

VIII. BIOMEDICAL WASTE

A. Definitions

Biomedical wastes means waste materials which are capable of producing an infectious disease which are not otherwise regulated as hazardous waste. Examples of biomedical waste include:

1. cultures and stocks of infectious agents and associated biologicals;
2. biological tissues;
3. human blood and blood products;
4. pathological wastes;
5. contaminated sharps including hypodermic needles, syringes, (with or without the attached needle), Pasteur pipettes, scalpel blades, suture needles, and needles with attached tubing and other types of broken or unbroken glassware that have come in contact with infectious agents (such as used slides and cover slips);
6. used blood collection bags, tubes, and vials;
7. animal carcasses and body parts, and contaminated bedding;
8. wastes from surgery, autopsy and other medical procedures;
9. soiled dressings and other patient-care materials;
10. dialysis unit wastes;
11. isolation wastes, unless determined to be non-infectious by the infection control committee at the health care facility;
12. HIV containing cell or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV;
13. pharmaceutical wastes;
14. laboratory reagents contaminated with infectious body fluids;
15. all materials which have come in contact with cytotoxic/antineoplastic agents or other hazardous drugs; and
16. any other material or contaminated equipment which, in the determination of the facility infection control staff or Institutional Biosafety Committee,

presents a significant danger of infection because it is contaminated with, or may reasonably be expected to be contaminated with, etiologic agents.

B. Guidelines for Disposal

1. Ethidium bromide, antineoplastic/cytotoxic agents, controlled substances, hazardous drugs, and associated solid wastes require special disposal by incineration. See Section V., "Hazardous Waste".
2. If any infectious waste is also a chemical waste, call the EHSO for assistance with disposal after disinfection.
3. Biomedical wastes that are also radioactive should be treated according to requirements for both biomedical and radioactive waste. Contact the OU Radiation Safety Office for appropriate procedures.
4. Prior to any treatment, all biomedical wastes, including those to be incinerated, should be enclosed in a puncture-resistant, red biohazard bag that is color coded or labeled with the biological hazard symbol.
5. All sharps intended for disposal, whether contaminated or not, must be enclosed in a specially designed sharps container.
 - a. Needles should not be clipped or recapped before being placed in a sharps container.
 - b. The sharps container should be:
 - (1) puncture-resistant,
 - (2) leak proof on the sides and bottom,
 - (3) color-coded or labeled with the biohazard symbol, and
 - (4) not be allowed to overfill (a good guideline is to dispose when approximately two-thirds full).
 - c. Sharps containers should be selected with consideration of appropriate safety features such as lids that lock tight for safe disposal, containers that are specifically constructed for the method of sterilization that will be used (if sharps containers are not specifically constructed to be autoclaved, the resulting mass of melted plastic is extremely hazardous due to the needles that often protrude), clear tops that would allow visual inspection, and appropriate opening sizes that allow the sharps in, but do not allow hands or fingers to enter and possibly be injured.
6. Untreated biomedical waste is not to be disposed of in the municipal

waste stream. All biomedical waste, including sharps and syringes must be treated by incineration, steam sterilization, or chemical disinfection before disposal in the municipal waste stream.

a. Off-Site Treatment/Incineration

- (1) Red biohazard bags or sharps containers should be placed in a cardboard box labeled with the biohazard symbol for shipment through an appropriate biomedical waste disposal vendor for off-site treatment or incineration. The box must be obtained from the vendor. Contact the EHSO for current vendor information.
- (2) Boxes containing biomedical waste that should be incinerated rather than other treatment methods should be labeled with "incinerate only" on both sides of the container. Such labels are available from the vendor or the EHSO.
- (3) Packaging, labeling, and manifesting this waste must follow the procedures in Section VIII.E, "Regulated Medical Waste Shipping Procedures".

b. Steam Sterilization

- (1) Biomedical waste that is to be steam sterilized should be collected in biohazard bags and transported to the sterilization site in a durable, leakproof container which is closed for transport from the laboratory.
- (2) Sterilization should be validated using methods described in Section VIII.D., "Autoclave Sterilization Validation".
- (3) After sterilization, but before disposal in the municipal waste stream, all treated biomedical wastes should be enclosed in an unmarked outer bag or box that is **not** red or labeled with the biohazard symbol. Any biomedical waste that has been treated as described above and packaged such that it is clearly evident that the waste had been effectively treated is not subject to regulation as biomedical waste and may be collected, transported, and disposed of as municipal waste.

c. Chemical Disinfection

Chemical or liquid disinfectants may be used for treatment of bio-medical waste where contact time, concentration, and quantity of the chemical disinfectant are sufficient to achieve microbial inactivation of the waste.

- (1) Chemical disinfection may not be used for:
 - (a) porous material;
 - (b) material embedded with infectious agents, such as agar plates;
 - (c) mixed waste such as material that is both biomedical and radioactive waste
 - (d) hazardous drug waste;
 - (e) pharmaceutical waste; or
 - (f) contaminated sharps collected in a sharps container.
- (2) If chemical disinfectants are used, they must have been shown to be effective against the organisms present. Important considerations include:
 - (a) temperature;
 - (b) time of contact;
 - (c) pH;
 - (d) concentration;
 - (e) penetrability; and
 - (f) reactivity of organic material at the site of application (for example, for blood or media containing significant organic material, autoclaving should be considered instead).
- (3) Use manufacturer's specifications and procedures when using chemical disinfectants.
- (4) Biomedical waste that has been effectively treated can be disposed of into the regular solid waste receptacle unless the material qualifies as "sharp", in which case the material should be placed in a puncture-proof container (**not** labeled with the biohazard symbol) prior to disposal.
- (5) Certain chemical disinfectants, such as bleach and alcohol, can be poured down the sink after being used for treatment. Other disinfectants, such as phenol and

gluteraldehyde, require management as a hazardous waste (see procedures in Section V). The management after use should be considered when selecting chemical or liquid disinfectants.

Sources: Oklahoma Department of Environmental Quality Solid Waste Management Rules, OAC 252:515 Subchapter 23
Department of the Army Biological Defense Safety Policy and Procedures (32 CFR 627.33)

C. Autoclave Procedures

An autoclave will only work if it is used properly and safely. There are potential physical and biological hazards associated with improper use, as well as the potential for contamination of the research being performed and damage of the equipment. Follow these procedures to minimize these hazards.

1. If the autoclave has an Autoclave Use Log, complete it before every use of the autoclave.
2. If the autoclave is dirty, contact the previous user to clean the machine. DO NOT USE the autoclave until it is cleaned. Clean the drain strainer before loading the autoclave.
3. Place all items in a tub before autoclaving. Never place glassware or bags directly on the bottom or floor of the autoclave. Place items inside a heat resistant plastic tub that will sit on a shelf or rack. Ensure tubs are not cracked.
4. Do not overfill the tubs. Nothing should hang over the edges or be tall enough to touch the top or sides of the autoclave. Overloading may lead to the center of the load not getting sterilized properly.
5. Place tubs in the center of the chamber. It is important to allow the steam to circulate freely throughout the chamber.
6. Never autoclave a sealed container of liquids. Before loading containers of liquids into the autoclave, the caps must be loosened to ensure proper sterilization and to avoid having the bottles shatter during pressurization or when the container is opened.
7. Add a quarter- to a half-inch of water to a tub of empty bottles that are to be autoclaved. This will allow the bottles will heat more evenly.
8. For solid waste, do not pack the bags too full; bags packed to capacity with biohazardous waste will not be properly decontaminated.
9. Add one cup of water to each bag of solid waste and keep the bags open. Polypropylene biohazard bags are impervious to steam.

10. Do not load non-autoclavable plastic materials into the autoclave. They will melt and cause damage to the autoclave.
11. Make sure the door of the autoclave is properly closed before starting the cycle.
12. Know the contents of the bags being placed in the autoclave in order to know which cycle to use, then use the proper cycle. Do not use a gravity cycle for liquid nor a liquid cycle for solids. Use of the wrong cycle can cause improper sterilization or spillage.
13. Be sure you know what you are doing if you want to adjust the temperature or run time. Increasing the temperature can melt trays or containers. Decreasing the temperature or run time can impair the sterilization procedure. Most pre-set programs can accomplish what you need without adjusting the time or temperature.
14. Do not override an autoclave's built-in safety control features under any circumstance.
15. Do not abort a run just because you are in a hurry and want the cycle to finish faster. Aborting of cycles can cause the sterilizer to jam if it happens often, requiring a service call to get the autoclave running again.
16. Wait a full five to ten minutes before removing items after the completion of a run. If the autoclave load contains dry glassware wait five minutes and ten minutes if the load contains liquids.
17. Wear heat-resistant gloves when first opening the door after a run. When removing items from the autoclave, wear a rubber apron in addition to rubber sleeve protectors, heat resistant mitts and a face shield.
18. Let glassware cool for 15 minutes before touching it with ungloved hands.
19. Let liquid loads stand in an out-of-the-way place for a full hour before touching with ungloved hands. With liquid loads be alert for a bottle still bubbling.
20. Close the autoclave door after each use.

D. Autoclave Sterilization Validation

Sterilization failure can result from a number of factors including improper loading, insufficient time and/or temperature, or equipment failure. Therefore, it is important to ensure that complete sterilization of biomedical waste has occurred prior to disposal. The use of a biological indicator is the most reliable method for this determination.

1. It is recommended that spore strips inoculated with *Geobacillus*

stearothermophilus, *Bacillus atrophaeus* or other suitable and reliable biological indicator be used at least once per week to monitor the adequacy of sterilizer performance. Some commercial spore strips have a color change indicator. This color change does not indicate that sterility was achieved, only that minimal process parameters were attained. Do not rely on this color change to ensure sterilization.

2. Place the spore strips in the middle or most inaccessible portion of the autoclave load, preferably inside a filled biohazardous waste bag. One way to be able to safely remove the strip from the load after autoclaving is to place a fresh spore strip inside a glass screw cap tube. Tie a string around the neck of the tube. Bury the tube in the center of the load as you build it. Thread the string out of the top of the bag. After the cycle is completed, you can pull on the string to retrieve the spore strip for incubation.
3. Process and incubate the spore strips according to manufacturer or vendor procedures.
4. If the processed spore strips indicate microbiological growth, first try increasing the run time or verifying the waste is properly loaded. If growth still occurs with run times of 45 minutes or more, the autoclave may need maintenance or repair. Notify Physical Plant or department technician as soon as possible and do not use the autoclave until it has been repaired. Maintenance and/or repair may need to be completed by a manufacturer's technician if University personnel can not fix the problem. Notify others who may use the equipment as well.
5. Record all spore strip results in a permanent location.

Sources: *Principles and Methods of Sterilization*, "Sterilizer Controls, Sterilization Indicators, and Culture Tests"
AMSCO Product Literature

E. Regulated Medical Waste Shipping Procedures

If the biomedical waste is to be shipped for disposal through a qualified biomedical waste disposal company, the Department of Transportation (DOT) requires additional training on the following information for those persons packing, shipping, or signing the documentation for such shipments.

1. Definitions
 - a. *Regulated Medical Waste* (RMW) is "a waste or reusable material medical treatment of an animal or human, which includes diagnosis and immunization, or from biomedical research, which includes the production or testing of biological products." Regulated medical waste may **not** include laboratory cultures of Class A organisms (see the *University of Oklahoma Shipping Biological Materials Manual* or contact the EHSO for a description

and list of Class A organisms).

- b. *Sharps* are “any object contaminated with an pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or packaging material. Containers must be properly closed and lidded prior to transport. Sharps include; needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken ridged plastic, wood shaft cotton swabs and exposed ends of dental wires.” Sharps (including syringes, even if the needle has been removed) must be placed in sharps containers prior to shipment for disposal.

2. Packaging Procedures

DOT requires that RMW be packaged properly for shipment as follows.

- a. It is the responsibility of the generator to make sure that biomedical/regulated medical waste bags are closed properly by one of the following three methods which will seal the bag closed such that no fluid or other material may escape when the bag is turned upside down.
- (1) Twist the open end and tie the end into one knot. (Do not tie alternate corners into knots. This will not appropriately close the bag.)
 - (2) Twist the open end and fold it over into a gooseneck. Tape the folded end shut with duct tape.
 - (3) Use a twist tie that is of sufficient length and strength which will effectively close the bag.
- b. The closed bag or sharps container must then be placed in an appropriate outer (secondary) container for shipment. Containers (boxes/tubs) provided by the current vendor will meet the requirements. Do not try to use containers/boxes not supplied by the current vendor. The requirements for the container are that it must:
- (1) be made of rigid material (plastic or cardboard),
 - (2) be impervious to outside moisture,
 - (3) be able to prevent tearing or bursting under normal use,
 - (4) be puncture-resistant for loose sharps,

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- (5) have no visible leaking or external contamination,
 - (6) not be ruptured or damaged in any way.
 - (7) not have objects may be protruding from the container, and
 - (8) not be overfilled.
- c. If liquids are present in the waste, the container lids must be tightly lidded or stoppered and the secondary container must contain sufficient absorbent material that is enough to handle 150% of the fluid amount inside the container.
 - d. The outer packaging is required to have the following markings:
 - (1) Regulated Medical Waste
 - (2) UN 3291
 - (3) The word "BIOHAZARD" and black biohazard symbol
 - e. The maximum material weight limit of any single red bag is 22 pounds. A 28 gallon container (tub) must not weigh more than 60 pounds.

3. Shipping Documents/Manifests

DOT requires that all hazardous materials be accompanied by shipping documents, also known as manifests. The main purpose of these is to provide clear communication in the event of an emergency when the hazardous material is in transit. It is very important that they are complete, correct and have the following information:

- a. Proper shipping name: "Regulated Medical Waste, n.o.s." (not otherwise specified)
- b. Hazard Class: "6.2"
- c. Identification #: "UN3291"
- d. Packaging Group: PG II
- e. Quantity of material shipped - weight or volume
- f. Emergency response number (must be attended at all times during the shipment)

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- g. Shipper's certification (generator signature)
 - (1) Only persons knowledgeable about the package and trained in the DOT shipping requirements for RMW should sign the manifests (it is a violation of DOT regulations to have an untrained person sign the manifest).
 - (2) Copies of the manifest must be retained and be easily retrievable for a DOT inspector for two years.

4. Hazardous Materials/RMW Security

Many materials that are classified as hazardous materials are essential products to research and industry, but potential deadly weapons in the hands of a terrorist. In the wake of increased concerns over terrorists threats and attacks, shippers and carriers who offer, transport or store hazardous materials have an increased responsibility to safeguard personnel, facilities and the hazardous materials themselves. Lost, stolen, or unprotected hazardous materials may be used for malicious acts that can cause harm, destruction, or other illegal activities. There is additional concern that during a biological event, such as an outbreak of pandemic flu, SARS, smallpox, etc., a potential terrorist strategy could be the theft of potentially infectious waste resulting from the care of such patients. Many potential terrorists do not fit a preconceived picture of a criminal. Many have been known to live and work within the community for years before carrying out an actual attack. Disgruntled employees or patients may also be persons who may carry out acts of violence. For this reason, security of hazardous materials, including RMW, constitutes an essential component in protecting employees, students, the public, and the environment. These procedures should be followed.

- a. Packages containing hazardous materials should be properly identified and accounted for at all times. Hazardous materials must never be left unsecured. Materials are considered secure if they are in the possession of a trained employee or secured within a controlled, locked area. Control measures include:
 - (1) Don't prop open doors to areas where hazardous materials are stored or used.
 - (2) Account for and secure keys and access codes. Don't leave them unattended or give to unauthorized persons.
 - (3) Report lost keys.
 - (4) Secure all areas when not attended.
 - (5) Be aware of unfamiliar persons or visitors.

- (6) Report tampering with doors, locks, etc.
 - (7) Avoid discussions with strangers about the storage location and shipment dates of hazardous materials.
 - (8) Report any missing hazardous materials to OU Police immediately.
- b. Recognition of dubious actions ranks as a primary guard in keeping hazardous materials secure. Immediately report suspicious activities to OU Police. Examples of suspicious activities include:
- (1) observing a person monitoring or casing buildings or operations. The person may be taking pictures or notes, using binoculars, drawing maps, or collecting information by other means.
 - (2) people in buildings or areas who do not appear to be conducting legitimate business (loitering, etc.).
 - (3) unauthorized personnel in restricted, sensitive or private areas.
 - (4) repeatedly seeing an unknown vehicle in a sensitive area without an explanation.
 - (5) noticing repetitive suspicious activities by the same person or vehicle.
 - (6) break-ins or noticing signs of attempted break-ins to sensitive areas.