Northeastern University
Academic and Research Safety

MEDICAL AND BIOLOGICAL WASTE MANAGEMENT PROGRAM

Responsible Administrator: Institutional Biosafety Officer
Version: 2.0
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Summary: The Northeastern University Medical and Biological Waste Management Program was established to maintain compliance with federal, state and local regulations. The purpose of this program is to define the policies and procedures for the safe handling, containment, and disposal of regulated medical, biological, recombinant, and sharps waste.

1.0 SCOPE

1.1 OVERVIEW

The Northeastern University Medical and Biological Waste Management Program was established to maintain compliance with federal, state and local regulations. The policies and procedures outlined in this program were developed to assist personnel in the proper handling, collection, and disposal of medical, biological, and sharps waste in order to minimize the risk of serious injury, exposure, or environmental release.

Northeastern University manages biological waste in accordance with the Massachusetts State Sanitary Code (105 CMR 480.000). Biological waste is defined as wastes that may cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible illness; or pose a substantial present potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed. This includes the following:

- Blood and blood products
- Animal and animal wastes if treated with or contaminated with an infectious agent
- Culture of infectious agents or attenuated vaccines
- Sharps
- Biotechnology effluent materials

All medical or biological waste must be treated on-site or transported off-site for treatment at a minimum once per calendar year.

1.2 GENERAL APPLICABILITY

The Northeastern University Medical and Biological Waste Management Program is applicable to all individuals generating medical or biological waste at or under the jurisdiction of Northeastern University.

1.3 PURPOSE

The purpose of the Medical and Biological Waste Management Program is to define the policies, procedures and compliance regulations for the safe handling, containment, and proper disposal of regulated medical, biological, and sharps waste.

2.0 DEFINITIONS

2.1 MEDICAL OR BIOLOGICAL WASTE

Medical and biological waste, per 105 CMR 480 are waste that because of its characteristics may cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible illness; or pose a substantial present potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed. Including:

2.1.1 BLOOD OR BLOOD PRODUCTS

Discarded bulk human blood and blood products in free draining, liquid state; body fluids contaminated with visible blood; and materials saturated/dripping with blood. Blood products shall not include feminine hygiene products.

2.1.2 PATHOLOGICAL WASTE

Human anatomical parts, organs, tissues and body fluids removed and discarded during surgery, autopsy, or other medical or diagnostic procedures; specimens of body fluids and their containers; and discarded material saturated with body fluids other than urine. Pathological waste shall not include: teeth and contiguous structures of bone without visible tissue, nasal secretions, sweat, sputum, vomit, urine, or fecal materials that do not contain visible blood or involve confirmed diagnosis of infectious disease.

2.1.3 CULTURE AND STOCKS OF INFECTIOUS AGENTS AND ASSOCIATED BIOLOGICALS

All discarded cultures and stocks of infectious agents and associated biologicals, including culture dishes and devices used to transfer, inoculate, and mix cultures, as well as discarded live and attenuated vaccines intended for human use, that are generated in:

(a) Laboratories involved in basic and applied research
(b) Laboratories intended for educational instruction or
(c) Clinical laboratories.

2.1.4 CONTAMINATED ANIMAL WASTE

Contaminated carcasses, body parts, body fluids, blood or bedding from animals known to be:

(a) Infected with agents of the following specific zoonotic diseases that are reportable to the Massachusetts Department of Agricultural Resources, Bureau of Animal Health pursuant to 105 CMR 300.140: African Swine Fever, Anthrax, Avian Influenza – H5 and H7 strains and any highly pathogenic strain, Bovine Spongiform Encephalopathy (BSE), Brucellosis, Chronic Wasting Disease of Cervids, Eastern Equine Encephalitis Virus, Foot and Mouth Disease, Glanders, Exotic Newcastle Disease, Plague (Yersinia pestis), Q fever (Coxiella burnetti), Scrapie, Tuberculosis, Tularemia (Francisella tularensis), West Nile Virus;
(b) Infected with diseases designated by the State Epidemiologist and the State Public Health Veterinarian as presenting a risk to human health;
(c) Inoculated with infectious agents for purposes including, but not limited to, the production of biologicals or pharmaceutical testing.

2.1.5 SHARPS

Discarded medical articles that may cause puncture or cuts, including, but not limited to, all needles, syringes, lancets, pen needles, Pasteur pipettes, broken medical glassware/plasticware, scalpel blades, suture needles, dental wires, and disposable razors used in connection with a medical procedure.

2.1.6 BIOTECHNOLOGY BY-PRODUCT EFFLUENTS
Any discarded preparations, liquids, cultures, contaminated solutions made from microorganisms and their products including genetically altered living microorganisms and their products.

2.2 BIOSAFETY LEVEL
Biosafety levels comprised of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities specifically appropriate for the operations performed, the documented or suspected routes and ease of transmission of the infectious agents used, the severity of the disease, and the laboratory function or activity conducted according to the U.S. Department of Health and Human Services publications, Biosafety in Microbiological and Biomedical Laboratories, and the NIH Guidelines for Research Involving Recombinant DNA Molecules.

2.3 RISK GROUP
Risk group levels resulting from the classification of the biohazardous agents based on their association with human disease, and the resulting severity of the disease, according to the U.S. Department of Health and Human Services publications, Biosafety in Microbiological and Biomedical Laboratories, and the NIH Guidelines for Research Involving Recombinant DNA Molecules.

3.0 ROLES AND RESPONSIBILITIES

3.1 MEDICAL OR BIOLOGICAL WASTE GENERATORS
Medical or biological waste generators, including Principal Investigators (PI), research, laboratory, and teaching staff are responsible for:

- Managing biological waste within areas that generate biological waste including collection, segregation, packaging, labelling, and transport of biological waste to designated waste pick-up areas within Northeastern University for Vendor Disposal.
- Obtain, manage, and maintain waste supplies within the research area, including biohazard burn boxes, biohazard bags, sharps containers, autoclave bags, and disinfectant.

3.2 BIOLOGICAL WASTE CONTRACTOR
The biological waste contractor is responsible for:

- Providing pick-up of packaged biohazard burn boxes from designated waste storage locations on a weekly or biweekly basis depending on waste volume.
- Providing cardboard biohazard burn boxes, red biohazard waste bags, and white generator labels for biological waste collection.
- Provides tracking, manifest and documentation of pick-up, treatment and disposal ‘cradle to grave’ management of waste.
- Transports biological waste to off-site treatment facility for appropriate treatment and disposal.

3.3 OFFICE OF ACADEMIC AND RESEARCH COMPLIANCE (OARS)
OARS is responsible for:

- Manage biological waste contractor in coordination with Environmental Compliance and Occupational Safety (ECOS) office.

- Develops and provides regulated medical waste training to all biological waste generators.
- Participates in the selection of biological waste disposal vendors.
- Manages, verifies and maintains the documentation involved with shipping biological waste and record-keeping for off-site treatment, including (a) the date of each shipment, (b) the total number of containers, (c) type of waste, (d) total combined weight or volume, (e) name and identification information of transporter.
- Participates in the review and approval of biological waste storage and pick-up locations and maintains a current list of approved locations.
- Verifies and signs waste manifests at the time of shipping and provides signed copy to OARS.
- Managing contractor-provided supplies at designated waste storage areas.
- Manage keycard access for waste storage locations.
- Provide packing tape and transport dolly to researchers for burn box packaging and transport.

4.0 BIOLOGICAL WASTE CONTRACTOR INFORMATION

UNITED WASTE MEDICAL MANAGEMENT INC.
20 Oakhurst Rd, Sutton, MA 01590
508-234-2400

5.0 BIOLOGICAL WASTE REQUIREMENTS

5.1 BIOLOGICAL WASTE BAGS

Waste generators are responsible for containing and storing medical or biological waste appropriately. All medical or biological waste, except sharps, shall be contained in a primary container which is a red, fluorescent orange or orange-red plastic bag that is impervious to moisture and has sufficient strength to resist ripping, tearing, or bursting under normal conditions of use and handling, and which meets the American Society for Testing Materials (ASTM) standard D1922 06a and ASTM D1709-04. Each primary container shall:

(1) Be marked prominently with the universal biohazard warning symbol and the word “Biohazard” in a contrasting color.

(2) Be secured so as to prevent leakage and to preclude loss of contents during handling, storage, and/or transport.

5.2 SHARPS

Sharps shall be segregated from other wastes and aggregated immediately after use in red, fluorescent orange or orange-red leakproof, rigid, puncture-resistant, shatterproof containers that resist breaking under normal conditions of use and handling, and that are marked prominently with the universal biohazard warning symbol and the word “Biohazard” in a contrasting color.

Sharps containers are available in waste storage areas or can be purchased by the laboratories. Containers used for collection cannot exceed 20 inches in height and 16 inches in width. This restriction is necessary because sharp containers must be transferred closed and intact into the biohazard burn box prior to disposal.

Overfull or open sharps containers must not be put into the biohazard burn box, but be corrected or have the container closed. Contact OARS for more information or if assistance is required.

5.3 STORAGE

All medical or biological waste must be treated on-site or transported off-site for treatment at a minimum once per calendar year.

Biohazard waste bags must be secured and sealed in the provided cardboard biohazard burn box displaying universal biohazard symbol with white generator labels as indicated in section 7.3 Researchers are required to transport packaged waste to storage area as indicated in section 7.4

Storage areas are required to have the following:

- Prominent hazard communication signage to indicate space is used for the storage of regulated medical or biological waste.
- Be designed or equipped to prevent unauthorized access.
- Location must be uncarpeted with impervious, cleanable, non-absorbent flooring, used exclusively for waste storage.
- Be designed or located to protect the waste from the elements and prevent access by vermin.
- Provide sufficient space to allow for clear separation of regulated medical or biological waste from any other waste, when applicable.
- Be adequate to accommodate the volume of regulated medical or biological waste generated prior to removal of waste for either waste transport offsite or on-site treatment.
- Be maintained such that there is no putrescence or off-site odors, using refrigeration when necessary.

5.4 DISPOSAL AND LABELING

The following methods of treatment and disposal are currently acceptable for the handling of infectious waste at Northeastern University: Incineration at an approved incineration facility and Chemical disinfection; Steam sterilization is no longer being recommended, but is available if approved by OARS and the Institutional Biosafety Committee (section 8.0).

All wastes not treated on campus and to be sent out for treatment and disposal will be placed in shipping containers provided by OARS. Generators authorized to ship out containers on their own must receive special training from OARS. The Regulated Medical Waste Shipping Training is provided as an online course available from our website.

In addition, the following wastes identified below must be handled in the following manner:

Blood and Blood Products

Since Northeastern University is connected to a municipal sewerage system, free draining blood and blood products except blood-saturated materials may be disposed of into this system. This method is not presently restricted by the Massachusetts Water Resources Authority (MWRA). If the above method is not practical or it should become prohibited by the MWRA, blood and blood products, except blood saturated materials, shall be placed in a 3 mil red/orange biohazard bag and transferred into an infectious/biohazard box provided by OARS. Once properly packaged and manifested they will be scheduled by OARS to be sent to an approved treatment facility.

Every container or bag of waste, which has not been rendered noninfectious, shall be distinctly marked with the international biohazard symbol and colored red to indicate that it contains potentially biohazardous waste. Sharps waste must be distinctly labeled to indicate that it contains sharp waste capable of inflicting punctures or cuts. Information on what type of sharp containers to purchase will be provided on the EHS website. Every container or bag of waste which has not been rendered noninfectious and which will be transported off the premises of the waste generator shall in addition to the requirements of this section be placed in boxes, which are:
a) rigid b) leak resistant c) impervious to moisture d) of sufficient strength to prevent tearing or bursting under normal conditions of use and handling e) sealed to prevent leakage during transport
Each box shall bear a label that states the name, address and telephone number of the generator. The label shall be affixed in a manner, which ensures that it cannot be easily removed. Boxes meeting these requirements will available through OARS. In addition to the labeling on the box, the outer bag inside the box is required to have a label with the same information. A hazardous waste disposal label used in our chemical waste program will be appropriate to meet this requirement. Prior to transport for off-site disposal, waste, which has been rendered noninfectious by a method other than incineration, shall be placed in a black four-mil disposal bag so as to clearly identify it as non-biohazardous and to identify the waste generator responsible for the treatment. Once clearly signed, bagged and sealed, such waste may be disposed of in the same manner as regular rubbish handled by the Building Services Department. The generator will be required to clearly sign the disposal bag in the appropriate area.

5.5 RECORD KEEPING
OARS keep medical waste tracking forms for all waste picked up by a licensed vendor for off-site treatment and disposal. The generator shall maintain records of temperature and dwell times used in each instance where waste has been rendered noninfectious by gas or steam sterilization. Any department utilizing an autoclave to render waste noninfectious in order to verify efficiency of the autoclave will routinely do biological spore tests and must be approved by OARS. The above records must be stored and retained for at least three years. The generator shall also maintain records of volume and type of waste rendered noninfectious on-site which shall be available for OARS review. OARS will provide a standard form for all generators to use.

5.6 SPECIAL CONSIDERATIONS
Compactors or grinders shall not be used to process medical or biological waste until it has been rendered noninfectious and safe for disposal in accordance with 105 CMR 480.150.

Free draining blood and blood products and biotechnology by-product effluents shall be stored at all times in leakproof containers that are securely sealed.

5.7 SHIPPING INFECTIOUS WASTE
Only personnel trained and approved by OARS are allowed to ship out biohazardous waste from Northeastern University. Shipping boxes are limited to eighty pounds maximum capacity. All boxes must be lined with bags provided by our approved vendor. Sharps placed into these shipping containers must be contained in sharps containers. These bags must be tied off before closure and the outer bag must be labeled with the generators name, address and telephone number. The vendor will refuse unlabeled, bulging,

crushed, or leaking boxes. Manifests must be filled out for all shipments and a copy must be sent to OARS.

OARS will assist generators in preparing manifests when necessary. The generator shall appoint a designee to prepare and sign the manifest. Original copies must be sent to OARS so that they are available for various record keeping needs. Manifests provided by OARS will include the following information:
a) Description of waste to be shipped; b) Total quantity of waste; and c) Type of container in which waste is transported

The Massachusetts Department of Public Health off-site treatment recordkeeping log will be maintained at OARS.

6.0 BIOLOGICAL STORAGE AREA LOCATIONS

Boston Campus:
Mugar 016
Hurtig 044
140 The Fenway- Rm 205
Egan 251
Behrakis 603
ISEC 029

Burlington Campus:
Building 5 room 130
Elliott Hall room 139

Nahant Campus:
Bunker 11

7.0 BIOLOGICAL WASTE MANAGEMENT PROGRAM

The Northeastern Biological Waste Management Program outlines the requirements for the safe handling of medical or biological waste in accordance with Massachusetts Department of Public Health State Sanitary Code, OSHA Bloodborne Pathogen Standard, CDC BMBL 6th edition, NIH Guidelines, and Northeastern University Biosafety Manual.

Personnel are required to adhere to the safe handling procedures as described in the Northeastern University Biosafety Manual, research-specific standard operating procedures and approved biological research registration. Personnel protective equipment (PPE) should be specified in research-specific standard operating procedures and located on the approved biological research registration. Gloves should not be used on elevator, door knobs or on other items which are touched with ungloved hands.

Researchers are responsible for the appropriate collection, packaging, and transport of sealed biohazard burn boxes to designated biological storage areas (Section 6.0).

7.1 TRAINING

Waste generators are required to complete applicable trainings based on research biosafety level and activities involving medical, biological, recombinant, or sharps waste. The following minimum trainings are required and provided by OARS:

- Regulated Medical Waste Training
- Laboratory Safety I
- Laboratory Safety II
- Biosafety I
- Biosafety II

Annual refresher training are required or Laboratory and Biosafety. Additional regulated medical waste training may be required if significant changes to the waste procedures. OARS provides keycard access to designated waste storage area(s) upon completion of training.

7.2 BIOLOGICAL WASTE COLLECTION

7.2.1 SUPPLIES

Biological waste generators may obtain biological waste collection materials and equipment in designated waste storage areas (Section 6.0). The following will be provided in all storage area location(s) for use by authorized personnel:

- Biohazard burn boxes (cardboard)
- Red biohazard bags
- Sharps containers
- Packing tape with dispenser
- White generator labels
- 4-wheel dolly
- Burn box lid

7.2.2 SET-UP

(1) Obtain biohazard burn box, red bags, dolly and lid provided at waste storage area.
(2) Open and turn over biohazard burn box, fold inner bottom flaps together then outer, seal outer bottom flaps with packing tape. Double tape.
(3) Tape all bottom side seams to ensure no leakage.
(4) Turn box upright and line box with two red biohazard bags provided.
(5) Secure with provided burn box re-usable lid. Decontaminate lid with appropriate disinfectant prior to re-use.
(6) Place set biohazard burn box on provided dolly and in close proximity to area where waste will be generated.

7.2.3 BIOHAZARD BURN BOX USE

(1) Collect any solid medical, biological, or recombinant waste materials in biohazard burn box as it is generated with lid closed when not in use. This includes any human, biological agent or recombinant or synthetic nucleic acid-contaminated solid, non-liquid, non-sharp, non-animal, and non-pathological wastes; culture flasks/plates/petri-dishes, plastic tubes, pipette tips, serological pipettes, PPE (gloves, disposable gowns etc.).
(2) Serological pipettes and pipette tips may puncture the biohazard bag, but are not considered sharps, so the appropriate procedure will be to stack linearly, horizontally, or place in cardboard or plastic container or small biohazard bag.
(3) Sharps must be placed in sharps container and securely closed prior to placing in burn box.

(4) Mixed wastes containing chemical or radiological materials in addition to biological waste must be discarded in the chemical or radiation waste streams respectively.

7.3 PACKAGING

(1) Safely secure and package biohazard burn box once ¾ full. Remove lid and decontaminate for next use. Wear appropriate PPE including gloves.
(2) Use a gooseneck (gather, twist end, make loop with twisted end, seal with tape or tie) or overhand knot (gather and twist end, make loop, loop end through to create knot). Do not use bunny ear tie as this is not secure.
(3) Securely close and seal top of box by folding inner top flaps, then outer top flaps together and at center seam. Tape all seams to ensure no leakage.
(4) Place white generator labels (available in storage area) in upper right corner of box and check any applicable category of waste.

7.4 TRANSPORT

Researchers are responsible for transporting sealed biohazard burn box, using provided dolly, to designated waste storage area (section 6.0). Do not use gloves on elevator, door knobs, or where ungloved hands may touch.

7.5 LIQUID BIOLOGICAL WASTE

All liquid biological wastes (RG2 or RG1) are decontaminated and disposed of inside the laboratory or as mixed waste. Any liquid containing recombinant or synthetic molecules and/or genetically modified microorganisms or material are considered biological waste.
If a vacuum system is used for collection, a double-flask with HEPA filter and secondary containment to hold contents must be used. Prior to disposal, waste must be disinfected using an Environmental Protection Agency (EPA) registered disinfectant appropriate for biological material or infectious agents being decontaminated. If household bleach is used, a final bleach concentration of at least 10% must be made with at least 30 minute contact time. After complete disinfection, waste liquid is discharged down the sink drain in the research area or in the chemical or radioactive waste stream for appropriate mixed waste.

7.6 ANIMAL WASTE

All solid animal carcasses or tissues that meet the definition in section 2.1.4 must be processed for incineration.

8.0 AUTOCLAVING

Autoclaves are no longer permitted for routine decontamination of medical, biological, or recombinant or synthetic nucleic acid waste. Items containing hazardous chemicals, including bleach, and radioactive materials cannot be autoclaved. OARS, in coordination with the Institution Biosafety Committee and Biosafety Officer, may permit exceptions based on agents and research materials, which may include the treatment or pre-treatment of specific biological wastes, organisms, or microorganisms as outlined in an approved biological research registration. Pre-treated solid waste will be autoclaved by trained personnel and discarded in the biohazard burn box for final treatment and disposal by approved contractor. Any autoclaves permitted to be used for pre-treatment or treatment of any waste must be registered with the IBC and OARS and validated quarterly with a biological indicator. Annual calibration and maintenance of autoclaves used for decontamination of biological waste is required.

A written standard operating procedure must be developed by the laboratory and approved by the IBC and Biosafety Officer and include records of date, time, cycle pressure and temperature, validation, transport and annual calibration.

OARS will provide labels with the University's name, address and phone number, for all infectious waste that is treated on campus. These labels will be used to identify the material as noninfectious and will meet all the labeling requirements in the regulation. The black bags are not autoclavable. Generators will still be required to provide their own autoclave bags when handling and treating the waste on site. These bags must be clear, three mil thick and must not have a biohazard symbol or the word “biohazard” written on them.

All individuals who are or are planning to operate an autoclave to treat medical and biological waste on-site must have training covering the operation of the specific autoclave, routine testing of the autoclave using biological tests (bacterial spore strips or spore vials) and maintaining a logbook of all items autoclaved. Clear autoclave bags must be used and not red bags. All red bags will be considered infectious. Transport to and from the autoclave must be done in an appropriate secondary container that can prevent spills and release of the waste and cart for transportation. Autoclavable trays must be used when autoclaving to prevent melting or release of toxic vapors.

The state of Massachusetts requires that a specific logbook be maintained at each autoclave and that each load be entered into the logbook at the time of disinfection.

9.0 GUIDELINES AND REFERENCES

- Occupational Health and Safety Administration (OSHA) 29 CFR 1910.1030 Bloodborne Pathogen Standard
- National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Centers for Disease Control and Prevention, Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th edition
- Commonwealth of Massachusetts, 105 CMR 480.00 State Sanitary Code Chapter VIII: Minimum requirements for the management of medical or biological waste https://www.mass.gov/regulations/105-CMR-48000-minimum-requirements-for-the-management-of-medical-or-biological-waste-state-sanitary-code-chapter-viii
- Northeastern University Biosafety Manual