ENVIRONMENTAL HEALTH AND SAFETY
STANDARD OPERATING PROCEDURES

SOP No. 24.01.01.W1.23AR Biological Safety Procedure
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Environmental Health and Safety at WTAMU is composed of two distinct but integrated environmental safety departments that report to the Vice President of Research and Compliance. Academic and Research Environmental Health and Safety (AR-EHS) is responsible for research and academic related compliance, which includes laboratory and academic research and the associated compliance committees. Fire and Life Safety (FLS-EHS) is responsible for fire related compliance and conducts fire and life safety inspections of campus buildings and assists with the testing all fire detection and suppression systems.

Supplements **TAMUS Regulation 24.01.01**

Contents

1. Purpose

The following information is provided to assist WTAMU departments in developing procedures, including biological safety SOP and Laboratory Manuals, to meet biological safety requirements to protect students, employees, and the environment. This procedure sets forth recommended minimum requirements that need to be followed to maximize the safety of all workers.

2. Scope

The following procedure applies to all WTAMU Departments including all staff, students, employees, and visitors who may come in contact with or be near any biological hazards or biological experiments. The procedure is provided to ensure the safety of all occupants of WTAMU.

3. Responsibility

The AR-EHS will:

- Assist in identifying safety procedures as necessary.
- Assist with training as appropriate.
- Monitor program compliance.
- Assist in the selection of atmospheric monitoring equipment, personal protective equipment, and other necessary equipment.

The department/supervisor will:

- Identify persons handling biological agents.
- Provide atmospheric monitoring equipment, personal protective equipment, and all other necessary equipment.
- Provide proper training for persons handling biological agents.

The employee/student will follow guidelines described in this procedure and other required programs to assure safe biological material handling procedures.

4. Principles of Biosafety

The primary principle of biological safety (i.e., biosafety) is containment. The term *containment* refers to a series of safe methods for managing infectious agents in the laboratory. The purpose of containment is to reduce or eliminate human and environmental exposure to potentially harmful agents.

4.1. Primary and Secondary Containment

There are two levels of biological containment: primary and secondary.

- Primary containment protects people and the immediate laboratory environment from exposure to infectious agents. Good microbial techniques and safety equipment provide sufficient primary containment. Examples of primary barriers include safety equipment such as biological safety cabinets, enclosed containers, and safety centrifuge cups. Occasionally, when it is impractical to work in biological safety cabinets, personal protective equipment, such as lab coats and gloves, may act as the primary barrier between personnel and infectious materials.
- Secondary containment protects the environment external to the laboratory from exposure to infectious materials. Good facility design and operational practices provide secondary containment. Examples of secondary barriers include work areas that are separate from public areas, decontamination facilities, hand-washing facilities, special ventilation systems, and airlocks.

4.1.1. Elements of Containment

The three key elements of biological containment are:

- Laboratory practices.
- Safety equipment.
- Facility design.

To ensure minimal exposure, employees must assess the hazards associated with their work and determine how to apply the biosafety principle appropriately.

IMPORTANT: Employees working with infectious agents or potentially infectious materials must be aware of the hazards associated with their work. These workers must be trained and proficient in biosafety procedures and techniques.

5. General Biosafety Guidelines

Biohazardous materials require special safety precautions and procedures. Follow these guidelines when working with infectious agents:

5.1. Personal Hygiene Guidelines:

Wash your hands thoroughly, as indicated below:

- After working with any biohazard.
- After removing gloves, laboratory coat, and other contaminated protective clothing.
- Before eating, drinking, smoking, or applying cosmetics.
- Before leaving the laboratory area.

Do not touch your face when handling biological material.

Never eat, drink, smoke, or apply cosmetics in the work area.

5.2. Clothing Guidelines:

Always wear a wrap-around gown or scrub suit, gloves, and a surgical mask when working with infectious agents or infected animals.

- Wear gloves *over* gown cuffs.
- Never wear contact lenses around infectious agents.
- Do not wear potentially contaminated clothing outside the laboratory area.

To remove contaminated clothing, follow these steps:

- Remove booties from the back.
- Remove head covering from the peak.
- Untie gown while wearing gloves.
- Remove gloves by peeling them from the inside out.
- Remove the gown by slipping your finger under the sleeve cuff of the gown.

5.3. Handling Procedures:

To avoid accidents in the laboratory resulting from improper handling of materials:

- Use mechanical pipetting devices.
- Minimize aerosol production.
- Add disinfectant to water baths for infectious substances.
- Use trunnion cups with screw caps for centrifuging procedures. Inspect the tubes before use.
- Use secondary leak-proof containers when transporting samples, cultures, inoculated petri dishes, and other containers of biohazardous materials.

5.4. Syringes

Avoid using syringes and needles whenever possible. If a syringe is necessary, minimize your chances of exposure by following these guidelines.

- Use a needle-locking or disposable needle unit.
- Take care not to stick yourself with a used needle.
- Place used syringes into a pan of disinfectant without removing the needles.
- Do not place used syringes in pan containing pipets or other glassware that requires sorting.
- Do not recap used needles.
- Dispose of needles in an approved sharp container.

5.5. Work Area

- Keep laboratory doors shut when experiments are in progress.
- Limit access to laboratory areas when experiments involve biohazardous agents.
- Ensure that warning signs are posted on laboratory doors. These signs should include the universal biohazard symbol and the approved biosafety level for the laboratory.
- Ensure that vacuum lines have a suitable filter trap.
- Decontaminate work surfaces daily and after each spill.
- Decontaminate all potentially contaminated equipment.
- Transport contaminated materials in leak-proof containers.
- Keep miscellaneous material (i.e., books, journals, etc.) away from contaminated areas.
- Completely decontaminate equipment before having maintenance or repair work done.

5.6. Universal Precautions

Clinical and diagnostic laboratories often handle specimens without full knowledge of the material's diagnosis; these specimens may contain infectious agents. To minimize exposure, observe universal precautions when handling any biological specimen. Consider all specimens to be infectious and treat these materials as potentially hazardous.

6. CDC and NIH Biosafety Levels

The Centers for Disease Control (CDC) and the National Institute of Health (NIH) have established four biosafety levels consisting of recommended laboratory practices, safety equipment, and facilities for various types of infectious agents. Each biosafety level accounts for the following.

- Operations to be performed.
- Known and suspected routes of transmission.

- Laboratory function.

6.1. Biosafety Level 1

Biosafety Level 1 precautions are appropriate for facilities that work with defined and characterized strains of viable organisms that do not cause disease in healthy adult humans (e.g., *Bacillus subtilis* and *Naegleria gruberi*). Level 1 precaution relies on standard microbial practices without special primary or secondary barriers. Biosafety Level 1 criteria are suitable for undergraduate and secondary education laboratories.

6.2. Biosafety Level 2

Biosafety Level 2 precautions are appropriate for facilities that work with a broad range of indigenous moderate-risk agents known to cause human disease (e.g., hepatitis B virus, salmonellae, and *Toxoplasma* spp.). Level 2 precautions are necessary when working with human blood, body fluids, or tissues where the presence of an infectious agent is unknown. The primary hazards associated with Level 2 agents are injection and ingestion.

NOTE: Most WTAMU research laboratories should comply with Biosafety Level 2 criteria.

6.3. Biosafety level 3

Biosafety Level 3 precautions apply to facilities that work with indigenous or exotic agents with the potential for aerosol transmission and lethal infection (e.g., *Mycobacterium tuberculosis*). The primary hazards associated with Level 3 agents are autoinoculation, ingestion, and inhalation. Level 3 precautions emphasize primary and secondary barriers. For primary protection, all laboratory manipulations should be performed in a biological safety cabinet or other enclosed equipment. Secondary protection should include controlled access to the laboratory and a specialized ventilation system.

NOTE: There are currently no Biosafety Level 3 facilities at WTAMU.

6.4. Biosafety Level 4

Biosafety Level 4 precautions are essential for facilities that work with dangerous and exotic agents with a high risk of causing life-threatening disease, the possibility of aerosol transmission, and no known vaccine or therapy (e.g., Marburg or Congo-Crimean viruses). Level 4 agents require complete isolation. Class III biological safety cabinets or full-body, air-supplied, positive-pressure safety suits are necessary when working with level 4 agents. In addition, isolated facilities, specialized ventilation, and waste management systems are required.

NOTE: There are no Biosafety Level 4 facilities at WTAMU.

6.5. Biosafety Summary

Safety Level	**Agent Characteristics**	**Safety Practices**	**Primary Barriers**	**Secondary Barriers**
1	Not known to cause disease in healthy adults.	Standard Microbial Practices	None	Open bench top sink required.
2	Associated with human disease.	Level 1 precautions plus: -Limited access -Biological Safety SOP	Class I or II Biological safety cabinet or other physical containment	Level 1 precautions plus: -Autoclave available

		- Biohazard warning signs - Biosafety manual defining needed waste decontamination or medical surveillance policies	devices: - Laboratory coat - Gloves - Face protection as needed	
3	Indigenous or exotic agent with the potential for aerosol transmission. Known to cause disease with serious or lethal consequences.	Level 2 precautions plus: - Controlled access - Decontamination of all waste - Decontamination of laboratory clothing before laundering - Baseline serum collected and stored	- Class I or II Biological safety cabinet or other physical containment - Protective clothing - Gloves - Respiratory protection as needed	Level 2 precautions plus: - Physical separation from access corridors - Self-closing, double door access - Exhausted air not re-circulated - Negative airflow into laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease and aerosol transmitted infection. Related agents with unknown risk of transmission.	Level 3 precautions plus: - Clothing change before entering - Shower upon exit - All material decontaminated upon exit from facility	- All procedures conducted in Class III biological safety cabinets or in Class I or II safety cabinets with full-body, air supplied, positive pressure personnel suits.	Level 3 precautions plus: - Separate building or isolated zone - Dedicated supply/exhaust, vacuum, and decontamination system - Other requirements, as necessary

6.6. Animal Biosafety

Refer to the Laboratory Safety and Health Management Procedure 24.01.01.W1.18AR 3.2.1 and 3.2.2 for more information regarding the use of hazardous materials with laboratory research animals.

IMPORTANT:
A copy of the CDC/NIH criteria for laboratory and animal biosafety levels is available from the AR-EHS Office.

7. Recombinant DNA Research

WTAMU is obligated to ensure that all recombinant DNA (rDNA) work conducted by its faculty and staff conforms to federal rDNA guidelines. The Institutional Biosafety Committee (IBC) reviews all protocols involving rDNA, decides the appropriateness of proposed containment procedures, and sets suitable biosafety levels. AR-EHS & the Biosafety Officer inspects individual laboratories and verifies that practices and facilities meet the requisite biosafety level assigned by the IBC. The federal rDNA guidelines define rDNA as "...molecules which are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell." The federal definition also includes the replicated progeny of these molecules as well as cells, plants, and animals that harbor such molecules. Transgenic plants and animals also come

under the guidelines, even if the transgenic DNA was not cloned prior to introduction. Investigators, researchers, or faculty who possess rDNA in any form must notify EHS and comply with all IBC requirements.

8. Disinfection and Sterilization

Biological safety depends on proper cleanup and removal of potentially harmful agents. Disinfection and sterilization are two ways to help ensure biological safety in the laboratory.

- Disinfection: Reduction of the number of pathogenic organisms by the direct application of physical or chemical agents.
- Sterilization: Total destruction of all living organisms.

The following sections discuss guidelines and procedures for biological disinfection and sterilization.

8.1. General Guidelines

Choosing the best method for disinfection and sterilization is very important. The proper method depends on the following:

- Target organisms to be removed.
- Characteristics of the area to be cleaned.

Once you have chosen the proper method for disinfection or sterilization, follow these guidelines to ensure laboratory safety:

- Frequently disinfect all floors, cabinet tops, and equipment where biohazardous materials are used following guidelines for dilution and contact time according to the manufacturer's instructions.
- Use autoclavable or disposable materials whenever possible. Keep reusable and disposable items separate.
- Minimize the amount of materials and equipment present when working with infectious agents.
- Sterilize or properly store all biohazardous materials at the end of each day.
- Remember that some materials may interfere with chemical disinfectants. Use higher concentrations or longer contact time.
- Use indicators with autoclave loads to ensure sterilization.
- Clearly mark all containers for biological materials (e.g., *BIOHAZARDOUS - TO BE AUTOCLAVED).*

Use the following table to aid in the selection of disinfectants:

8.2. Types of Disinfectant

Disinfectant	**Uses (assumes proper dilution and contact time)**
Alcohols	Ethyl or isopropyl alcohol at 70-80% concentration is a good general purpose disinfectant; not effective against bacterial spores.
Phenols	Effective against vegetative bacteria, fungi, and viruses containing lipids, unpleasant odor.
Formaldehyde	Concentration of 5-8% formalin is a good disinfectant against vegetative bacteria, spores, and viruses; known carcinogen; irritating odor.
Quaternary Ammonium Compounds	Cationic detergents are strongly surface-active; extremely effective against lipoviruses; ineffective against bacterial spores, naked viruses and mycobacteria; may be neutralized by anionic detergents (i.e., soaps).
Chlorine	Low concentrations (50-500 ppm) are active against vegetative bacteria and most viruses; higher concentrations (2,500 ppm) are required for bacterial spores; corrosive to metal surfaces; must be prepared fresh; laundry bleach (5.25% chlorine) may be diluted and used as a disinfectant.

Iodine	Recommended for general use; effective against vegetative bacteria and viruses; less effective against bacterial spores; Wescodyne diluted 1 to 10 is a popular disinfectant for washing hands.

8.3. Sterilization Methods

There are three common methods for sterilizing laboratory materials: wet heat, dry heat, and ethylene oxide gas.

8.3.1. Wet Heat

When used properly, the damp steam heat from an autoclave effectively sterilizes biohazardous waste. Sterilization occurs when contaminated materials reach 15-psi pressure at 250 degrees F or 121degrees C for at least 15 minutes.

IMPORTANT:

- For the autoclave process to be effective, sufficient temperature, time, and direct steam contact areessential. Autoclave testing and documentation is conducted by AR-EHS
- Every WTAMU department that autoclaves biohazardous waste should have written documentation toensure the waste is sterile.
- Parameters for sterilization and standard operation procedures should include requirements for verifying sterilization. If a test failure results for an autoclave, the PI must work with AR-EHS personnel to ensure adequate sterilization exists before the autoclave is subsequently used.

Potential problems with wet heat sterilization and autoclaves include the following:

- Heavy or dense loads require higher temperature and/or longer run time for sterilization.
- Poor heat conductors (e.g., plastic) take longer to sterilize.
- Containers may prevent steam from reaching the materials to be sterilized.
- Incomplete air removal from the chamber can prevent contact between the steam and the load.
- Deep trays can interfere with air circulation.
- Tightly stacked loads can impede steam circulation and air circulation.
- Double bagging will impede steam penetration.
- Carcasses do not allow steam penetration.
- Some bags and containers rated as autoclavable have thermal stability but they do not allow steam penetration.
- To ensure that all materials are sterile, always test autoclave loads. Remember, however, that some sterilization indicators are incomplete. Autoclave tape, for example, verifies sufficient external temperature exposure, but it does not indicate internal equipment temperature, exposure time, or steam penetration. Thermocouples or other instrumentation can also indicate temperature, but they do not verify sterility. A biological indicator is the most effective monitor to ensure sterility. Commercially available strips or vialsof *Bacillus* species endospores, for example, are suitable biological indicators.

8.3.2. Dry Heat

Dry heat is less effective than wet heat for sterilizing biohazardous materials. Dry heat requires more time (two to four hours) and a higher temperature (320-338 degrees F or 160-170 degrees C) to achieve sterilization. A *Bacillus* species biological indicator can verify dry heat sterilization.

8.3.3. Ethylene Oxide Gas

Ethylene oxide gas is lethal to all microorganisms. Because it is also a known carcinogen and potentially explosive (freon and carbon dioxide mixtures are stable), minimize your exposure and use extreme care when working with this gas. Ethylene oxide sterilizers and aerators must be properly vented. Ethylene oxide gas is most effective with heat-resistant organisms and heat sensitive equipment.

The effectiveness of ethylene oxide gas may be affected by the following:

- **Temperature:** The antimicrobial activity of ethylene oxide increases with increased temperature.Normal sterilization temperature is 120-140 degrees F or 49-60 degrees C.

- **Ethylene Oxide Concentration:** Sterilization time decreases with increased gas concentration. Normal concentration is 500-1000 mg/L.
- **Humidity:** Relative humidity of 30-60% is necessary.
- **Exposure Time:** Follow the manufacturer's recommendations.

9. Biological Safety Cabinets and Clean Benches

A biological safety cabinet is a primary barrier against biohazardous or infectious agents. Although biological safety cabinets surround the immediate workspace involving an agent, they do not provide complete containment (i.e., aerosols can escape). Therefore, careful work practices are essential when working with agents that require a biological safety cabinet.

NOTE: A biological safety cabinet is often referred to by other names such as biohood, tissue culture hood, or biological fume hood.

All biological safety cabinets contain at least one High Efficiency Particulate Air (HEPA) filter. These cabinets operate with a laminar airflow (i.e., the air flows with uniform velocity, in one direction, along parallel flow lines.). Biological safety cabinets must be inspected and certified

- When newly installed.
- After filter or motor replacement.
- After being moved.
- Annually.

Contact AR-EHS for more information about inspection.

9.1. Types of Biological Safety Cabinets

The following sections discuss safety procedures and guidelines for working with various types of biological safety cabinets.

The following table outlines various types of biological safety cabinets:

Type of Cabinet	Operation and Use
Class I	Only exhaust air is filtered. The user and environment are protected but the experiment is not. Operator's hands and arms may be exposed to hazardous materials inside the cabinet. This cabinet may be used with low- to moderate-risk biological agents.
Class II	Vertical laminar air flow with filtered supply and exhaust air. The user, product, and environment are protected.
Type A	Recirculates 70% of the air inside the cabinet. Do not use with flammable, radioactive, carcinogenic, or high-risk biological agents.
Type B1	Recirculates 30% of the air inside the cabinet and exhausts the rest to the outside. May be used with low- to moderate-risk agents and small amounts of chemical carcinogens or volatiles.
Type B2	Offers total exhaust with no recirculation.
Type B3	Same as Class II Type A, but vented to the outside of the building.
Class III or Glove box	Gas-tight and maintained under negative air pressure. Used to work with highly infectious, carcinogenic, or hazardous materials. All operations are conducted through rubber gloves attached to entry portals.

9.2. Using Biological Safety Cabinets

Follow these guidelines for using biological safety cabinets properly:

- Preparation
  - Turn the blower on and purge the air for at least five minutes before beginning work.
  - Never turn off the blower of a biological safety cabinet that is vented to the outside.
  - Turn off the UV light if it is on. Never work in a unit with the UV light illuminated. (UV radiation can be damaging.)
  - Do not depend on the UV germicidal lamp to provide a sterile work surface; wipe down the surface with a disinfectant (70% alcohol is usually suitable)and allow sufficient contact time for the disinfectant to perform its function.
  - Place everything needed for your procedure inside the cabinet prior to beginning work. Arrange the equipment in logical order.
  - Provide a container for wastes inside the cabinet. (Remember, nothing should pass through the air barrier until the entire procedure is complete.)
  - Never place any items on the air-intake grilles.
  - Place a disinfectant-soaked towel on the work surface to contain any splatters or spills that occur.
  - Keep the laboratory door shut and post signs stating "CABINET IN USE" on all the doors. Restrict activities that will disturb the cabinet's airflow, such as entry, egress, and walking traffic.

- Cabinet Use
  - Conduct work at least four inches from the glass view panel. The middle third area is ideal.
  - Limit arm movement and avoid motions that could disturb airflow.
  - If a burner is necessary, use the Touch-O-Matic type with a pilot light. Since flames cause air turbulence, place burners to the rear of the workspace.
  - Never use flammable solvents in a biological safety cabinet unless it is a total-exhaust cabinet (e.g., Class II B2).

- Experiment Completion
  - Enclose or decontaminate all equipment that has been in direct contact with the infectious agent.
  - Cover all waste containers.
  - To purge airborne contaminants from the work area, allow the cabinet to operate for ten minutes with no activity inside the cabinet.
  - Remove all equipment from the cabinet.
  - Decontaminate interior work surfaces.

IMPORTANT: Biological safety cabinets are not a substitute for good laboratory practices. Because aerosols can escape, take precautions to minimize aerosol production and protect yourself from contamination.

9.3. Clean Benches

A clean bench has horizontal laminar air flow. The HEPA-filtered air flows across the work surface towards the operator, providing protection for the product but no protection for the user. Because clean benches offer no protection, use a clean bench only to prepare sterile media. Do not use clean benches when working with pathogenic organisms, biological materials, chemicals, or radioactive materials.

10. Importing and Shipping Biological Materials

The Public Health Service provides Foreign Quarantine regulations for importing etiologic agents and human disease vectors. Other regulations for packaging, labeling, and shipping are administered jointly by the Public Health Service and the Department of Transportation. The U.S. Department of Agriculture regulates the importation and shipment of animal pathogens. It prohibits the importation, possession, and use of certain animal disease agents that pose a serious threat to domestic livestock and poultry.

11. Biological Spill Response

The exact procedure for responding to a biological spill depends on the material, amount, and location of the spill. In general, follow these steps immediately after a biological spill occurs.

- Warn others.
- Leave the room; close the door.
- Remove contaminated garments.
- Wash your hands.
- Notify your department head/supervisor, Biological Safety Officer and AR-EHS.

Follow these steps to clean up a biological spill:

- Wait for any aerosols to settle.
- Put on protective clothing, as appropriate.
-
- Cover the area with paper towels to contain the material, absorb the material, and absorb the chemical disinfectant being used to treat the area..
- Apply disinfectant or chemical sterilant to the contaminated area and allow sufficient contact time to perform its function
- Pick up the towels and place in a biohazard bag.
- Wipe the area dry with additional absorbent towels and place those towels in the biohazard bag.
- Mop the floor with an appropriate chemical sterilant.
- Rinse the mop and, if appropriate, dispose of the mop head in the biohazard bag.
- Autoclave all contaminated wastes.

NOTE: Spill cleanup must be appropriate for the hazards involved. Call AR-EHS at 651-2270 for assistance.

If a spill occurs inside a biological safety cabinet, follow these steps.

- Decontaminate materials while the cabinet is operating to prevent contaminants from escaping.
- Spray or wipe all affected equipment with an appropriate disinfectant. Wear gloves while doing this.
- If the spill is large, cover with absorbent towels then flood the work surface with disinfectant and allow sufficient time to perform its function.
- Dispose of towels and any consumable items in a biohazard bag.
- Autoclave all contaminated wastes.

12. Biological Waste Disposal

In Texas, disposal of biohazardous waste is regulated by the Texas Commission on Environmental Quality (TCEQ). Depository landfill regulations also apply. **"BIOLOGICAL WASTE"** means discarded biological material from teaching and research laboratories and operations. This does not include household or office trash, waste from Food Services, Physical Plant, bedding and manure from normal agricultural operations or bedding and litter from noninfectious animals. **"BIOHAZARDOUS WASTE"** means any solid or liquid biological waste that is hazardous because of its physical and/or biological nature and is differentiated from that which contains hazardous chemicals or radioactive materials. All waste that contains infectious material or which, because of its biological nature, may be harmful to humans, animals, plants or the environment is biohazardous waste. This includes:

- Waste from infectious animals, bulk human blood, or blood products.
- Infectious microbiological waste, including contaminated disposable culture dishes and disposable devices used to transfer, inoculate, and mix cultures.
- Pathological waste.
- Sharps.
- Hazardous products of recombinant DNA biotechnology and genetic manipulation.

Definitions of other terms used in this document can be found in APPENDIX A.

Biohazardous waste generated at WTAMU is collected by AR-EHS and collected quarterly by a contracted biowaste transportation company or is treated by thermal or chemical disinfection or by encapsulation (solidification) and then discarded with routine municipal solid waste. Biohazardous waste may also be called "medical waste," "special waste," "red bag waste," "infectious waste," or "pathological waste." For simplicity, the present document will refer to all such material as "BIOHAZARDOUS WASTE." Definitions in this document are derived from Title 25, Texas Administrative Code Chapter 1.

Sharps must be segregated from other waste and placed in puncture resistant containers. Sharps which have been treated by an approved method which incorporates grinding and/or shredding may be disposed as routine municipal

solid waste if the sharps have been made unrecognizable and significantly reduced in ability to cause puncture wounds. Unused hypodermic needles, syringes with attached needles, and scalpel blades shall be disposed of as treated sharps. Liquid waste should be disinfected and discharged into the sewer system. Treatment of all laboratory biological waste prior to disposal is good laboratory practice, and is highly recommended. Biohazardous waste must be treated and properly labeled and records must be maintained. Personnel with potential for contact with biohazardous material must be appropriately trained in the safe handling of the material. Never attempt to retrieve items from a sharps container.

Biohazardous waste which is mixed with hazardous chemical waste, radioactive waste, or both must be treated to eliminate the biohazard prior to disposal. After treatment, the waste must be managed as hazardous chemical waste through the WTAMU AR-EHS.

12.1. Segregation of biological waste

The following are guidelines for the segregation of biological waste.

- Any waste that could produce laceration or puncture injuries must be disposed of as "SHARPS." Sharps must be segregated from other waste. Metal sharps and broken glass may be commingled with each other but not with non-sharp waste.
- Waste that is to be incinerated should not be commingled with glass or plastics.
- Biological waste must not be commingled with chemical waste or other laboratory trash.
- Hazardous biological waste should be segregated from other biological waste.

12.2. Containers

Containers must be appropriate for the contents, not leak, be properly labeled, and maintain their integrity if chemical or thermal treatment is used. Containers of biohazardous material should be kept closed. The proper containers and labeling methods for biological waste are given below.

- Metal sharps - Place in a rigid, puncture resistant container (heavy walled plastic is recommended). The container should be used for encapsulation (see Section I.4) and disposal. Label the container "ENCAPSULATED SHARPS." Container and encapsulated contents must withstand an applied pressure of 40 psi without rupture.
- Broken Glassware - Place in a rigid, puncture resistant container (plastic, heavy cardboard, or metal). Seal securely and clearly label "BROKEN GLASS."
- Solid Biohazardous Waste - Use heavy-duty plastic "BIOHAZARD BAGS" (autoclave bags) or containers for solid biohazardous waste (including contaminated disposable plastic labware, paper, bedding, etc [NOT SHARPS]).
- Nonhazardous Biological Waste - Heavy duty plastic bags or other appropriate containers without a biohazard label are preferred. Red or orange biohazard bags or containers should not be used for nonhazardous material.
- Liquids - should be placed in leak-proof containers able to withstand thermal or chemical treatment. Do not use plastic bags to contain liquids.

Note: If the waste contains free liquids in containers, the plastic bag and/or the rigid container shall contain absorbent material sufficient to absorb 15% of the volume of free liquids in the container.

12.3. Storage of Biological Waste

Biohazardous waste should be treated and disposed of promptly and not allowed to accumulate. Containers holding biohazardous material must be clearly labeled, including the Biohazard Symbol. Biological waste may be held temporarily under refrigeration, prior to disposal, in a safe manner that does not create aesthetic (visual or odor) problems. Storage enclosures must be clean and orderly with no access to unauthorized persons (warning signs must be posted).

12.4. Treatment of Biohazardous Waste

Biohazardous waste must be rendered harmless by appropriate treatment prior to disposal. Waste should be treated as near the point of origination as possible. Treatment methods include incineration, chemical disinfection, thermal disinfection, and encapsulation.

12.5. Handling and Transport of Biological Waste

The following procedures are for the handling and transport of biological waste at WTAMU.

- Properly trained laboratory personnel (not custodial) shall be responsible for transporting treated biological waste from the generation site to the appropriate disposal receptacle. Untreated biohazardous waste shall only be handled by properly trained technical personnel.
- Treated waste must be properly contained and labeled before transport to the WTAMU dumpster or trash barrel for disposal.
- Transport of untreated biohazardous materials or foul or visually offensive material through non-laboratory or populated areas should be avoided.
- Trash/laundry chutes, compactors, and grinders cannot be used to transfer or process untreated biohazardous waste.

12.6. Labeling of Biohazardous Waste

The following procedures are for the labeling of biohazardous waste at WTAMU.

- Each container of untreated biohazardous waste must be clearly identified as such and must be labeled with the Biohazard Symbol.
- Each container of treated biohazardous waste intended for disposal must be labeled to indicate the method of treatment and to cover biohazard markings.
- Label autoclave bags with commercially available autoclave tape that produces the word "AUTOCLAVED" upon adequate thermal treatment. Apply this tape across the Biohazard Symbol on the bag before autoclaving.
- All containers of encapsulated sharps must be labeled as "ENCAPSULATED SHARPS."
- Containers of nonhazardous biological waste should be labeled as "NONHAZARDOUS BIOLOGICAL WASTE."

12.7. Disposal Methods

- Material that remains hazardous because it contains hazardous chemicals must be disposed of through the AR-EHS. Do not dispose of hazardous chemicals in municipal waste or discharge into the sewer system.

- Animal carcasses and body parts are not defined as medical waste unless the animals were intentionally infected with a human pathogen. Landfill disposition of uninfected animal parts is acceptable.
  *Avoid conditions that may create visual or odor problems.

- Metal sharps (contaminated or not) that may cause puncture or cuts, must be placed in the appropriate container and disposed of in a manner that prevents injury to laboratory, custodial, and landfill workers. Needles, blades, etc., are considered biohazardous even if they are sterile, capped, and in the original container. Encapsulation provides the highest degree of safety possible at a reasonable cost and also eliminates the possibility of the use of needles/syringes for illegal purposes. The disposal methods for sharps include
  - Encapsulation (solidification) in a properly labeled, puncture resistant container; place in a WTAMU dumpster or trash barrel. (See "Encapsulation"' APPENDIX A.)
  - Needles, such as those used for gas chromatography, should be thoroughly rinsed to remove hazardous chemicals and then disposed with non-contaminated broken glassware.

NOTE: Never place sharps that are not encapsulated in a trash container or plastic bag that might be handled by custodial staff or attempt to recap, bend, break, or cut discarded needles.

- Pasteur Pipets and Glassware:
  - Contaminated With Biohazardous Material
    - Disinfect by thermal or chemical treatment; place in a properly labeled, leak proof and puncture resistant container; place in a WTAMU dumpster or trash barrel.
    - Encapsulate in a properly labeled, rigid, puncture resistant container, and place in a WTAMU dumpster or trash barrel.

  Note: Encapsulation is required if glass is commingled with metal sharps.
  - Not Contaminated: Place in a puncture resistant container, then place in a WTAMU dumpster or trash barrel. The container must be clearly labeled to indicate that it contains broken glass.

- Plastic Waste:

- Contaminated With Biohazardous Material: Place in a properly labeled, leak proof container, disinfect by thermal or chemical treatment; place in a WTAMU dumpster or trash barrel.
- Not Contaminated: Place in a WTAMU dumpster or trash barrel for disposal.

- Microbiological Waste:
  - Solid waste must be placed in a properly labeled, leak-proof container, disinfect by thermal or chemical treatment; place in a WTAMU dumpster or trash barrel.
  - Liquid waste should be disinfected by thermal or chemical treatment then discharged into the sewer system.

NOTE: Excess proteinaceous material can clump and cause drain clogging. Grinding of treated waste may be necessary. Do not grind untreated biohazardous material.

- Human Pathological waste:
  - Human cadavers and recognizable body parts must be cremated or buried in accordance with 25 TAC 1.136(a)(4) December 21, 1994.
  - Other pathological waste from human and higher primates must be incinerated.

- Genetic Material: Disposal of materials containing recombinant DNA or genetically altered organisms must be consistent with applicable NIH guidelines, in addition to complying with the requirements contained in this document.

- Nonhazardous Biological waste
  - Biological waste that is not infectious or otherwise hazardous to humans, animals, plants, or the environment may be discarded as regular municipal waste (solid) or sewage (liquid).
  - There are no record keeping or labeling requirements for nonhazardous biological waste.
  - It is good laboratory practice to autoclave or disinfect all microbial products. Culture materials and biological specimens, including bacterial or "normal" cell cultures and primary tissues should be autoclaved or treated with a 10% sodium hypochlorite (or equivalent) solution. Liquid waste should be discharged into the sewer system. Avoid conditions that may create visual or odor problems. Nonhazardous waste should not be identified as hazardous. Containers should be labeled "NONHAZARDOUS LABORATORY WASTE." Do not use biohazard bags or "red bags" for nonhazardous waste.
  - Nonhazardous bedding (laboratory animal) and agricultural waste such as bedding, manure, etc. should be used as compost or fertilizer whenever practical. Minimize deposition of recyclable material.

- Chemical Waste: Biohazardous waste which also contains hazardous chemicals must be treated to eliminate the biohazard and then managed as hazardous chemical waste through the WTAMU AR-EHS Office. Hazardous chemicals must not be placed in the trash or discharged into the sewer system.

12.7.1. Disposal Training and Hazard Communication

The principal Investigator or individual with primary supervisory responsibility must assure that all personnel who dispose of potentially biohazardous material are informed of the hazards and are trained in the proper procedures and equipment needed to avoid exposure, proper disposal of biohazardous wastes, and recognition of symptoms of infection or exposure.

12.8. Written Procedure and Records

Each biohazardous waste generating entity at WTAMU is required to maintain written records which, at a minimum, contain the following information.

- Date of treatment
- Quantity of waste treated
- Method/conditions of treatment
- Name (printed) and initials of the person(s) performing the treatment.

If an entity generates more than fifty (50) pounds of biohazardous waste per calendar month, the records must also include

- A written procedure for the operation and testing of any equipment used and a written procedure for the preparation of any chemicals used in treatment.
- Processes for which the manufacturer documents compliance with specified performance standards (e.g.,

temperature, pressure, pH, etc.), and for processes which produce a continuous readout (e.g. strip chart or chart paper), routine parameter monitoring may be used to verify efficacy. Otherwise, biological monitoring is required to document a 99.99% reduction using an appropriate biological indicator (Bacillus species) at the following intervals.

- 50-100 pounds per calendar month requires testing once per month.
- 101-200 pounds per calendar month requires testing biweekly.
- More than 200 pounds per calendar month requires testing weekly.

- Records must be maintained for at least three (3) years for EACH CONTAINER ofbiohazardous waste treated (including sharps that are encapsulated).

13. Record Retention

No official state records may be destroyed without permission from the Texas State Library as outlined in Texas Government Code, Section 441.187 and 13 Texas Administrative Code, Title 13, Part 1, Chapter 6, Subchapter A, Rule 6.7. The Texas State Library certifies Agency retention schedules as a means of granting permission to destroy official state records.

West Texas A & M University Records Retention Schedule is certified by the Texas State Library and Archives Commission. West Texas A & M University Environmental Health and Safety will follow Texas A & M University Records Retention Schedule as stated in the Standard Operating Procedure 61.99.01.W0.01 Records Management. All official state records (paper, microform, electronic, or any other media) must be retained for the minimum period designated.

14. Training

West Texas A & M University Environmental Health and Safety will follow the Texas A & M University System Policy 33.05.02 Required Employee Training. Consult with AR-EHS staff to ensure appropriate training is assigned and completed. Staff and faculty whose required training is delinquent more than 90 days will have their internet access terminated until all trainings are completed. Only Blackboard and Single Sign-on will be accessible. Internet access will be restored once training has been completed. Student workers whose required training is delinquent more than 90 days will need to be terminated by their manager through Student Employment.

15. Bloodborne Pathogens

WTAMU does have a Bloodborne Pathogen Procedure that is available from AR-EHS (24.01.01.W1.15AR).

16. Reference Material

- West Texas A&M University IBC SOP No. 15.99.05.W1.03AR
- Centers for Disease Control/National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, 2009.
- SDS for Infectious Agents
- CDC/NIH Primary Containment for Biohazards: Selection, Installation and Use of Biological SafetyCabinets
- NIH Recombinant DNA Guidelines (2016)
- Importation Permits for Etiologic Agents
- Interstate Shipment of Etiologic Agents (42 CFR Part 72)
- Introduction of Regulated Articles (APHIS)
- Title 25 Texas Administrative Code, Chapter 1, 1.131-1.137. December 21, 1994. (Definition, Treatment and Disposition of Special Waste from Health Care Related Facilities).
- Title 30 Texas Administrative Code, Chapter 330, 330.24, 330.136, 330.641-643, 330.1001-1010. December 20, 1994. (Solid Waste Management Rules for Medical Waste Management, Disposal, Transportation, Collection, & Storage).
- WTAMU Bloodborne Pathogen SOP No. 24.01.01.W1.15AR

Related Statutes, Policies, or Requirements

Contact Office

WTAMU Academic and Research Environmental Health and Safety
(806) 651-2270

Appendix A

Animal Waste - includes carcasses; body parts; whole blood and blood products, serum, plasma and other blood components; and bedding of animals

Biohazardous Waste - includes any waste that is infectious or, because of its physical and/or biological nature, may be harmful to humans, animals, plants, or the environment. Biohazardous waste includes:

- Animal waste known or suspected of being contaminated with a pathogen.
- Bulk human blood or blood products.
- Microbiological waste.
- Pathological waste.
- Infectious waste.
- Waste products of recombinant DNA biotechnology and genetic manipulation.
- Sharps.

Biological Indicator - Commercially available microorganism (e.g. spore strips or vials of Bacillus species) that can be used to verify the performance of waste treatment equipment and/or processes.

Bulk Blood and Blood Products - Discarded bulk (>100 ml.) blood and blood products (higher primate or human) in a free draining, liquid state; body fluids contaminated with visible blood; and materials saturated or dripping with blood.

Chemical Disinfection - the use of a chemical agent such as 10% hypochlorite or EPA-approved chemical disinfectant/sterilant (used according to manufacturer's direction) to significantly reduce biological activity of biohazardous material.

Deposition in a Transfer Station/Landfill - means in accordance with Title 30, Chapter 330 of the Texas Administrative Code.

Discharge into the Sewer Station - means the discharge or flushing of treated biological waste into the local sewer system followed by copious quantities of water.

Encapsulation - the treatment of waste, especially sharps, using a material such as Plaster of Paris (or a commercial product such as Isolyser) which when fully reacted, will encase the waste in a solid protective matrix. The encapsulating agent must completely fill the container. The container and solidified contents must withstand an applied pressure of 40 psi without disintegration.

Incineration - burning biological waste in an incinerator permitted by the Office of Air Quality, Texas Commission on Environmental Quality.

Infectious Waste - waste containing pathogens or biologically active material, which because of its type, concentration, and quantity is capable of transmitting disease.

Microbiological Waste

- Discarded cultures and stocks of infectious agents and associated biological material.
- Discarded cultures of specimens from medical, pathological, pharmaceutical, research, and clinical laboratories.
- Discarded live and attenuated vaccines.
- Discarded disposable culture dishes intentionally exposed to pathogens.
- Discarded disposable devices used to transfer, inoculate, and mix cultures intentionally exposed to pathogens.

Pathogens - any agent or microorganism transmissible to humans and capable of causing disease.

Pathological Waste - materials from human and higher primates that includes, but is not limited to,

- Human materials removed during surgery, labor, delivery, spontaneous abortion, autopsy or biopsy, including body parts, tissues and fetuses, organs, bulk blood, and body fluids.
- Laboratory specimens of blood, tissue, or body fluids after completion of laboratory examination.
- Anatomical remains.

Sharps Waste - Any device having acute rigid corners or edges or projections capable of cutting or piercing, including

- Hypodermic needles, syringes, and blades.
- Glass pipets, microscope slides, and broken glass items.

Thermal Treatment

- Autoclaving at a temperature of not less than 121 degrees C, and a minimum pressure of 15 psi for at least 15 minutes (longer times may be required depending on the amount of waste, water content, and type of container used).
- Subjecting biological material to dry heat of not less than 160 degrees C under atmospheric pressure for at least two hours. (Exposure begins after the material reaches the specific temperature and does not include lag time.)

Treatment - chemical, thermal, or mechanical processes that significantly reduce or eliminate the hazardous characteristics or that reduce the amount of a waste.