FAU
FLORIDA ATLANTIC UNIVERSITY

Division of Administrative Affairs

Environmental Health and Safety
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Biomedical Waste Program Manual

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1. PURPOSE:

Cover page for FAU Biomedical Waste Program Manual

2. CONTENTS:

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Approved and issued by order of:

Wendy Ash Graves
Director, Environmental Health and Safety

DATE: 02/01/22

POLICY MAINTENANCE SECTION

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Version	Date	Summary of Changes	Reviewed By
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FLORIDA ATLANTIC UNIVERSITY
ENVIRONMENTAL HEALTH AND SAFETY

Biomedical Waste Program Manual

Florida Atlantic University

Office of Environmental Health and Safety

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Purpose and Scope

To establish minimum sanitary practices relating to the segregation, handling, labeling, storage, treatment, and disposal of biological/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/biomedical 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 biological 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

biological/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 biological/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 BIOLOGICAL/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.

Responsibilities

Environmental Health and Safety (EH&S) has the overall responsibility for management of the Biomedical Waste Program, including:

- Contract Management: Ensures that the waste is picked up regularly in accordance with Florida Administrative Code (FAC) 64E-16. This also includes maintenance of shipping manifests, invoices, and other contract documents.

- Inspection Coordination: Coordinates Department of Health (DOH) biomedical waste inspections and provides assistance to DOH inspector. Prepares corrective action reports and forwards them to the DOH.

- Training: Offers online training to FAU personnel and students through Skillsoft Percipio.

- Principal Investigators, Instructors and Clinical Supervisors are responsible for supervising biomedical waste practices in their respective areas. This includes:

    - Ensuring that all biological/biohazardous/biomedical waste (hereafter referred to as biomedical waste) is handled and disposed of in accordance with the requirements of the FAU Biomedical Waste Program.

- Maintaining training documentation for all affected personnel.

Segregation of Biomedical Waste

Biomedical waste must be separated from all other waste streams at the point of origin per the requirements of FAC 64E-16. Once separated, the waste must be placed in either a sharps container or a red bag. Each individual location is required to have an adequate number of sharps containers and approved red bags to dispose of the biological/biomedical waste generated.

Mixed chemical and biomedical waste

Biological/biomedical waste mixed with chemical waste, as defined in FAC 62-730, must be managed as hazardous waste. Any biomedical waste that is mixed with chemical waste must be separated if possible. Any questions pertaining to mixed chemical and biological waste disposal should be directed to EH&S.

Mixed radioactive and biomedical waste

Biomedical waste mixed with radioactive waste must be managed in accordance with the provisions of FAC 64E-16, after the radioactive component has decayed in storage as provided for in FAC 10D-91. Packaging requirements of FAC 10D-91 shall be followed unless the requirements of FAC 64E-16 are more restrictive. Any questions pertaining to mixed radioactive and biological waste should be directed to EH&S.

Animal Waste/Animal Carcasses

Animal waste/carcasses exposed to pathogens, all nonhuman primate carcasses and all identifiable human tissues must be segregated from other biomedical waste. The biomedical waste bags used for this type of waste must be placed within leak-proof containers labeled “Pathological Waste” and “For Incineration Only.” Biomedical waste bags storing this type of waste may be placed in freezers or refrigerators until packaged for shipment to an off-site incinerator.

Containment

The following minimum containment standards must be met according to FAC 64E-16:

- Generators of biomedical waste shall purchase red bags from vendors who certify that their bags meet the applicable standards and maintain a copy (EH&S orders the red bags and supplies to the labs).

- Sharps containers shall meet the requirements of FAC 64E-16. Generators of biomedical waste shall purchase sharps containers from vendors who meet the above standards (EH&S purchases sharps containers and supplies to the labs).

- Place all contaminated sharps into red sharps containers at the point of origin. Non-infectious needles and needle-syringe units must be placed in sharps containers. Sharps containers must be sealed and labeled prior to disposal by the biomedical waste transporter.

- Sharps shall be discarded at the point of origin into single use or reusable sharps containers. Sharps containers must be sealed when filled to the line indicated on the container.

- Sharps containers are considered full when materials placed into it reach the designated fill line, or, if a fill line is not indicated, approximately ¾ full.

- Red bags must be placed into an outer container at the point of origin prior to disposing of any biomedical waste. The outer container must 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. Red bags must be sealed and labeled prior to disposal by the generator.

- Packages of biological/biomedical waste shall remain sealed until picked up by the waste management company for treatment and disposal.

- Ruptured or leaking packages of biomedical waste must be placed into a larger container without disturbing the original seal.

Labeling

- 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 CFR 1910.1030(g)(1)C, Occupational Exposure to Bloodborne Pathogen Standard.

- All sealed biomedical red bags and sharps containers must be labeled with the following information:
    - Facility Name (e.g., FAU)
    - Facility Address or department physical address
    - If a sealed red bag or sharps container is placed into a larger red bag prior to transport, labeling the exterior bag is sufficient. Outer containers are labeled by the biomedical waste transporter with their name, address, registration number and 24-hour phone number.

Storage

Storage of biomedical waste shall not exceed 30 days. The 30 days commences:

- 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.

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.

Outdoor storage areas, including containers and trailers, shall, in addition to the above criteria, be conspicuously marked with the international biological hazards symbol as described in FAC 64E-16.004(2)(b), 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.

Transport

On the Boca Raton, Jupiter and HBOI campuses, EH&S will pick up biomedical waste from labs and transport the waste to our storage facilities on each campus. Pickups are conducted at least weekly. Transportation and treatment of biomedical waste off campus is conducted by our medical waste transport vendor. Currently that vendor is: Stericycle.

Training for Personnel

Biomedical waste training is required annually by FAC 64E-16.003(2)(a) for all personnel that handle biomedical waste. EH&S provides online biomedical waste training through Skillsoft Percipio (see the FAU training page: https://www.fau.edu/ehs/training/; course title: Biosafety Hazardous Waste and Disposal). 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

Each facility (lab; generator) must maintain records of employee training. Training records must be kept for participants for a minimum of three (3) years and must be available for review by Department of Health (DOH) inspectors. EH&S has access to digital training records for all FAU-based faculty, staff, and students.

Treatment

For BSL1 and BSL2 labs, solid biomedical waste does not require pre-treatment prior to being transported by EH&S and/or our Biomedical Waste Transport Vendor. For BSL3 laboratories, pre-treatment is recommended using steam sterilization methods. Autoclaves used for waste treatment must meet performance guidelines as set by FAC 64E-16.007. Before any dry waste treatment is conducted onsite, the FAU Biosafety Officer must be contacted for a consultation.

For BSL1 and BSL2 labs, liquid biomedical waste should be treated with bleach at a final concentration of 10% (1 part undiluted bleach to 9 parts liquid waste) for a minimum of 30 minutes (overnight is best) prior to disposal down the sanitary drain. Other requirements:

- Aerosol formation from the waste material is minimal
- Personal protective equipment is used by the person discharging the waste
- EH&S has approved disposal of liquid waste

The table below summarizes specific waste streams and how they are to be handled.

Type of Biowaste	Treatment Requirement	Required Container	Disposed of by
Blood and body fluids (Regulated Medical Waste) or other biohazardous liquids	Treated with 10% bleach (final concentration; minimum 30 minutes treatment time) and disposed through the sanitary sewer	Liquid-tight container	User
Microbiological Waste, including Risk Group 1, 2 and 3 organisms: (Regulated Medical Waste)	Autoclaved by vendor (Stericycle)	Red bags, box and BT-96	Vendor (Stericycle)
Pathological Waste (animal carcasses infected with human Risk Group 1, 2 and 3 organisms; including transgenic mice)	Incinerated by vendor (Stericycle)	Red bags, box and BT-96 (Marked Pathological Waste for Incineration)	Vendor (Stericycle)
Pathological Waste (animal carcasses that were used for in vivo testing of pharmaceuticals; Regulated Medical Waste)	Incinerated by vendor (Stericycle)	Red bags, box and BT-96 (Marked Pathological Waste for Incineration)	Vendor (Stericycle)

Spill Clean-Up Procedure

Dry biomedical waste spill:

- Put on appropriate PPE (minimum lab coat, gloves, eye/face protection)
- Put spilled waste into a new red bag
- Place old reg bag into new red bag, then place into biomedical waste container
- Wipe down area of spill with 10% bleach solution or appropriate germicidal disinfectant
- Place waste from cleanup into red bag

Liquid biomedical waste spill**:**

- Inform lab of spill, evacuate lab, place sign on door so that no one enters area
- Let aerosols settle for 15 minutes
- Put on appropriate PPE (minimum lab coat, gloves, eye/face protection
- Place absorbent material gently over the spill (e.g., paper towels)
- Gently pour bleach solution (or other appropriate germicidal disinfectant) around and on the spill starting at the outer edge of the spill and working your way to the center
- Let bleach/disinfectant work for the appropriate amount of time (minimum 30 minutes for bleach)
- Place absorbent material into red bag
- Spray area again with 10% bleach or disinfectant and wipe up with absorbent towels; ensure that surrounding areas where spill may have splashed are also disinfected
- Place all clean up material into red bag, then place the red bag into a second red bag before placing into biomedical waste container

Contingency Plan

In the event that the current Biomedical Waste Transport vendor (Stericycle) cannot provide disposal services, FAU will engage another transport vendor (e.g., Mediwaste Transport Solutions, HES Med Waste or Medigreen Waste).

Responsibility of Generating Unit

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

Generating Units

Biomedical waste is generated at the following FAU campuses and affiliated locations:

FAU
777 Glades Rd
Boca Raton, FL 33431

FAU McArthur Campus
5353 Parkside Dr
Jupiter, FL 33458

FAU Davie Campus
3200 College Ave
Davie, FL 33314

FAU HBOI Campus
5600 US-1
Fort Pierce, FL 34946

FAU College of Medicine Clinic
880 NW 13th St
Fl 4
Boca Raton, FL 33486

FAU Westgate Community Wellness Ctr
1650 Osceola Dr
West Palm Beach, FL 33409

FAU Northwest Community Health Alliance
720 8th St
West Palm Beach, FL 33401

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.

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Unit Specific Biological Waste/Biomedical Waste Operating Plan

Lab Director or Primary Investigator:_____Location: _____

1. Biological/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?
   Yes___ No___

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_____