utilizes moist heat in the form of saturated steam to decontaminate and sterilize biological, surgical, and pharmaceutical objects and materials. Temperature, time, and pressure are the key factors to render materials safe for handling and disposal.

BIOHAZARDOUS WASTE – Also called biomedical waste (see below), is any waste containing infectious materials or potentially infectious materials and includes sharps such as needles, scalpels or razor blades.

BIOLOGICAL WASTE – Any discarded material of biological origin generated from laboratories or clinical facilities which may or may not contain infectious agents. Also included are laboratory supplies, plastic, or glassware that have been in contact with biological material that is either biohazardous or non-biohazardous. Examples of non-biohazardous waste may include: animal carcasses, *E. coli* cloning strains, plasmids, cell cultures, medical devices, and plant material posing no risk to humans or the environment. Biological waste includes biomedical waste. (Definition below)

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

1. 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.
2. 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.

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.

BIOMEDICAL WASTE GENERATOR – A facility or person that produces biomedical/biohazardous 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, educational facilities, physician's offices, laboratories, veterinary clinics and funeral homes.

BODY FLUIDS – Those fluids which have the potential to harbor pathogens, such as human immunodeficiency virus and hepatitis B virus and include blood, blood products, lymph, semen, vaginal secretions, cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids. In instances where identification of the fluid cannot be made, it shall be considered to be a regulated body fluid. Body excretions such as feces, urine and secretions such as nasal discharges, saliva, sputum, sweat, tears, and vomitus shall not be considered biomedical waste unless visibly contaminated with blood.

CONTAMINATED – Soiled by any biomedical waste.

DECONTAMINATION – The process of removing pathogenic microorganisms from objects or surfaces, thereby rendering them safe for handling.

EH&S – The Department of Environmental Health and Safety at Florida Atlantic University.

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

FAC – Florida Administrative Code.

HAZARDOUS WASTE – Hazardous chemicals and materials as defined in **Chapter 62-730, FAC**.

INFECTIOUS SUBSTANCE – Biological agents or materials which are capable of producing an infection or disease in humans.

LEAK RESISTANT – Prevents liquid from escaping to the environment in the upright position.

OUTER CONTAINER – Any rigid type container used to enclose packages of biomedical waste.

PACKAGE – Any material that completely envelops biomedical waste. This includes red bags, sharps containers and outer containers.

POINT OF ORIGIN – The room or area where the biomedical waste is generated.

PUNCTURE RESISTANT – Able to withstand punctures from contained sharps during normal usage and handling.

RESTRICTED – The use of any measure, such as a lock, sign, or location, to prevent unauthorized entry.

SATURATED – Soaked to capacity.

SEALED – Free from openings that allow the passage of liquids.

SHARPS – Objects capable of puncturing, lacerating, or otherwise penetrating the skin.

SHARPS CONTAINER – A rigid, leak and puncture resistant container, designed primarily for the containment of sharps, clearly labeled with the phrase and the international biological hazard symbol as described in the section on *Labeling*.

STEAM TREATMENT UNIT – See Autoclave

TREATMENT – Any process, including steam, chemicals, microwave shredding, or incineration, which changes the character or composition of biomedical waste to render it noninfectious so the waste can be safe for disposal.

UNIT – A clinical, laboratory or veterinary contiguous area under common administrative control in which one or more individuals work together and produce biomedical waste.

UNIT SPECIFIC BIOMEDICAL WASTE PLAN – The plan developed within each unit outlining the specific procedures for segregation, handling, labeling, storage, treatment, and disposing of biomedical waste generated by that unit.

WASTE MANAGEMENT COMPANY – A contracted service that will pick up biomedical waste for treatment and disposal.

POLICY AND PROCEDURES

1. Each generating unit must have a copy of this Biological Waste Program and describe how the unit will address procedures specific to their work area. These descriptions must be incorporated into a written operating Unit Specific Biomedical Waste Plan. The plan must be updated when regulations, facility policies, or procedures change. A Unit Specific Biomedical Waste Worksheet located on page 11 can be used as a guideline for specific procedures in the written operating plan.
2. Biomedical waste must be identified and segregated from other solid and liquid waste at the point of origin. Biomedical sharps must be segregated from non-sharps biomedical waste.
3. A laboratory that generates biohazardous and non-biohazardous biological waste must regard all waste as biomedical waste so that there is only one type of waste stream leaving the laboratory.
4. Biomedical waste mixed with hazardous waste, as defined in **Chapter 62-730, FAC**, must be managed as hazardous waste; for further information contact **EH&S**. Biomedical waste mixed with radioactive waste must be managed in a manner that does not violate the provisions of **Chapter 64E-5, FAC**; for further information contact the University's Radiation Safety Officer. Any other solid waste or liquid, which is neither hazardous nor radioactive in character, combined with untreated biomedical waste must be managed as untreated biomedical waste.
5. All biomedical waste known to contain infectious agents (for example, human immunodeficiency virus, hepatitis virus, or any other significant pathogen) must be rendered inactive through autoclaving or other decontaminating method before leaving the generating facility.
6. Before leaving the point of origin, biomedical waste except sharps, must be packaged and sealed in impermeable, red biohazard bags meeting the requirements outlined in the section on *Storage and Containment*.
7. Sharps must be discarded at the point of origin into a single use sharps containers. Needles, scalpels, and razor blades must not be placed directly into corrugated cardboard biohazardous waste

containers. Sharps containers must be sealed when full. Sharps containers are considered full when materials placed into them reach the designated fill line, or, if a fill line is not indicated, when container is $\frac{3}{4}$ filled. The international biological hazard symbol must be at least one inch in diameter on sharps containers.

8. Filled biomedical waste bags and sharps containers must be placed in the biomedical waste container(s) identified in the Unit Specific Biomedical Waste Plan.
9. Biomedical waste may be disposed into a sanitary sewer system if the following requirements are met:
 - a. Waste is in a liquid form and decontaminated before disposal
 - b. Aerosol formation from the waste material is minimal
 - c. Personal protective equipment is used by the person discharging the waste
 - d. EH&S has approved disposal of liquid waste
10. All surfaces and materials contaminated with spilled or leaked biomedical waste must be cleaned and disinfected with one of the following methods:
 - a. Autoclave at 121⁰C, 15 psi for at least 15 minutes.
 - b. Household bleach solution diluted to 10%, i.e. one part bleach to nine parts water.
 - c. Chemical germicides that are registered by the Environmental Protection Agency as approved disinfectants and are tuberculocidal when used at recommended dilutions.

All biohazardous material from a spill must be placed in an appropriate container and disposed of as biomedical waste.

IMPLEMENTATION OF PROCEDURES

1. Each facility generating biological waste can obtain supplies needed for managing the waste such as biohazardous bags, boxes, liners, clear autoclave bags, and sharp containers from EH&S. Each facility should have two-inch wide sealing tape and a marker to seal containers and label the waste properly.
2. Each biohazardous box should have a liner in place before putting red biohazardous bags into the box. The liner should not be used as a bag. All biohazardous bags placed in the box should be closed after use; bags should not be left opened.
3. All solid infectious waste except sharps must be placed in a biohazardous bag, decontaminated, and picked up for final treatment and disposal by the Waste Management Company. Biohazardous materials **must not be placed in the regular trash stream.**
4. Animal carcasses that are generated in the laboratory will be picked up by EH&S for disposal by the Waste Management Company. Animal carcasses must not be placed in the regular trash.
5. Biomedical waste must be stored in secured designated locations prior to being picked up for disposal. Biomedical waste must be sent to a licensed treatment and disposal facility within thirty

days. Pick up requests can be made on-line at <http://www.fau.edu/facilities/ehs/new-waste-form.php> or call 7-3129 to arrange for a pick up.

LABELING

1. Biohazardous waste bags, boxes, and sharps containers must be labeled with the generator's name and location where the waste was generated. The information on the box must be legible and written with an indelible marker.
2. If a biohazard bag or sharps container is placed into a larger box or container prior to transport, the label for the exterior container must comply with the above information. Inner bags and inner sharps containers are exempt from the labeling requirements above.
3. Outer containers must be labeled with the transporter's name, address, registration number, and 24-hour telephone number prior to transport.
4. All packages containing biomedical waste must 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 must be red, orange, or black and the background color must contrast with that of the symbol or comply with requirements cited in **Subpart Z of 29 CFR§1910.1030(g)(1)(C)**. The international biological hazard symbol must 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".

STORAGE AND CONTAINMENT

1. Storage of biomedical waste at the generating facility **must not exceed 30 days**. The 30-day period must commence when the first non-sharps item of biomedical waste is placed into a red bag or sharps container, or when a sharps container housing only sharps is sealed.
2. Indoor storage areas must have restricted access and be designated in the Unit Specific Biomedical Waste Plan. They must be located away from pedestrian traffic, be vermin and insect free, and must be maintained in a sanitary condition. They must be constructed of smooth, easily cleanable materials that are impervious to liquids.
3. Outdoor storage areas, including containers and trailers, must, in addition to the above criteria, be conspicuously marked with the international biological hazard symbol, and be secured against vandalism and unauthorized entry. The international biological hazard symbol on an outdoor storage area must be a minimum of six inches in diameter.
4. Biomedical waste shall be packaged and sealed at the point of origin in impermeable red biohazard bags or sharps containers. Packages of biomedical waste shall remain sealed until picked up by the waste management company for treatment and disposal. Ruptured or leaking packages of biomedical waste shall be placed into larger container without disturbing the original seal.

5. All outer containers must be rigid, leak resistant, and puncture resistant. Reusable outer containers must be constructed of smooth, easily cleanable materials and must be decontaminated after each use by an approved method.

TREATMENT

FAU has a contract with a Waste Management Company that will transport, treat and dispose of all biomedical waste generated on campus. If a generating unit wants to treat and dispose of their own biomedical waste, they must adhere to the following FAC 64E-16 requirements. Contact the Biosafety Officer for further information on treatment of waste.

1. Biomedical waste must be treated by steam, incineration, or an alternative process approved by the County Health Department as described in section **64E-16.007(4), FAC**, prior to disposal.
2. Steam treatment units must have operating parameters outlined in **64E-16.007(2)(a), FAC** which must be documented and approved by the County Health Department before a unit can be placed into service.
3. Prior to treatment, test loads of biomedical waste which consist of the maximum weight and density of the biomedical waste to be treated shall be prepared to determine temperature, pressure and treatment time. *Bacillus stearothermophilus* spores shall be placed at the bottom, top, front, rear, and center of each biomedical waste bag or container. 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 autoclave may be placed into service and must operate under those parameters once approved by the County Health Department.
4. 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 must 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 will not be considered treated if the tape or equivalent indicator fails to show that a temperature of at least 250°F (121°C) was reached during the process.
5. Each steam treatment unit must be evaluated for effectiveness with spores of *Bacillus stearothermophilus* at least once each 7 days for permitted treatment facilities, or **once each 40 hours of operation** for generators who treat their own biomedical waste. The spores must be placed at the center of the waste load. Evaluation results must be maintained onsite and available for review by the County Health Department.
6. A written log must be maintained for each steam treatment unit. The following shall be recorded for each usage:
 - a. The date, time, and operator name
 - b. The type 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, or

- (2) the temperature and pressure monitoring indicator
 - d. Dates and results of calibration and maintenance
 - e. The results of sterilization effectiveness testing with *B. stearothermophilus* or equivalent
7. A current written operating procedure must specify, at a minimum, the following:
- a. Parameters, determined from testing, that provide consistent treatment, such as exposure time, temperature, and pressure.
 - b. Identification of standard treatment containers and placement of the load in the steam treatment unit.
8. Steam treatment units must also be serviced for preventative maintenance in accordance with the manufacturer's specifications. Records of maintenance must be onsite and available for review.
9. After biomedical waste has been treated, a permitted waste transport service company must pick up the waste for disposal. Treated waste **must not** be placed into the municipal solid waste stream unless approval has been obtained by the local government responsible for solid waste collection and disposal.

TRANSPORT REQUIREMENTS

1. Persons handling packages or spills of biomedical waste must wear appropriate personal protective equipment as specified in **Subpart Z of 29 CFR§1910.1030(d)(3)**, which includes, but is not limited to, gloves, gowns, laboratory coats, and face shields or masks and eye protection.
2. Ruptures or leaking packages of biomedical waste must be repackaged prior to transport.
3. Contract personnel, appropriately trained by the contractor, will remove biomedical waste containers for disposal.
4. Only transporters registered with the Florida Department of Health must be used to transport biomedical waste.

CONTINGENCY PLAN

EH&S has developed a Hazardous Waste Storage Facility Contingency Plan that outlines policies and procedures to manage waste in the event of an emergency. The Waste Management Company also has a contingency plan if there is an emergency during transport or they are unable to pick up the waste in a timely manner.

BIOLOGICAL WASTE TRAINING

Employees who handle biomedical/biological waste as part of their work responsibilities must be trained in the proper management of biological waste before these duties commence and annually thereafter. The unit specific written operating plan shall include a description of the training. EH&S will provide this training in classroom and on-line formats. If training is not provided by EH&S, then the training curriculum must be approved by EH&S and copies of all training records must be forwarded to EH&S.

PERMITS AND EXEMPTIONS

1. All biomedical waste generating facilities must obtain a permit from the County Health Department on an annual basis if the waste is more than 25 lbs in a 30-day period. Permits expire every year on September, 30th.
2. Facilities generating less than 25 lbs of waste in a 30-day period are issued an exemption for three years.
3. EH&S will maintain permit and exempt information for all FAU campuses.
4. Copies of the permit will be sent to each generating facility to post in a conspicuous place.

RECORDKEEPING AND INSPECTIONS

Records of waste disposal and management must be maintained for three years and must be available for review by the County Health Department. The County Health Department conducts annual inspections for all permitted facilities.

RESPONSIBILITY OF GENERATING UNIT

The PI, supervisor, or facility manager is responsible for ensuring the proper management, storage, and disposal of all biological or biomedical waste generated by their facility. Waste that is improperly managed must be corrected immediately. All leaky containers of biomedical waste must be repackaged into a leak-proof container, and the responsible party must decontaminate all spills from the biomedical waste as outlined in this manual.

ENFORCEMENT AND PENALTIES

Any one in violation of F.A.C. 64E-16, or who interferes with, hinders, or opposes any County Health Department employee in the discharge of his duties, is chargeable with a misdemeanor of the second degree.

If any violation occurs, the County Health Department may deny, suspend, or revoke any biomedical waste permit or impose an administrative fine of up to \$2500 per day for each violation of the FAC 64E-16.

FLORIDA ATLANTIC UNIVERSITY
UNIT SPECIFIC BIOMEDICAL WASTE WORKSHEET

Lab Director or Primary Investigator: _____ Location: _____

1. Biomedical/biohazardous waste is segregated, decontaminated, and contained in the following location(s):

2. What type of decontaminating method is being used?

3. What type of treatment method is being used?

4. If County Health Department permitted steam (autoclave) treatment is used, please answer the following as they apply (as written in the *TREATMENT* section of this manual):

Initial efficacy test using Bacillus spores was approved by the County Health Department. Yes ___ No ___
Temperature properly monitored either through onboard unit or chemical indicator. Yes ___ No ___
Preventative maintenance completed routinely and records maintained. Yes ___ No ___
A standard operating procedure for the autoclave in maintained. Yes ___ No ___

5. Are red biomedical/biohazardous waste bags and properly labeled sharps containers being used? _____

6. Biological waste storage area or containers used to store accumulated waste until disposal are located at:

7. The company which disposes of the accumulated biomedical/biohazardous (storage time does not exceed 30 days) in our facility is: _____

8. Work surfaces and laboratory equipment contaminated with spilled or leaked biomedical/biohazardous waste are properly cleaned and decontaminated with:

9. The spill kit for decontamination of work surfaces and cleaning spills is located at:

10. All employees who handle biomedical/biological waste as part of their work responsibilities have gone through Biological Waste Training given by **EH&S**? Yes ___ No ___ (mark one)