

# **The University of Texas at El Paso**

## **Biological Safety Manual**



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## **1. Introduction**

Personnel who work in biological laboratories at The University of Texas at El Paso may handle or come into contact with hazardous biological agents. Over the years, there have been many documented cases of lab personnel acquiring diseases, some of which are fatal, due to their work with biological agents. Only approximately 20% of these reported cases have been attributed to a specific known incident, the rest are assumed to be related to work practices in the lab, specifically exposure to infectious aerosols. Effective risk assessment, proper handling based upon the conclusions of the risk assessment, and final disposal of biohazards materials after adequate disinfection treatment, greatly reduce the potential for exposure to infectious or harmful agents. Therefore, whenever work with biological agents is performed, all appropriate steps must be taken to protect personnel and the environment.

This Biological Safety Manual presents general information and biosafety practices as recommended by the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH). The guidance presented in this manual should be used and may be customized for specific applications and protocols applicable in each individual laboratory and can be used in conjunction with other available scientific information on risk assessment, to further minimize the potential for laboratory- associated infections. The HHS Publication, [Biosafety in Microbiological and Biomedical Laboratories—6th Edition \(cdc.gov\)](https://www.cdc.gov/biosafety/publications/m306.pdf), is a very good source for agent specific information to aid in the risk assessment process.

This Biological Safety Manual is supplemental to the University's Laboratory Safety Manual which addresses safe working practices in the lab and Industrial Hygiene aspects of the laboratory work up to and including medical prophylaxis and monitoring for laboratory worker protection.

## **2. Responsibilities**

Principal Investigators (PIs) are responsible for ensuring that all work with infectious agents is conducted according to CDC and NIH guidelines, as outlined in this manual, including universal precautions when handling blood and blood products. The Principal Investigators are responsible for performing a risk assessment to ensure that all the appropriate equipment, including safety equipment, is available and maintained in the laboratory. PIs are to have all laboratory staff who work with infectious agents attend the biological safety class and laboratory safety class provided by EH&S. The Principal Investigator must ensure that laboratory personnel attend to EH&S sponsored safety classes before access to the laboratory is granted. The Principal Investigators are also responsible for training all laboratory staff both on the specific hazards of the infectious material they will be working with and on the proper usage and maintenance of laboratory safety equipment. The Principal Investigator is also responsible to initiate consultative discussions with the biological safety officer on security issues, opportunities for risk reduction, the potential need for medical monitoring or prophylaxis, and other issues surrounding the well-being of the laboratory staff.

Laboratory staff is responsible to only use infectious materials for which they have been trained, and only utilizing the practices and procedures adopted in their specific laboratory. Laboratory staff is

expected to follow the Principal Investigator's instructions regarding the use of infectious materials in the lab and to observe the written Standard Operating Procedures (SOP) for the laboratory and the guidelines in this manual. Laboratory staff is encouraged to openly inquire about questions and concerns they may have regarding activities within their lab.

EH&S staff is responsible to provide biosafety services to the laboratories and the University. Those services include collection of hazardous wastes, spill response services, periodic monitoring of practices and procedures utilized in the laboratories, radioactive materials services, periodic inspection of chemical and biological materials storage, periodic inspection and testing of eyewashes, safety showers, chemical fume hoods and biological safety cabinets, and reporting noted deficiencies to laboratory management as necessary.

A member of EH&S staff shall be available to offer suggestions and opinions on security and safe practices to the principal investigators and the laboratory staff. EH&S staff is responsible to the University as a monitor to reassure continued adequacy of practices and conditions within the laboratories, to report noted inconsistencies with accepted standards, to identify developmental and facility needs to further enhance the University's capacity to meet its academic mission. To satisfactorily achieve the responsibilities of the EH&S department, it will during its routine visits to the bioscience laboratories, initiate dialog, offer assistance where appropriate, and follow-up where necessary. Annually the laboratories will be inspected to document that all aspects of the laboratory operations are meeting recognized standards. If necessary, follow-up visits to laboratories will be scheduled with the Principal Investigators, with copies of the re-inspection reports being forwarded up management channels as warranted.

### **3. Biological Hazards and Controls**

This chapter will discuss biological hazards and their classification in the basis of hazard type; biological safety guidelines as recommended by CDC/NIH; laboratory biosafety levels; laboratory equipment, including the biological safety cabinet; personal protective equipment and emergency procedures for responding to biological spills and releases.

#### ***a. Classification of Biological hazards***

The NIH defines biological hazards as "agents presenting a risk or potential risk to the well-being of man, or other animals, either directly through infection or indirectly through disruption of the environment." Biological hazards include materials or organisms known or suspected to contain infectious agents, recombinant DNA molecules, and oncogenic viruses.

#### ***Infectious Agents (Etiologic Agents)***

An infectious agent is a viable microorganism, or its toxin, which causes or may cause disease in humans or animals. This classification includes bacteria, viruses, parasites, and fungal agents

that have been assigned to risk groups 1 through 4 on the basis of the hazards they present. Examples of infectious agents include Salmonella (Risk Group 2 Bacterial Agent) and Influenza viruses (Risk Group 2 Viral Agent).

A class of infectious agents of particular concern is Bloodborne Pathogens. A human bloodborne pathogen is a pathogenic microorganism present in human blood and bloody fluids, such as semen, vaginal fluid, amniotic fluid, saliva, and urine that can cause disease in humans. The bloodborne pathogens of greatest concern are hepatitis B (HBV) and human immunodeficiency virus (HIV). Whenever work with any bloodborne pathogen is performed, the CDC's "Universal Precautions" should be practiced. (Universal Precautions are discussed in the Biological Safety Guidelines section and the University's Exposure Control Plan.)

### ***Recombinant DNA Molecules***

Recombinant DNA molecules are molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or DNA molecules that result from the replication described above.

### **Oncogenic Virus**

An oncogenic virus is a virus that is believed to cause tumors in humans or animals.

### ***b. Biological Safety Guidelines***

The following are biological safety guidelines for the safe handling of biological agents in the laboratory. Additional biosafety guidelines are available from [Biosafety in Microbiological and Biomedical Laboratories—6th Edition \(cdc.gov\)](#) and [NIHs "Guidelines for Research Involving Recombinant DNA Molecules."](#) All work involving biological agents at UTEP should follow CDC/NIH guidelines.

1. All work involving infectious agents must be performed in properly functioning Biological Safety Cabinets (BSC) appropriate for the agent. Containment is very important to minimize exposure to biological aerosols.
2. Wear single use, disposable gloves when working with infectious agents to protect against exposure by contact. Other ways to control contact exposure include using absorbent paper on work surfaces and frequently disinfecting work surfaces. Gloves should be selected based on the chemical(s) used as one type of gloves is not suitable for all types of chemicals.
3. Gloves must not be worn outside of the laboratory areas.
4. Wash your hands thoroughly after working with any biological agents, after removing gloves, and before leaving the lab to minimize chances of exposure due to ingestion or mucous membrane contact.

5. Exercise extreme caution when using “sharps”, such as needles, razor blades, and glass pipettes, to minimize inoculation hazards. Engineered safe needle devices can reduce risk of injury.
6. After using a needle, do not re-cap, bend, break, remove it from the syringe, or otherwise manipulate it in any other way, as many persons have accidentally inoculated themselves while doing so. After use, all sharps should promptly be placed as is into a conveniently placed puncture-resistant sharps container to prevent any injuries.
7. Handle lab animals carefully as inoculation can also occur through infected animal bites. Restraint devices can be used when handling animals to reduce the risk of exposure.
8. Eye, face, and respiratory protection should be used in rooms containing infected animals.
9. Be sure to disinfect work surfaces when finished with an experiment and after any spill or splash.
10. All contaminated waste must be handled and stored properly, including disinfection, to prevent contact exposure of other lab personnel as well as housekeeping staff and waste handlers.
11. Eating, drinking, handling contact lenses, and applying cosmetics is not permitted in the laboratories.
12. Food must be stored outside of the laboratory area in cabinets or refrigerators designated and used for food storage only.
13. Plastic ware should be substituted for glassware whenever possible.
14. Broken glass must not be handled directly. Instead use the spill kit available in the lab to contain the spill and collect the broken glass. The spill kit contains absorbent pads, a brush, and a dustpan. Use forceps and/or tongs to pick-up broken glass.
15. Animal and plants not associated with the work being performed in the lab are not permitted in the laboratory.
16. Lab coats must be worn while working with infectious or potentially infectious agents. Lab coats must be laundered at UTEP, contact Laboratory Animal Resources Center (LARC) for more information on scheduling time at the laundry machine for your lab. Remove lab coats before leaving for non-laboratory areas such eating areas, offices, the library, etc.
17. Eye protection must be worn in the laboratory while working with infectious agents if individuals wear contact lenses.
18. Eye and face protection (safety glasses, face shield, splatter guard, or safety goggles) must be used by all individuals when there is an anticipated exposure to infectious agents due to working outside of a BSC or other containment device.

**c. Universal Precautions**

Under Universal Precautions, all human blood and certain body fluids are considered potentially infectious for HIV, HBV, and other bloodborne pathogens. Universal Precautions apply to blood, blood contaminated body fluids, semen and vaginal secretions. Universal Precautions also apply

to tissues and to the following fluids: cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids. Universal Precautions do not apply to feces, saliva, nasal secretions, sputum, sweat, tears, urine and vomits unless they are visible contaminated with blood. The Universal Precautions are summarized below and should be practiced whenever work is performed with human blood or body fluids listed above.

1. Use protective barriers such as gloves, gowns, aprons, masks, or protective eyewear to reduce the risk of skin or mucous membrane exposure to potentially infectious material. Remove all protective clothing before leaving the laboratory.
2. Wash hands and other skin surfaces immediately of after finishing work, when contaminated, and after the removal of gloves.
3. Take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices. After using a needle, do not re-cap, bend, break, remove it from the syringe, or otherwise manipulate it in any other way. All sharps should be promptly placed as is into a conveniently located puncture-resistant sharps container to prevent any injuries.
4. Keep all specimens of blood, body fluids, or other potentially infectious materials in well-constructed, durable containers with a secure lid to prevent leakage during collection, handling, processing, storage, or transport within UTEP.
5. Use biological safety cabinets whenever procedures are conducted that have a high potential for generating aerosols.
6. Never pipette by mouth. Mechanical pipetting devices must be used.
7. Decontaminate work surfaces promptly after a spill and when work activities are completed.

**d. Laboratory Biosafety Levels**

The CDC and the NIH describe four biosafety levels (BSL) for activities involving infectious agents. The levels are designated in ascending order by degree of protection provided to lab personnel, the environment, and the community. BSL1 is for work with infectious agents that pose minimal or no hazards while BSL4 is for work with infectious agents which pose greatest hazard. Each level recommends facility design, lab practices, and safety equipment appropriate for working with the infectious agent involved. BSL1 through BSL4 are discussed below. A more exhaustive discussion of biosafety level criteria can be found in CDC/NIHS “Biosafety in Microbiological and Biomedical Laboratories.”

**Biosafety Level 1**

BSL1 practices, safety equipment, and facilities are appropriate for undergraduate teaching laboratories using microorganism not known to cause disease in healthy adult humans.

BSL1 represents a basic level of containment that relies in standard microbiological practices and use of personal protective equipment (PPE) with no primary or secondary barriers recommended.

### **Biosafety Level 2**

BSL2 practices, safety equipment, and facilities are recommended for clinical, diagnostic, research, or teaching laboratories involving moderate risk agent associated with human disease of varying severity. The primary hazards to lab personnel working with these agents include accidental skin or mucous membrane exposures, or ingestion of infectious materials. Lab supervisors must ensure that individuals are proficient in microbiological practices before they are allowed to work with risk group 2 agents unsupervised.

BSL2 is appropriate when work is done with any human-derived blood, body fluids, or tissues where the presence of an infectious agent may be unknown.

Primary barriers recommended include biological safety cabinets (BSC) and personal protective equipment (PPE). Secondary barriers recommended include waste decontamination facilities.

### **Biosafety Level 3**

BSL3 practices, safety equipment, and facilities are recommended for clinical, diagnostic, research, or teaching laboratories involving indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection. Primary hazards to lab personnel working with these agents include autoinoculation, ingestion, and exposure to infectious aerosols.

Primary barriers include BSCs or other enclosed equipment. Secondary barriers for this level include controlled access to the laboratory, a specialized ventilation system, and waste decontamination facilities. More information is available in the document UTEP BSL3 Manual and Operating Procedures.

### **Biosafety Level 4**

BSL4 represents maximum containment and is required for dangerous and exotic agents which pose a high risk of life-threatening disease, which may be transmitted via the aerosol route, and for which there is no available vaccine or therapy.

#### ***e. Laboratory Equipment***

A general understanding of biological laboratory equipment and how it works is essential to working safely with infectious agents. The following is a discussion of typical biological laboratory equipment, including biological safety cabinets, centrifuges, sonicators, homogenizers, and blenders, and guidelines for their proper use. All equipment that must be



repaired or sent for surplus must first be decontaminated before it is removed from the laboratory. The Equipment Decontamination Form is available via the EH&S website at [ehs.utep.edu](http://ehs.utep.edu).

## **Biological Safety Cabinets**

Biological Safety Cabinets (BSC) are among the most effective, as well as the most commonly used, primary containment devices in laboratories working with infectious agents and should be used whenever possible. BSCs can protect against procedures that generate infectious aerosols or splashes from pipetting, grinding, blending, shaking, opening containers, some centrifugation, etc. Contact EH&S if your work is not well suited for the BSC as other physical containment devices may be used. The BSC is designed to capture and contain infectious particles or aerosols generated within the BSCs interiors and exhaust air thorough a high-efficiency particulate air (HEPA) filter into the laboratory, or the outside. The three general types of BSCs are available (Class I, II, and III) are discussed below. More detailed information on BSCs can be found in CDC/NIHs "Biosafety in Microbiological and Biomedical Laboratories."

### **Class I**

The Class I BSC is a negative-pressure, ventilated cabinet usually operated with an open front. All of the air from the cabinet is exhausted through a HEPA filter either into the laboratory, or to the outside. The Class I BSC is designed for general microbiological research with low- and moderate –risk agents (Biosafety Level 1 and 2) and is useful for the containment of mixers, blenders, and other equipment. These cabinets are not appropriate for handling research materials that are vulnerable to airborne contamination, since the inward flow of unfiltered air from the laboratory can carry microbial contaminants into the cabinet.

### **Class II**

The Class II BSC is similar to the Class I BSC except Class II BSCs have an increased face velocity and the additional advantage of providing protection to the research material by HEPA filtration of the air flow into the cabinet across the work surface. This type of cabinet will protect the user, environment, and the research material and is suitable for work moderate- to high risk-agents (Biosafety Level 2 and 3).

Class II BSCs are classified into two types: A and B. Basically, type A cabinets exhaust 30% of the cabinet air into the laboratory and recirculates 70% within the cabinet. Since the air is re-circulated within the laboratory, volatile or toxic chemicals and radionuclides should not be used inside this type of cabinet. Type A is sub-divided into sub-types A1 and A2. Type B cabinets are ducted to the exhaust system that is maintained under negative pressure, thus allowing work to be done with volatile or toxic chemicals and radionuclides. Type B cabinets are divided into sub-types B1 and B2.

### **Class III**

The Class III BSC is a negative pressure, totally enclosed and gas-tight ventilated cabinet that offers the highest degree of protection to personnel, environment, and research materials. The Class III cabinet is suitable for work with extremely high-risk agents (Biosafety Level 3 or 4 agents.) All operations in the work area of the cabinet are performed through rubber gloves attached to entry portals. Supply air is HEPA-filtered, and the cabinet exhaust air is filtered by two HEPA filters in series, or HEPA filtration followed by incineration, before discharge to the outside of the facility.

### **Proper Use**

As with any other piece of laboratory equipment, personnel must be trained in the proper use of the biological safety cabinets. Perform all procedures to minimize the creation of aerosols and/or splashes. Of particular note are those activities that may disrupt the inward directional airflow through the work opening of Class I and II cabinets. Repeated insertion and withdrawal of the workers' arms in and from the work chamber, opening and closing doors to the laboratory or the isolation cubicle, improper placement or operation of materials or equipment within the work chamber, or brisk walking past the BSC while it is in use are demonstrated causes of the escape of aerosolized particles from within the cabinet. Class I and II cabinets should be located away from traffic patterns and doors. Fans, heating and air-conditioning registers, and other air handling devices can also disrupt airflow patterns if located adjacent to the BSC. Strict adherence to recommended practices for the use of BSCs and proper placement in the laboratory are important in attaining the maximum containment capability of the equipment and maintaining mechanical performance of the equipment itself.

BSC must be tested and certified annually to ensure adequate operation of the unit. EH&S will cover the cost of the annual testing and certification. If the testing determines that the BSC is in need of repair the PI and or lab supervisor must cover the cost of repair or replacement.

The following are additional safety guidelines for proper use of the BSC:

1. Let the BSC operate for at least 20 minutes if the unit was off to allow enough static electricity to build up in the HEPA filter. These units are built to operate 24/7.
2. Disinfect the work surface of the BSC before and after use. A 1:10 bleach solution is a suitable disinfectant. Follow the bleach wipe down with a wipe down using 70% alcohol solution.
3. Be careful not to place any objects on the air intake or exhaust grills as this would disrupt the airflow.
4. A sign can be posted on any doors around the cabinet stating that the cabinet is in use and thereby prevent unnecessary opening and closing of doors which disrupts the BSC air flow.

5. Always wear a lab coat while using the cabinet and conduct your work at least four inches past the BSC opening.
6. It is a good idea to keep a disinfectant handy in the event that a spill might occur.
7. Operate the cabinet for five minutes after completing any work inside the cabinet to purge any air-borne contaminants.
8. Thoroughly wash your hands and arms before leaving the lab.

It is very imperative that Class I and II BSCs are tested and certified at the time of installation within the laboratory, at any time BSC is moved, and at least annually thereafter.

### **Centrifuges, Sonicators, Homogenizers, and Blenders**

These instruments deserve special consideration because of their potential to create aerosols. If carcinogens, toxic chemicals, or infectious agents are going to be used in any of these instruments, then precautions must be taken to prevent the exposure of lab personnel to generated aerosols.

#### **Centrifuges**

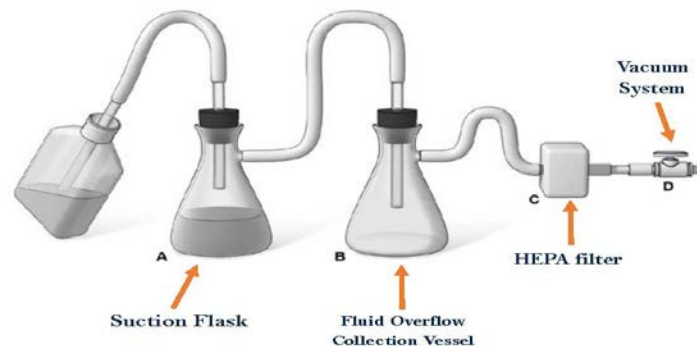
Safety features for the centrifuge include sealed buckets, centrifuges safety cups, removable rotors, or sealed heads to prevent the escape of infectious aerosols and liquids. Additional safety guidelines for proper centrifuge use are:

1. Make sure the lid is on and secured before operating the centrifuge.
2. Always balance the load in the centrifuge; if you are not filling the entire centrifuge rack, position the tubes opposite one another. If you have an odd number of tubes, use a tube filled with appropriate amount of water to equal the weights of the other tubes.
3. If vibration occurs, stop the centrifuge and check the load balance. Never operate an unbalanced centrifuge as the excessive vibration could result in breaking the tubes inside and generating hazardous aerosols.
4. Keep the rotors and buckets clean and promptly clean and decontaminate any breakage or spills. Spills must be reported to the lab supervisor and EH&S.
5. Routinely inspect your centrifuge to ensure leakage is not occurring. An indicator, such as Fluorescein, can be used to detect leaks. Fluorescein can be added to water and then centrifuged. A UV fluorescent light can be used to detect fluorescein on the work surface, floors, and walls.
6. High concentrations or large volumes of infectious agents should be centrifuged using sealed rotor heads or centrifuge safety cups. Inspect the rotor gaskets routinely to ensure they are in good condition.

## Sonicators, Homogenizers, and Blenders

The use of any of these instruments with infectious agents should be conducted inside a biological safety cabinet to contain any hazardous aerosols that are generated. Blenders should have leak-proof bearings and a tight-fitting gasket lid. Inspect the lid and gaskets routinely to ensure they are in good condition. Household blenders are not appropriate as they do not prevent the spread of aerosols.

Vacuum lines should be protected to prevent contamination of the building vacuum system. Make sure to use a two-flask system followed by an in-line filter. The first capture flask should contain a disinfectant solution enough to inactivate the potentially infectious liquids. The second flask is the overflow flask. See illustration below:



- i. Figure A: Protection of a house vacuum. Reference: BMBL pg. 396.
- ii. [Biosafety in Microbiological and Biomedical Laboratories—6th Edition \(cdc.gov\)](https://www.cdc.gov/biosafety/biosafety-in-microbiological-and-biomedical-laboratories-6th-edition)

### ***f. Personal Protective Equipment***

The type of personal protective clothing or equipment recommended depends on the Biosafety Level of the laboratory (see Section C) For BSL1 and BSL2 laboratories, standard protective clothing includes a lab coat and disposable single-use gloves. Additional protection, such as a face shield, safety glasses or goggles, may be necessary where there is a splash potential and when handling human blood and body products. BSL3 laboratories have more specific requirements for protective clothing including solid-front or wrap around lab gowns (typically button-down-the-front lab coats are not acceptable), and possibly respirators. BSL4 laboratories have the most stringent requirements for protective clothing including positive pressure suits that totally enclose and isolate the user from the surrounding lab environment.

Whenever lab coats, gloves, protective clothing or equipment becomes contaminated it should be removed and either decontaminated or replaced. Disposable protective clothing and

equipment should be discarded in the red biohazard bins. Do not reuse disposable single-use gloves, discard after use or when torn. Wearing double layers of gloves provides extra protection in the event the outer gloves becomes contaminated and needs to be removed and discarded without exposing the skin. Leave all protective clothing in the lab; do not wear it outside the lab. Always wash your hands after removing gloves and before leaving the lab.

**g. Emergency Procedures for the Spill or Release of an Infectious Agent**

Biological laboratories must be prepared for spills or releases involving infectious agents. Response to a spill or release of an infectious agent must be thorough and prompt to prevent further injury and contamination. The following are only general guidelines; each lab should design their own response plan based on their unique hazards and the location of the laboratory.

*In the Event of a Biological Spill ...*

1. Notify the people in the immediate area and if necessary evacuate the lab. The decision to evacuate is a judgment call based on the properties and hazards of the spilled material. Notify the lab supervisor and EH&S. Notify UTEP Police if after hours to ensure appropriate University personnel are notified.
2. Always attend to injured persons before attending to the spill. Seek medical help if necessary.
3. Try to contain the spill to keep it from spreading.
4. If the spill contains controlled substances a report to the local DEA office and EH&S must be made by the registrant.
5. If the spill contains recombinant or synthetic DNA a report to the NIH Office of Science Policy (formerly Office of Biotechnology Activities).

The following spill clean-up procedures are based on the biosafety level of the agent involved.

Spills or Releases involving BSL1 Agents:

1. Wear a lab coat and disposable gloves.
2. Cover the spill area with paper towels, pour a freshly prepared 1:10 bleach solution around the edges of the spill and then into the spill area.
3. Place the paper towel(s) and gloves into a biohazard for disposal.

Spills or Releases involving BSL2 Agents:

1. If infectious aerosols or droplets are generated from the spill or release, evacuate and close the lab. Allow 30 minutes for the droplets to settle and the aerosol concentration to decrease.

2. Wear appropriate protective clothing and equipment including gloves, lab coat, and an approved respirator equipped with HEPA filters, if necessary. Contact EH&S for assistance.
3. Cover the spill area with paper towels, pour a freshly prepared 1:10 bleach solution around the edges of the spill and then into the spill area. Allow 30 minutes contact time for proper disinfection.
4. Use paper towels to clean the area, working from the outer edges to the center. Clean the area with fresh towels soaked in a disinfectant.
5. Place all clean-up materials and gloves into biohazard bag for disposal or decontamination. Wash hands and arms thoroughly.
6. A small spill of material that did not result in the generation of aerosols or significant contamination can be cleaned using steps 2-5 above.

Spills or Releases involving BSL3 Agents:

1. If the spill occurs inside a biological safety cabinet, keep the cabinet running and clean the spill following the steps outlined in “Spills or Releases involving BSL2 agents”, with the exception that protective clothing appropriate for BSL3 be worn. If the spill inside the cabinet is substantial, it may be necessary to decontaminate the cabinet’s fan, filters, and airflow plenums. More detailed information is found in the BSL3 Manual. Contact EH&S for assistance.
2. If a minor spill occurs outside of a biological safety cabinet, clean the spill following the steps outlined in the BSL3 Manual, contact EH&S for assistance.
3. If a substantial spill occurs outside the biological safety cabinet, evacuate the lab and notify the appropriate personnel, including UTEP Police and EH&S. More detailed information is found in the BSL3 Manual.

#### **4. Infectious Waste Management**

Infectious waste from biological laboratories and medical facilities is regulated by The Texas Commission on Environmental Quality (TCEQ) and The Texas Department of State Health Services (TDSHS). These infectious materials are considered as “special” waste. A special waste is any solid waste that is not regulated as hazardous waste but because of its quantity, concentration, physical and/or chemical characteristics, or biological properties requires special handling, decontamination, and disposal to protect human health and the environment. Types of infectious waste will be discussed in the following sections along with proper treatment and disposal methods, and record keeping requirements.

##### **a. Infectious Wastes**

Infectious waste includes waste from microbiology and pathology labs, laboratory animal facilities, blood and blood products, and sharps; that is known or suspected to contain viable infectious microorganisms.

Potential sources of infectious wastes from microbiology laboratories are discarded cultures, stocks of infectious agents and associated biologicals; discarded cultures of specimens from medical, pathological, pharmaceutical, research, clinical, commercial, and industrial laboratories; discarded live and attenuated vaccines, but not the empty containers; used disposable culture dishes; and used disposable devices used to transfer, inoculate, or mix cultures.

Potential sources of infectious wastes from pathology laboratories are any human materials such as tissues and body parts, laboratory specimens of blood and tissue after completion of laboratory analysis and anatomical remains.

Potential sources of infectious wastes from laboratory animal facilities are bedding of animals exposed to pathogens, animal carcasses or body parts, and animal blood and blood products.

Blood and blood products include all human blood, serum, plasma, and other blood components. As required by the Universal Precautions, all blood and blood products should be handled as if it is known to contain pathogens.

“Sharps” is a broad term used to describe any sharp object that has the potential to puncture the skin if handled improperly, thus presenting an inoculation hazard if the “sharp” is contaminated. Sharps include syringes, razor and scalpel blades, glass pipettes, and microscope slides.

#### ***b. Infectious Waste Treatment***

The most common infectious waste treatment and disposal methods are chemical disinfection, steam sterilization, and incineration. These methods will be discussed below with some guidelines. All cultures, stocks, and other potentially infectious materials must be decontaminated before disposal. All materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport to the autoclaves or incinerator.

#### **Chemical Disinfection**

Liquid and gaseous chemicals are used routinely for decontaminating infectious waste. Common liquid disinfectants include alcohol (ethyl or isopropyl), formaldehyde, and chlorine compounds (bleach) while ethylene oxide is a common gas disinfectant. All waste that has been immersed in a liquid disinfectant must be thoroughly drained before disposal.

#### **Steam Sterilization (Autoclaving)**

Steam sterilization, or autoclaving, usually is considered to be the treatment method of choice for decontaminating non-disposable cultures, laboratory glassware, pipettes, syringes, or other

small items known to have infectious agents. Non-disposable sharps must be placed in a hard-walled container for transport to an autoclave for decontamination. Autoclaving provides a technically sound treatment method for rendering infectious material safe. Autoclaving is not recommended for treating large volumes of waste or insulated materials such as animal carcasses.

Autoclaving temperature, pressure, and time settings are very important to ensure adequate decontamination. The temperature and pressure settings differ depending on the type of autoclave used and the time setting varies according to load conditions. Gravity displacement autoclaves operate at 121 C and 15 psi for a recommended minimum of 60 minutes under normal conditions while vacuum-type autoclaves operate at 132 C and 27 psi for a recommended minimum of 10 minutes. The shorter time period for this type of autoclave is due to the higher temperatures and pressures attained therefore resulting in greater steam penetration. In most buildings on campus once a waste has been autoclaved it is disposed of in the red Stericycle biohazard bins located by the autoclaves. The bins are collected by Stericycle for final treatment and disposal. Additionally, biological waste that has been autoclaved and is no longer infectious, can be disposed of through the general trash. However, this must be coordinated through EH&S. Do not place "Biohazard" bags into the general trash, instead, attach a "Waste Treated" tag available from EH&S, to the biohazard bag and place it into a general black trash bag before discarding.

### **Incineration**

Incineration is the method of choice for treating larger volumes of infectious waste, animal carcasses, contaminated bedding, and human anatomical parts. The main advantage of incineration is the significant reduction in waste volume and the unobjectionable end product, ash.

Complete combustion of waste material is crucial to proper incineration. The factors involved in complete combustion are time, temperature, and turbulence. The waste should be retained in the combustion chamber(s) for a long enough time and at a high enough temperature to allow for mixing (turbulence) with excess oxygen, so that the combustion reactions can go to completion.

A deficiency in any or more of these critical combustion parameters can result in smoke or odor production, excessive emissions of harmful gaseous by-products, and the discharge of incompletely burned waste residue. Another important consideration is how the waste is introduced into the incinerator or feed rate. Overfeeding an incinerator can result in smoke, odors and incomplete combustion.

For those who do not have access to the incinerator located in campus, commercial treatment and disposal is available. Contact EH&S for more information. To request a biological waste pick-



up from EH&S, contact the EH&S office at 915-747-7124. Waste must be disinfected/decontaminated prior to any pick-ups.

***c. Record Keeping***

All lab personnel who treat and dispose of infectious waste on site must keep the following records.

1. Date of treatment;
2. Description of waste treated;
3. Treatment method used and conditions of treatment; and
4. Name printed of person(s) performing treatment.

***d. Disposal Methods of Treated Waste:***

**Chemical Disinfection**

Treated waste may be disposed of as general waste in the municipal landfill. All waste material must be thoroughly drained before disposed. Chemical liquid waste material, used as disinfectant must be characterized as hazardous or non-hazardous waste, prior to disposal. Contact EH&S for assistance on properly characterizing the waste. If chlorine compounds (bleach) are used, this substance may be disposed of through the sanitary sewer.

**Stream Sterilization (Autoclaving)**

Waste treated through this process, may be disposed of in the municipal landfill. EH&S recommends that autoclaved waste be disposed of in the red biohazard bins located by the autoclaves. The bins are collected by Stericycle, an infectious waste disposal company who does the final autoclave treatment before disposal in the sanitary landfill.

**Incineration**

The ash generated through this treatment process may also be disposed of in the municipal sanitary landfill.

**Sharps**

Sharps containers filled to the recommended fill line should be sealed and placed in the red biohazard waste bins located by the autoclaves. Do not autoclave sharps container. Stericycle will collect and disposed of the sharp containers.

Sharps treated and containerized with one of the approved methods as described under 25 TAC 1.136(a)(5) shall be disposed of in a permitted landfill in accordance with 30 TAC 330. Unused sharps shall be disposed of as treated sharps.

All clean broken glassware and pipettes shall be placed in puncture-resistant packaging and discarded with routine municipal solid waste.

***e. Labeling Waste***

All treated waste material that is not collected by Stericycle must be identified by the use of label which states that the contents of the disposable container have been treated in accordance with the provisions of 25 TAC 1.136(a). All other markings on the package must be covered or removed, prior to disposal. Contact EH&S for appropriate labels.

***f. Off-Site Treatment and Manifesting***

If waste is not to be treated on site, it shall be released only to a registered medical waste transporter for disposal. The University is currently using Stericycle for all of the biohazardous and medical waste collected on campus. The registered transporter shall provide a signed manifest for each shipment using a form approved by TCEQ.

The generator must maintain all shipping/treatment manifests for a period of three years following the date of shipment. Within 45 days of each off-site shipment a treatment record must be returned by the transporter. This record should be attached to the shipping manifest as proof that all shipments have been properly disposed of. Any failure of the transporter to return a treatment record within 45 days should be reported immediately to EH&S for further action and resolution.

## **5. Occupational Health**

As a matter of practice, it is always a primary consideration to remove through engineering controls any risk associated with an action. Many research protocols provide for the direct use of hazardous chemicals, infectious agents and toxins, or perhaps even the use of vertebrate animals in the production of the research findings. As such, the performance of the research protocols requires engineering controls (such as BSCs and chemical fume-hoods), the use of personal protective equipment (such as gloves, eyewear and respiratory protection), and aggressive diligent hygiene practice of Universal Precautions. The engineering controls, PPE and hygiene practices used in the laboratory are in combination critical to the protection of laboratory workers. Likewise, the risk assessment performed by the Principal Investigator in consultation with the Environmental Health and Safety office is an essential element to determine to what extent these measures should be employed in the laboratory performance of the protocol.

In addition to the preventive measures taken by the laboratory personnel, adequate knowledge of the chemical hazards present in the laboratory is necessary to ensure personnel are safe. As such the Principal Investigator must keep a listing of hazardous materials available for the lab personnel to review and should instruct the personnel on those hazards and how to avoid them. Knowledge of the emergency procedures and available emergency equipment is crucial to the safety of the laboratory personnel. The location of exits and meeting places, the sounds of relevant alarms, and the whereabouts of emergency eyewashes, alarm pull stations, fire extinguishers, prepared disinfectants and spill kits all must be addressed in the laboratory specific training.

Despite all of the engineering controls and the personal working knowledge of a laboratory and its inherent hazards, medical prophylaxis, vaccination or other intervention is sometimes warranted. It is the responsibility of the Principal Investigator during the risk assessment to identify if a vaccine, other medical procedures, or monitoring are called for regarding the risk inherent to the research. To be considered during the risk assessment are zoonotic diseases, infectious agent exposures, sharps exposures, chemical sensitivities, physical hazards, and any treatments or procedural methodologies that could effectively minimize the risk associated with those exposures. Where available, licensed vaccines for which the benefit clearly outweighs the risk will be *required to be offered* for all personnel identified as at risk. Other treatments may be *available or recommended* if the benefits do not clearly outweigh the risk. Specific information on a variety of agents and available treatment is available in the BMBL. One should not undertake any inoculation or treatment without the proper advisement by an Attending Medical Physician. All cost associated with the medical treatments should be at the expense of University and shall not be charged back to the treated individual.

### **Laboratory Animal Hazards**

UTEP researchers who handle laboratory animals and/or enter animal holding rooms are potentially exposed to animal dander, urine, saliva, tissues, and sera. Animal-related allergies are one of the most significant health hazards faced by laboratory animal workers. The literature indicates that about 10 to 46 percent of exposed personnel develop laboratory animal allergies, with symptoms progressing from those of minor rhinitis to more severe signs of asthma.

Inhalation is one of the most common ways for allergens to enter the body. After a period (frequently for several months, but sometimes many years), you may inhale enough quantities of allergens to become sensitized that is, you could develop symptoms when exposed again, even to small amounts of the allergen. More serious reactions to inhaled allergens may result in asthma symptoms such as cough, chest tightness, wheezing, or shortness of breath. A laboratory worker who has developed asthma symptoms from animal allergies can improve or recover completely if he or she immediately stops being exposed to dusts containing the animal allergens. However, the longer the exposures continue, the more likely the illness will persist, even after all contact with animals has stopped.

Symptoms from animal-related asthma and allergies can be severe and may require affected laboratory workers to change jobs or careers. Avoiding skin contact with animal products such as animal dander, serum, and urine may decrease your risk of sensitization. Gloves, lab coats, and approved particulate respirators with face shields can all decrease exposure.

### **Pregnancy and Other Health Risks**

Faculty, staff and students who are pregnant or have other health concerns may voluntarily contact EH&S for consultation and evaluation in reference to laboratory risks. Pregnant faculty, staff and students should consult their physician for advice on whether or not to perform experiments in the laboratory. It is encouraged that treating physicians be provided with a list of the chemicals that might be a source of exposure while in the lab. One should also check the Safety Data Sheets to be aware of the hazards of the chemicals.

Upon receiving questions of health risks for a particular laboratory or section, faculty and TAs should direct the student or other staff member to EH&S and shall provide the student the appropriate Safety Data Sheets for the laboratory space(s) in question. EH&S will assist the student, staff or faculty member in the review of the Safety Data Sheets and answer any questions regarding how they may reduce their personal health risks.

Students, staff or faculty requiring more detailed information regarding health risks will be referred to their personal physician. EH&S will respect the individual's privacy on all health matters divulged and thus will not report back regarding these issues to the faculty or TA. If special accommodations are requested, the Center for Accommodations and Support Services (CASS) will determine if the student qualifies for an accommodation. EH&S will work closely with the Faculty member to ensure accommodations are appropriate and implemented. The student is able to appeal the decision of the CASS Office to the University's ADA Coordinator.

### **Serum Banking and Post Exposure Injury Management**

The University of Texas at El Paso will not store employee or student serum. Depending on the accident appropriate institutions such as the CDC or Health Department will be contacted for assistance. Post exposure prophylaxis and testing will be provided as necessary to mitigate the risk of infection.

In the event of an accident or injury that occurs in the performance of laboratory functions or field work done as part of the regular activities of the University or its research, notification of the accident time, date, persons involved, severity, etc., must be reported to the lab supervisor and the Environmental Health and Safety office. In all cases the immediacy of the injury should be dealt with first, with any required reporting occurring only after the injury has been stabilized. The reports must be done preferably on the same business day but at a minimum within 24 hours of the event. Environmental Health and Safety will keep records involving injuries.

Records shall be maintained by the department in order to document the risk assessment, the decision to require or offer medical intervention, and proof as to the administration of such or the declination, whichever may be the case. Decisions regarding medical treatments shall be a topic of discussion at both the Institutional Biosafety Committee and the Institutional Animal Care and Use Committee meetings, as appropriate and applicable.

## **6. Transport and Acquisition of Infectious Agents**

In recent years it has become increasingly necessary to be vigilant in our activities relating to shipping, receiving and storing of infectious agents. Many infectious materials must now be tracked very closely and in a quantifiable way from the date of shipping from the supplier, through the final use, and even through the destruction. The intent of this section of the Biological Safety Manual is to describe for the researchers how they must comply, at what point different diligent levels of administrative controls apply.

### **a. Shipping and Receiving**

The transportation of infectious substances and materials that are known or suspect to contain them are regulated as hazardous materials by the US Department of Transportation (DOT), foreign governments, and the International Civil Aviation Organization (ICAO), and their transportation is subject to regulatory controls. The Dangerous Goods Regulations issued by the International Air Transportation Association (IATA) are based on the ICAO Technical Instructions and apply to all shipments of dangerous goods through air.

The Environmental Health and Safety (EH&S) department at UTEP has individuals who have received training and are certified to ship hazardous materials under the IATA Dangerous Goods Regulations (air) and the DOT hazardous Materials Regulations (ground). Contact the EH&S Office for guidance and assistance in shipping regulated items.

## **7. Security of Select Agents and APHIS Controlled Agents**

A Select Agent is an infectious material that is listed by the Health and Human Service (HHS), Centers for Disease Control (CDC) as a possible terrorist weapon for use against humans. The U.S Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) has a similar list of materials which are recognized as potential terrorist weapons because of the impact they could have upon food supplies in the nation. For the purposes of this manual the term “Select Agent” is intended to be synonymous with APHIS Controlled Agent and the controls mentioned apply to both. A current listing of the Select Agents and APHIS listed agents may be found at 42 CFR part 73 and 9 CFR part 121, respectively.

Currently, the University of Texas at El Paso doesn't have any listed Select Agents, nor does it have a registration to acquire Select Agents. This being said we must still recognize that as the University grows, and its research becomes even more diverse with the addition of specialized containment systems, it is inevitable that the use of Select Agents in research will become so in the not too distant future.

Therefore, it is important in this manual to describe the processes and requirements that will become part of standard operations.

a. **Preliminary Approval**

Select Agents and APHIS listed agents both require significant containment and security measures. As such, these materials are strictly controlled by the Federal Government. Each laboratory planning to propose use of Select Agents in research must first draft a research protocol and request a security risk assessment from a joint team of both UTEP Police and EH&S office. This request shall be routed through the EH&S office. The Biological Safety Manager will determine what level of compliance requirements will be applicable, depending upon Select Agent and laboratory proposed. The purpose of this screening inspection and security risk assessment is to determine the ability of the lab in question and its assigned personnel to meet the requirements for “registration” with the CDC (or APHIS) for use of the agent(s) in question. UT System policies regarding background investigations have been revised and are now available.

If it appears that the security and the containment capabilities of the laboratory, the proposed level of safety training and occupational health, and the laboratory personnel are all suitable to the proposed project, the Principal Investigator must then submit the proposed protocol, with EH&S and Police Department comments, to a work group assigned by the Office of Research and Sponsored Projects and the Dean of Science to review such matters. If the proposal is consistent with ORSP policies and the Dean of Science agrees with the space and source allocation necessary for the proposed research, it may then be presented for approval to the Institutional Biosafety Committee (IBC). The IBC may only indorse the project as meeting safety and health requirements. If animals are proposed as part of the protocol, then it must additionally be presented to and accepted by the Institutional Animal Care and Use Committee (IACUC).

b. **Registration**

Only after the Preliminary Approval is performed and all mentioned campus departments have endorsed their aspects of the project, a registration application may then be drafted and sent to the affect agency, CDC or APHIS. The University President has assigned the Assistance Vice President for Environmental Health and Safety as the “Responsible Facility Official” who would be responsible to file the registration application on behalf of the University and the laboratory involved.

Although UT System has specific requirements and methods stated regarding background investigations, all persons tentatively approved by UTEP or any other component institution for future access to select agents must be ultimately approved by the U.S Department of Justice (US DOJ) before a registration will be granted. The US DOJ’s approval for access to select agents will

be contingent upon a thorough background investigation performed either by the Federal Government or assigned contracted agency.

CDC and APHIS as well will have their own investigation teams who would be assigned to review the adequacy of the proposed protocol and the institutional policies that would support the successful safe and secure handling of the select agent(s) while in use on the campus. Only after this review process is done would a registration be granted to the specific laboratory and protocol proposed.

## **8. Other Institutional Policies, Publications and References**

- Laboratory Safety Manual, The University of Texas at El Paso.
- Radiation Safety Manual, The University of Texas at El Paso.
- Respiratory Protection Program, The University of Texas at El Paso.
- Emergency Response Guide, The University of Texas at El Paso.
- Hazardous Materials Handling and Disposal Policy and Procedures, The University of Texas at El Paso.
- Biosafety in Microbiological and Biomedical Laboratories, The Centers for Disease Control and Prevention and the National Institutes of Health, Sixth Edition, 2020.
- Biosafety in the Laboratory: Prudent Practices for the Handling and Disposal of Infectious Materials. National Research Council, Committee on Hazardous Biological Substances in the Laboratory, 1989.
- Biological Safety: Principles and Practices, 4<sup>th</sup> Edition. ASM Press, 2006.
- Guide for the Care and Use of Laboratory Animals, 8<sup>th</sup> Edition. National Research Council, 2011.
- Occupational Health and Safety in the Care and Use of Research Animals. Nation Research Council, 1997.
- Occupational Health and Safety Administration Standards, 29 CFR 1910.1030. Bloodborne pathogens.
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), Department of Health and Human Services, National Institutes of Health, April 2019.

## **9. Summary of Document Changes**

- June 2019 – Added a reference to the latest edition of the NIH Guidelines. Added Summary of Document Changes section.
- September 2020 – Added hyperlinks to the BMBL 5<sup>th</sup> edition as well as the NIH Guidelines.
- October 2021- Added reference to the latest edition of the BMBL 6<sup>th</sup> edition. Updated EH&S staff information. Added illustration diagram for house vacuum line protection.

- August 2022-Updated 30 TAC 330 reference regarding sharps containers and their disposal.
- December 2023, Added sub section “Laboratory Hazards” under section 5 Occupational Health. Added reference to the Respiratory Protection Program.