



Medical University
of South Carolina

BIOLOGICAL SAFETY POLICY

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Contacts

EMERGENCIES

Major Spills:

Clean up assistance: Risk Management(843-792-3604)
Help restrict access to contaminated areas: Public Safety..... (843-792-4196)

Accidental Exposure

SEEK IMMEDIATE MEDICAL FOLLOW-UP (do not wait 24 hrs)

Employees and students go to:

- Employee Health Services (during business hours: Monday-Friday, 7:30 am to 4 pm).
Address/Location: 57 Bee Street, Charleston SC 29425; Phone: (843) 792-2991
- MUSC Emergency Room (after business hours).
Address/Location: 96 Jonathan Lucas Street, Charleston SC 29425
- Be prepared to discuss the risks of the biohazardous agent with medical personnel.

REPORT EXPOSURE IMMEDIATELY to your supervisor or Principal Investigator and call the main number of the Department of Risk Management at 843-792-3604 to notify the Biosafety Officer (see section 13).

NOTIFY Employee Health Services within 24 hours by filing an ACORD First Report of Injury form at <https://www.carc.musc.edu/acord/>

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1. Overview

This manual provides biosafety guidelines for researchers at Medical University of South Carolina (MUSC) performing:

- 1) any work that requires registration with the MUSC [Institutional Biosafety Committee \(IBC\)](#), including recombinant or synthetic DNA, microorganisms and biological toxins, select agents and agents of dual use research concern, whether used *in vitro*, in research animals, or in a clinical trial, or
- 2) research in which biologicals, whether IBC registered or not, are administered to animals under the purview of the MUSC [Institutional Animals Use and Care Committee \(IACUC\)](#).

For safety involving the use of bloodborne pathogens in a clinical setting and other potentially infectious materials, such as research use of human-derived cells or fluids that are *not* modified with recombinant or synthetic DNA, please refer to the [MUSC Statement of Policy Regarding Bloodborne Pathogens](#).

1.1 Purpose

This manual is meant to be a reference and provides guidance for addressing biosafety issues at MUSC. This document is not meant to provide all biosafety requirements for highly specialized tasks, projects or locations at MUSC. The use of engineering controls, personal protective equipment (PPE) and modification of procedures are a few examples of ways to reduce the potential for exposure of people and the environment to biological agents. Principal Investigators (PIs) are responsible for ensuring the health and safety of their employees. Individuals may perform procedures that require more stringent precautions than the general biosafety principles covered in this manual. Therefore, PIs should evaluate each procedure and develop task-, project-, location- and/or device-dependent health and safety procedures to meet those requirements. Questions concerning biosafety practices or the development of specific protocols should be directed to the Biosafety Officer (BSO). This policy is intended to ensure compliance with all applicable local, state and federal guidelines and regulations for research involving biohazardous materials. Such governing documents include, but are not limited to:

GOVERNING DOCUMENT	PURPOSE
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines, current version)	Oversight of research involving recombinant or synthetic DNA.
Biosafety in Microbiological and Biomedical Laboratories (BMBL, current version)	Safety guidelines provided by the NIH and CDC for work involving biohazards.
United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern ("March 2012 DURC Policy")	Review of high-consequence pathogens and toxins for its potential to be dual use research of concern
HHS regulations Protection of Human Subjects (45 C.F.R. Part 46)	Protection of Human Subjects
FDA regulations (21 C.F.R.)	
Select Agent and Toxins Regulations (7 C.F.R. Part 331 , 9 C.F.R. Part 121 , and 42 C.F.R. Part 73)	Federal regulations requiring oversight of possession and use of biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products.
42 CFR Part 73 , Possession, Use, and Transfer of Select Agents and Toxins	
US PATRIOT Act	Federal regulation preventing "Restricted Persons" from gaining access to biological agents, toxins or delivery systems for reasons other than reasonably justified peaceful purposes.
International Air Transport Association Dangerous Goods Regulations	Regulations covering shipments of dangerous good/hazardous materials via air or internationally.
U.S. Department of Transportation Regulations (49 CFR Part 172)	Federal regulations covering shipping/transporting hazardous materials.
U.S. and South Carolina Occupational Safety and Health Regulations (29 CFR 1910 , SC Code of law-Title 41 , SC Code of regulations Chapter 71)	Federal and South Carolina regulations pertaining to occupational safety.
USDA/APHIS 7 CFR Part 340	Introduction of Organisms and Products Altered or Produced Through genetic Engineering and all APHIS Permit regulations/guidelines.
DHEC - S.C. Department of Health & Environmental Control regulations	Infectious Waste Program

1.2 Understanding oversight of research with biohazardous materials at MUSC

The [Institutional Biosafety Committee \(IBC\)](#) reviews and approves research projects involving recombinant or synthetic DNA, microorganisms, and biological toxins whether used *in vitro*, administered to animals (see IACUC) or used as part of a clinical trial (IRB). All such projects fall under the [MUSC Policies and Procedures for the Institutional Biosafety Committee](#). Investigators conducting such projects are required to adhere to these policies. The IBC is also charged with oversight responsibilities for all research projects that fall under the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. For additional information please refer to section 4.5

The [Institutional Animal Care and Use Committee \(IACUC\)](#) reviews any research involving live vertebrate animals. When recombinant or synthetic DNA, infectious agents, or biological toxins are administered, IBC approval is required *prior* to release of approval by IACUC. Administration of non-genetically modified cell lines, tissues and other biological materials (e.g. antibodies) also requires IACUC approval but not IBC approval. The Biosafety Officer will review use of non-IBC registered biological materials in animals as part of the IACUC review process. For additional information please refer to section 4.6.

The [Institutional Review Board \(IRB\)](#) reviews human research activities. Use of recombinant or synthetic DNA, microorganisms or biological toxins as part of a clinical trial requires IRB review as well as registration and review of the project by the IBC. Additional policies may apply (please refer to section 4.7).

The [Biosafety Officer \(BSO\)](#) serves as a member of the IBC and a consultant of the IACUC, reviews biosafety protocols (SOPs), conducts formal and informal facilities inspections, and reviews and approves administration of biological agents to animals. The BSO acts as a resource for appropriate safety processes and practices for PIs, research personnel, and human gene therapy study personnel. The BSO responds to accidental exposures and investigates reports of safety violations.

[University Risk Management \(URM\)](#) oversees the Occupational Health Services Program (OHSP), use of Bloodborne Pathogens, disposal of Medical Infectious Waste, manages the Biosafety Cabinet Certification program, assists with permits and shipping of biohazardous materials, and has the authority to shut down laboratories that are in violation of MUSC policies.

[Division of Laboratory Animal Resources \(DLAR\)](#) interacts with the IBC and IACUC with regards to biosafety involving animal research. DLAR may require testing of biological materials, such as rodent cell lines, that will be administered to animals.

2. Principles of Biosafety

2.1 General elements of containment

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL 5\) 5th Edition](#), published by the United States Department of Health and Human Services, is the definitive reference on biosafety. Oversight for working with recombinant and synthetic DNA is provided in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. These publications should be read and followed by all MUSC personnel working with applicable biohazardous agents.

Central to any discussion involving biosafety is the concept of containment of biohazardous materials to prevent contamination of people or the environment. Containment is also utilized to prevent contamination of research samples or animals. There are three general elements of containment: 1) facility design, 2) laboratory practices and techniques, 3) safety equipment. Each of these will be discussed briefly. For more detail, please refer to the section on Principles of Biosafety in [BMBL 5](#).

2.2 Facilities design

The design of a facility used to conduct research involving specific biological agents is highly dependent on the epidemiology and the risk and route of transmission associated with those agents. Facility design is viewed as a secondary barrier to protect workers, both inside and outside the facility. These secondary barriers may include separation of the laboratory work area from public access, availability of a decontamination area, hand washing facilities, specialized ventilation systems to assure directional airflow, air treatment systems to decontaminate or remove agents from exhaust air, controlled or restricted access zones, airlocks at laboratory entrances, and separate buildings or modules for isolation of the laboratory. More information on design criteria for specific agents and biosafety levels is found in the [BMBL 5](#).

2.3 Laboratory practices and techniques

Strict adherence to standard microbiological practices and techniques is essential for successful containment. Studies have indicated that over 80% of laboratory infections cannot be traced back to an overt incident. Most exposures and subsequent infections probably occur while performing routine procedures and techniques. In general personnel should handle all potentially infectious biological material as if known to be infectious (i.e. cell lines, body fluids etc.). In addition when working with animals, personnel should be aware of their proximity to the animal to avoid accidental direct contact.

2.3.1. Minimum requirements for good laboratory practice

- a. Access to areas containing biohazardous materials should be limited and is restricted at the discretion of the laboratory director or supervisor.
- b. Food and drink should not be kept in the same room or location where biohazardous materials are present. Freezers and refrigerators containing biohazardous materials should be marked with a universal biohazard sign and signage indicating that storage of food for human consumption is not permitted.
- c. Personnel must wear appropriate personal protective equipment (PPE).
- d. Hands should be kept away from the face. Eating, drinking, insertion of contact lenses, applying cosmetics (including lip balm) or smoking in laboratories where biohazardous materials are handled or stored are not permitted.
- e. Hands must be washed immediately after removal of gloves or other PPE, when leaving an area where biohazardous materials are handled (regardless of whether you handled the agent yourself), and before eating, drinking, or smoking.
- f. Mouth pipetting/suctioning of biohazardous materials is not allowed.
- g. Needles, syringes, glass Pasteur pipettes and other sharps should be used carefully to avoid injuries.
- h. Generation of aerosols should be minimized.
- i. All surfaces should be cleaned and decontaminated with an appropriate disinfectant after contact with biohazardous materials. Work surfaces should be decontaminated with an appropriate disinfectant after completion of procedures, immediately when surfaces are overtly contaminated, and at the end of the day if the surface may have become contaminated since the last cleaning or disinfection.
- j. Warning labels indicating the presence of a biohazard should be affixed to containers of biohazardous waste, refrigerators and freezers containing biohazardous agents, and other containers used to store, transport or ship these materials. All labels should include the universal biohazard symbol.
- k. Biohazardous waste must be handled in accordance with the [Hazardous Waste Management Program](#).

2.3.2. Sharps precautions

A contaminated sharp is any contaminated object that can penetrate the skin, including but not limited to: needles, scalpels, broken contaminated glass and broken capillary tubes. The use of needles and syringes should be restricted to those procedures for which there is no alternative. The use of self-sheathing or retractable needles is preferred when needles must be used. Broken glassware that may be contaminated should not be picked up directly by hand. Mechanical means such as a brush and dustpan or a set of tongs/forceps should be used. Sharps should be disposed of in red, leak-

proof and puncture-resistant sharps containers. Contaminated needles or sharps should not be bent, recapped or removed unless it can be demonstrated that no alternative exists or that such action is required by a specific procedure. If recapping or needle removal is required, techniques and/or devices should be used that minimize potential risk. Reusable sharps that are contaminated should not be stored or processed in a manner that requires employees to reach by hand into a container where these sharps have been placed. Dewars used to hold coolant for freezing tissue are to be decontaminated after the coolant has been poured out or has evaporated. Frozen tissue still presents a biohazard. Cryostats should be decontaminated on a regular basis, especially during defrosting. Since cryostats have an inherent cut hazard from the blades used to cut tissue, exposures due to cuts in cryostats should be considered serious.

2.3.3 Generation of aerosols

Every manipulation of a biological sample has the potential for releasing a portion of the sample in microdroplet form to the air and work surfaces. One simplistic but fundamentally valid way to view the potential for release of biological agents from a given sample is to consider the amount of energy that is used to manipulate the sample. High-energy techniques such as vortexing or homogenization have the potential to release aerosols of the sample if not properly contained. However, even low energy procedures such as removing screw caps and pouring or stirring of liquid media can release aerosols. Other examples of procedures that can generate aerosolized biohazards are washing down animal rooms, laboratory dishwashing, transferring tissue culture media, centrifugation, and separating blood serum. Aerosol formation has the potential to contaminate work surfaces, exposed skin and garments, and air in the breathing zone. Thus, aerosols can result in topical, oral, and respiratory exposures for workers. The results of one study investigating the formation of aerosols during common laboratory procedures are found in **Table 1** in Appendix I.

2.4 Safety equipment

Safety equipment includes safety centrifuge cups, biological safety cabinet (BSCs) and enclosed containers. Safety equipment also includes PPE such as gloves, lab coats (cloth or disposable), shoe covers, face shields, safety glasses and goggles. Safety equipment is often referred to as a primary barrier, since it generally represents the initial barrier(s) of protection downstream from standard microbiological practice. Combinations of various types of safety equipment can be used to create more than one primary barrier. However, circumstances may make it impractical to use equipment such as BSCs or completely enclosed containers, leaving PPE as the only primary barrier between the worker and a sample containing an infectious agent. This again illustrates the importance of standard microbiological practices because of the potential for PPE or other safety equipment failure. The use of safety equipment is discussed further in [BMBL 5](#).

2.4.1 Personal protective equipment

All personnel must wear appropriate PPE to protect against biological hazards. Common examples of PPE include: eye and face protection, hand and body protection, foot protection, and possibly respirators. The selection of PPE should be based upon the risk of exposure and/or transmission of biohazardous material to the worker. The PI is responsible for ensuring that proper PPE is being worn. For guidance on PPE selection go to Risk Management's [webpage on PPE](#). The BSO can also assist with questions regarding PPE selection.

Clothing and PPE that is appropriate both for the task to be performed and the location of the task is to be selected and worn at all times. PPE is considered "appropriate" only if it does not permit infectious biological fluids, biotoxins, or tissues to reach the employee's street clothes, scrubs, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time the protective equipment will be used.

Potentially contaminated PPE is not to be worn outside the work area, including public hallways, public bathrooms, and office spaces. Potentially infectious items transported outside work areas are to be decontaminated prior to transport or transported in decontaminated secondary containment. This practice obviates the need to wear gloves during transportation. If gloves will be needed at a location where they are not supplied, they must be taken there, not worn to the location.

Hand protection. Gloves are required to protect the hands and arms from biological materials that may result in absorption through the skin or reaction on the surface of the skin. Glove materials must be chosen with the specific tasks and agents used in mind (type of material, thickness, permeation rate, and degradation rate). Gloves should be inspected for defects or tears before and after each use and replaced as soon as a defect or tear is observed. Gloves should be removed when exiting the work area. Always wash hands after removing gloves. Latex or nitrile gloves are generally acceptable for most bloodborne pathogens associated with humans and animals. Disposable (single use) gloves should not be washed or reused.

Body protection. Personnel in any area where biological materials are routinely used or stored should wear a lab coat. Body coverings should be removed when exiting the work area and removed immediately if contaminated with hazardous materials. If cloth lab coats are worn and could be contaminated sufficiently that the clothing worn under the lab coat could also be contaminated, alternative clothing must be available.

Eye protection, prescription or non-prescription. Wrap-around safety glasses will generally be adequate, but safety goggles or face shields may be necessary.

Foot Protection. Open toed shoes should not be worn when working in areas where biohazardous materials are being handled. Shoe covers are available as additional protections against gross contamination of shoes and may be required in certain work areas.

Respirators. In certain situations where engineering controls cannot effectively control air contaminants within the work environment, personnel may be required to wear respiratory protective equipment. However, this is not a desirable situation. The use of BSCs should normally be sufficient to prevent the need for respirators. Personnel designated to use respiratory equipment must first have appropriate medical approvals, fit testing, and training. Before wearing any respirator, contact University Risk Management/OSHP (843-792-3604) for fit testing.

2.4.2 Biological safety cabinets (BSC)

Biological safety cabinets (BSCs) are often referred to as tissue culture hoods. BSCs are the primary engineering controls that researchers use to protect themselves from biohazards and their samples from contamination. BSCs are available in three general types, Class I, Class II and Class III, although Class I BSCs are no longer manufactured on a regular basis. Additional information on types and proper use of BSCs as well as the MUSC Biosafety Cabinet Service Program is found on the Risk Management's webpage [Biosafety Cabinet Service Program](#). BSCs should be used for all techniques involving the use of biological material where there is a significant potential for the generation of aerosols. A fume hood should not be used in the place of a BSC or vice versa. University Risk Management has established a centralized biosafety cabinet service program to facilitate the annual certification of biosafety cabinets, clean benches and cage changing stations in MUSC research facilities. Each investigator is responsible for ensuring the biosafety cabinets used for their experiments are certified at initial installation, annually thereafter and when moved or repaired.

3. Biosafety Levels and Risk Assessment

3.1 Biosafety levels

It is not the intent of this manual to establish the required biosafety level (BSL) for all tasks, projects and locations at MUSC. However, this manual does present the requirement for all PIs or supervisors to determine the hazards associated with a given process or project and take the steps necessary to protect workers. This process may require the establishment of a minimum BSL.

Assignment of BSL to a given project is highly sensitive to the risk(s) and route(s) of transmission associated with a specific infectious agent. There are four levels of biosafety assigned to operations conducted in laboratories. These are generally

referred to simply as BSLs 1-4. For those operations that involve the use of animals there are also four levels of biosafety designated as animal biosafety levels (ABSLs) 1-4:

BSL-1 is appropriate for agents not known to consistently cause disease in healthy adult humans. These agents are of minimal potential hazard to laboratory personnel and the environment. Examples include molecular cloning strains of *Escherichia coli* and yeast.

BSL-2 is applicable for agents that have a moderate potential hazard to cause disease in healthy adult humans and pose a moderate risk to the environment. If a worker contracts a disease related to BSL-2 agents, treatment is generally available. Examples include Hepatitis B Virus (HBV), *Staphylococcus aureus*, adenovirus, or clinical isolates of bacteria and fungi.

BSL-3 is used for agents that may be indigenous or exotic and are an aerosol transmission hazard. Diseases in this category may have serious health effects and treatment may or may not be available. Examples include *Mycobacterium tuberculosis* (TB), *Coxiella burnetii*, and St. Louis encephalitis virus.

BSL-4 is required for agents that are dangerous or exotic and pose a high risk of life threatening disease, are aerosol transmissible, or are related agents with unknown risk of transmission. Treatment for infections by these agents is generally not available. Examples include Marburg virus and Ebola virus.

BSL assignment should be conducted on a case-by-case basis. Reference to [BMBL 5](#) may simplify the process of selecting the BSL for a project by cross-referencing a large number of known human pathogens with the recommended BSL or ABSL requirements, thus consultation of BMBL5 is a recommended first step. However, the information for each agent in the BMBL represents the current knowledge base only for those agents and the listing of agents is not all-inclusive.

The BSL determination for an agent is multifactorial and could result in the agent being placed in a higher BSL rating since the determination depends on the specific manipulations involved. Some aspects to consider when determining the BSL level to be used include: the concentration of the agent, the type of manipulations proposed, and the training/experience of the individual performing the task. An example might be a BSL-2 agent that has been molecularly manipulated to increase the agent's pathogenicity. This manipulation may change the BSL determination from BSL-2 to BSL-3. Another example might be a BSL-2 agent that is concentrated in the laboratory. The concentration of the agent may be such that aerosol transmission is a possibility. This would result in the raising of the status to BSL-3 criteria.

3.2 Risk assessment

Risk assessment for a given activity that includes work with biohazards is a subjective process. The real issue is not whether or not a risk assessment has occurred, but rather how thoroughly the assessment has been conducted. PIs are responsible for the safety of any assigned employees and should be consulted for assistance regarding specific hazards of the task. Inherent in any risk evaluation of this nature is the extent of knowledge concerning the potential for transmission/exposure of a given agent while performing a specific activity. This clearly points to the need to do risk assessment on a case-by-case basis. Some aspects to consider when performing a risk assessment include the task being performed, the potential for aerosolization, the concentration of the agent, the route of transmission, and the consequences of infection.

Specific biohazards to pregnant women and their fetuses include, but are not limited to, agents in the TORCH group including T, *Toxoplasma gondii*, O, *Treponema pallidum* (syphilis), R, rubella, C, cytomegalovirus (CMV) and H, herpes simplex virus. However, there is also evidence that a number of other agents may result in adverse pregnancy outcomes. Bacterial agents of special concern are those classified as BSL3 agents and those BSL2 agents with known consequences to the fetus such as *Streptococcus agalactiae*, (group B Streptococcus, GBS) and *Listeria monocytogenes*. The Biosafety Officer can provide additional information on biological agents that pose increased risk during pregnancy.

A complete description of work practices, safety equipment, and facility design features for BSL-1 through BSL-4 is available in the [Biosafety in Microbiological and Biomedical Laboratories \(BMBL 5\) 5th Edition](#) (section IV). The [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) provide additional information as well as guidance for risk assessment of microorganisms and materials containing recombinant or synthetic DNA, which may increase or decrease the risk of the activities. Risk assessment is based on a number of factors:

- Pathogenicity, virulence, transmission route, stability, infectious dose, and antibiotic resistance of the biological agent
- Titer/volume of material used, which upon culturing of a biological agent, may increase several orders of magnitude compared to levels in clinical samples.
- The use of recombinant or synthetic DNA may alter any of the above risk factors and investigators should take these modifications into consideration when working with recombinant microorganisms.
- Amount and LD₅₀ of biotoxins
- Risks inherent to the procedure (e.g. probability of aerosol generation and/or inhalation of aerosols, auto-inoculation during animal procedures, static build up when working with powders, etc)
- Engineering controls
- Safety equipment availability and efficacy
- Personnel protective clothing and equipment availability and efficacy
- Health hazards (acute and chronic)
- Availability of prophylaxis and/or treatment
- Training and experience of personnel
- Identification of specific hazards and mitigation

4. Guidelines For Research Requiring IBC Registration

All use of recombinant and synthetic nucleic acid molecules, as well as all use and possession of microorganisms and biological toxins needs to be registered with the IBC. All microorganisms regardless of their risk group (RG) (Escherichia coli and other RG 1 organisms included) must be registered with the IBC. All possession, use and transfer of Select Agents¹⁴ at MUSC in any quantity must be registered with the IBC prior to bringing the Select Agents to MUSC. For administration of these materials to animals, additional approval is required by IACUC. For administration of these materials in clinical trial, additional approval is required by the IRB. All such projects fall under the [MUSC Policies and Procedures for the Institutional Biosafety Committee](#) and PIs conducting such projects are required to follow them.

Human blood, fresh tissue, or body fluids must be regarded as possibly infected with blood borne pathogens (BBP) as defined by OSHA Bloodborne Pathogen Standards. All research involving handling of human specimens must adhere to the standard precautions as described in the [Blood borne Pathogen Exposure Control Plan](#). Research whereby BBPs are isolated, propagated, amplified and/or concentrated from a human specimen, must be registered with the IBC.

4.1 Recombinant or synthetic DNA

All projects involving recombinant or synthetic DNA research require IBC registration. The NIH guidelines require that investigators classify their recombinant or synthetic DNA research along certain criteria. The classification/registration criteria as interpreted by the MUSC IBC are listed in **Table 2** in Appendix I. Molecular manipulations may change the biosafety level and requires determination of containment level on a case-by-case basis. The PI as part of the risk assessment makes the initial determination of risk involved with recombinant or synthetic DNA research but the IBC has the

final authority on determining biosafety level and containment. Initiation of any project is contingent on IBC approval and a satisfactory inspection of the facilities.

4.2 Microorganisms

Possession and use of microorganisms requires IBC registration. Investigators must be familiar with the microorganism including host range, mode of transmission, and potential health hazards. If the microorganism is genetically modified additional factors have to be considered. For example: How is the modified organism different from the wildtype organism? Does genetic manipulation change the host range, mode of transmission, antibiotic resistance, virulence, etc.? References to support statements in the IBC registration are required.

4.3 Biological toxins

Biological toxins are toxic substances that can be produced by bacteria, fungi, protozoa, insects, animals or plants and are classified separately from chemical toxins. They are non-replicative, non-infectious materials but can be extremely hazardous, even in minute quantities. The toxicity and health hazard of biological toxins vary greatly and toxins may be cytotoxic, neurotoxic, hemolytic or cause necrosis. Of primary concerns are acute biological toxins. In the laboratory setting, typical routes of exposure are through inhalation, mucous membrane contact (eyes, nose and mouth) and/or to open sores on skin, sharps injuries with contaminated materials, and ingestion of trace amounts of the material if hands are not washed prior to eating or smoking. Some biological toxins can be absorbed through intact skin, especially when solubilized in substances such as dimethyl sulfoxide (DMSO). All personnel working with a biotoxin or accessing a toxin laboratory must be familiar with the signs and symptoms of toxin exposure. Possession use and transfer of biological toxins with a mammalian LD₅₀ of ≤ 100 microgram/kg body weight must be registered with the IBC. When working with biological toxins, at a minimum, BSL2 containment and safety practices should be followed and a sign stating "Toxin in Use" should be posted at the lab entrance to provide hazard communication. This form is found in **Appendix II**.

4.4 Select agents

The Federal Select Agents and Toxin program (<https://www.selectagents.gov>) was created by the federal government in the wake of the anthrax mailings of 2001 in order to regulate possessions, use and transfer of biological agents which have been assessed to pose a severe threat to the public, animal or plant health or to animal or plant products. Registration is performed through the Centers of Disease control (CDC) for human pathogens and toxins while etiological agents of plants and animals are registered through United States Department of Agriculture Animal and Plant Health Inspection Services (USDA/APHIS). Overlap agents, such as *Bacillus anthracis* (anthrax), which pose a threat to both animals and humans can be registered with either government organization. All possession, use and transfer of select agents at MUSC in any quantity must be registered with the IBC. Federal penalties for violating the Select Agent and Toxin regulations include fines for individuals up to \$250,000, imprisonment for up to 5 years and institutional fines up to \$500,000 per incident.

Specific requirements for Select Agent Toxins include:

- A log of usage must be kept as an inventory control measure.
- The toxin must be stored in a locked and secure location to prevent theft.
- The Biosafety Officer must be contacted to witness and document the destruction of select agent toxin stocks.

4.5 Agents of Dual Use Research Concern (DURC)

Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The United States Government's (USG) oversight of DURC is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge,

information, products, or technologies provided by such research. It is each investigator's responsibility to assess whether the proposed research project may constitute a dual use research concern. On March 29, 2012, the USG issued its "Policy for Oversight of Life Sciences Dual Use Research of Concern". That policy formalized a process of regular USG review of USG-funded or -conducted research with certain high-consequence pathogens and toxins to identify DURC and implement risk mitigation measures, where applicable. On September 24, 2014, the USG issued its "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern," addresses institutional oversight of DURC. Oversight includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. The USG has limited the scope of this Policy as well as the March 2012 DURC Policy to a well-defined subset of life sciences research that involves 15 agents and toxins and seven categories of experiments. Institutions have the discretion to consider other categories of research for DURC potential and may expand their internal oversight to other types of life sciences research as they deem appropriate, but such expansion would not be subject to oversight as articulated in this Policy. Additional information on the USG DURC policies is available at <https://www.phe.gov/s3/dualuse/Pages/default.aspx>. Dual use agents undergo review in addition to IBC review (http://academicdepartments.musc.edu/research/ori/ibc/DURC/IBC_DURC).

4.6 Research involving biological materials in animals

Access to animal housing, use, and support areas is limited to authorized, trained, and informed personnel. Only those individuals with work-related requirements, and who have had the appropriate training, may enter animal areas unescorted. Visitors or service technicians who have not received training must be escorted at all times while in animal areas by a MUSC representative trained in biosafety procedures. Research involving animals performed in the medical center must comply with [MUSC Medical Center Policy C-128 – Animal Research](#). This policy requires IACUC approval for research involving live vertebrate animals. IACUC projects involving administration of materials posing potential biological hazards (including cells, biological fluids, recombinant or synthetic DNA, genetically modified cell lines, microorganisms, biological toxins) must be addressed in the IACUC application. Administration of recombinant or synthetic DNA, microbes, and toxins require IBC approval prior to IACUC approval. For the use of BSL-2 agents in animals an ABSL-2 safety protocol is required. Administration of non-genetically modified cells and biological fluids/ materials (e.g. antibodies, cytokines etc.) does not require review by the IBC but will be evaluated by the BSO and must be approved as part of the IACUC application review.

Laboratory animals should be anesthetized or restrained during experimental procedures if unexpected movement during the procedures may increase the laboratory personnel's risk of exposure to biological hazards. Biological safety cabinets should be utilized whenever experimental procedures may result in splashing or aerosolization of biohazards. If the use of BSC is impractical, additional PPE, such as face and eye protection must be worn.

Considerations for Animal Housing The majority of transgenic animals can be safely housed at Animal Biosafety Level 1 (ABSL-1). Animals receiving infectious agents including recombinant or synthetic DNA expressed in viral vectors, infectious/potentially infectious agents (such as human derived materials), or biological toxins should be housed under Animal Biosafety Level housing as determined by the IBC. The IBC will consider housing arrangements that guarantee proper containment and use of proper safety practices by researchers and animal caretakers who may be exposed to agents while handling animals or manipulating contaminated cages and spent bedding. DLAR can upgrade existing ABSL-1 rooms to ABSL-2, if additional ABSL-2 housing is required and space is available. Such an upgrade in containment level requires DLAR to modify air handling within animal rooms and implement ABSL-2 procedures for animal handling and cage changing. A minimum of 2 weeks advance notice should be provided to DLAR to accommodate requests for upgraded containment.

Administration of non-IBC registered biological materials to animals Administration of unmodified (no recombinant or synthetic DNA manipulation) human cell lines, tissue, fluids, to animals is classified as "Other Potentially Infectious

Material” in the [MUSC Bloodborne Pathogen Exposure Control Plan](#) and should be handled accordingly. If human cells are injected into animals, cages should be identified with a “Human cell hazard” sticker. Rodent cell lines administered to animals must comply with the [MUSC IACUC Cell Line Policy](#) requiring rodent pathogen testing (by PCR, Mouse/Rat Antibody Production MAP/RAP testing) of established cell lines or biologicals derived from human or other mammalian tissues that have been passed in rodents. Test results should be uploaded as part of the IACUC registration. Biological materials with a clear history that excludes contact with rodent materials are exempt. Biological materials that require testing prior to *in vivo* use include:

- Cell lines, transplantable tumors, serum, tissues, body fluids, and antibody preparations derived from rodents outside DLAR colonies.
- Non-rodent derived cell lines, transplantable tumors, serum, tissues, body fluids, and antibody preparations that have been passaged through rodents or exposed to rodents outside DLAR colonies.

4.7 Clinical trials involving administration of IBC registered agents

Clinical trials involving Human Gene Transfer (HGT) or gene therapy must obtain IBC approval as well as IRB approval in order to register MUSC as a study site. Depending on the needs of the HGT trial, the Investigator may need to refer to applicable Medical Center, Pharmacy and Infection Control policies as well as the applicable section of the MUSC IRB HRPP Program Guide ([section HRPP 4.11, Human Gene Transfer Studies Policy and Procedures](#)).

The NIH Guidelines for Research involving recombinant or synthetic nucleic acid molecules (Section III-C-1) define human gene transfer (HGT) as the deliberate transfer of either:

- Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules
- Synthetic nucleic acid molecules, or DNA, or RNA derived from synthetic nucleic acid molecules that meet any one of the following criteria:
 - Contain more than 100 nucleotides; or
 - Possess biological properties that enable integration into the genome (*e.g.* cis elements involved in integration); or
 - Have the potential to replicate in a cell; or
 - Can be translated or transcribed

Investigators and study coordinators must be aware of the general responsibilities assigned by NIH Guidelines to investigators conducting recombinant or synthetic DNA research. Other useful information may be found in the NIH Office of Biotechnology Activities (OBA). HGT trials originating at MUSC must be reviewed by the IBC and IRB. Only after the NIH protocol registration process is completed, may final IBC approval then be granted.

5. Training

Completion of several training modules in MyQuest (<http://www.musc.edu/myquest>) on Hazardous Materials and bloodborne pathogens is required annually. Training on shipping is also available (enter “shipping” as a keyword into the catalog search).

Biosafety Training is offered through MyQuest. The assigned modules will vary depending on the researcher’s role and activities.

It is the PIs responsibility to train personnel on IBC-approved biosafety procedures, prior to working in the laboratory.

- 1) PIs must have a biosafety protocol (a.k.a. Standard Operating Procedures or SOPs) to ensure compliance with safety guidelines outlined by the Center for Disease Control publication "Biosafety in Microbiological and Biomedical Laboratories, 5th Edition". Template biosafety protocols are located at http://research.musc.edu/ori/ibc/IBC_SOPs

- 2) Safety protocols are evaluated during review of Institutional Biosafety Committee applications and as part of lab inspections.
- 3) PIs must train the personnel on the biosafety procedures as approved by the IBC, prior to starting the work.
- 4) Each person listed on the IBC registration must sign the associated biosafety protocols indicating that they have read, understood, and agree to follow the specified biosafety procedures.

The BSO may provide additional hands-on training for lab personnel.

6. Laboratory Set-Up/Relocation Process

MUSC has established procedures that must be followed to relocate an existing lab. See <https://horseshoe.musc.edu/university/risk-management/forms/laboratory-relocation-notification-form>

To set up a new lab, Principal Investigators must follow the MUSC Laboratory Setup Policy: <https://horseshoe.musc.edu/~media/files/univ-files/risk-management-files/oshp-policies/musc-lab-setup-policy.pdf?la=en>

All laboratories must complete a [lab safety certificate](#) as part of OSHP requirements. Laboratories that work with biohazardous agents must also register these materials with the IBC. Work may not be initiated until IBC approval has been obtained. If no immediate work is planned, investigators must register with the IBC for storage of microorganisms and biotoxins. The IBC registration process is outlined in section 6 of the IBC Policies and Procedures. Depending on animal use or involvement of human subjects investigators may also be required to obtain IACUC or IRB approval, respectively.

- IBC registration submission information: http://research.musc.edu/ori/ibc/IBC_Submission.html
- IACUC registration submission information: <http://research.musc.edu/ori/iacuc/submissions/index.html> (NetID required)
- IRB registration submission information: <http://research.musc.edu/ori/irb/submissions.html>

For investigators who are currently registered with the IBC and are relocating, it is important to schedule an inspection with the BSO. Work with recombinant or synthetic DNA, microorganisms and biological toxins whether used *in vitro*, in research animals, or in a clinical trial, may not be performed prior to IBC approval, which also requires a satisfactory inspection of all facilities. Following a satisfactory inspection, it is the PIs responsibility to submit an amendment of the IBC registration that reflects the new location.

For completed or inactive IBC registered projects, the PI shall terminate the IBC registration within 30 days of project completion. [IBC Termination forms](#) are located on the IBC website. A human gene transfer trial may be closed after the last subject enrolled at MUSC has completed the study, or if the final report for the Investigational New Drug license has been submitted to the FDA. IBC staff reviews the Termination form to make sure disposition of all registered agents has been addressed. A copy of the IBC Termination form will be forwarded to the BSO, who will verify that all registered agents have been properly disposed of. If an investigator leaves MUSC but does not terminate the registration, the BSO will investigate the status of registered agents and has the authority to dispose of the remaining materials. Following BSO investigation and disposal, if applicable, the registration may be closed administratively.

7. Safety Protocols

Every Investigator registered with the IBC must have a specific biological safety protocol (SOP) to ensure compliance with safety guidelines outlined by the Center for Disease Control publication "[Biosafety in Microbiological and Biomedical Laboratories, 5th Edition](#)". A safety protocol serves as a lab-specific training tool and documents that personnel have been informed about the biological hazards in their laboratories and have been trained to prevent accidental exposure to the

hazards. Safety protocols are evaluated during the review of IBC applications and as part of lab inspections. This page is intended to aid researchers working at either Biosafety Level 1 (BSL-1) or Biosafety Level 2 (BSL-2) to prepare safety protocols. A general safety protocol should comply with the minimal requirements laid out in the sections of Biosafety in Microbiological and Biomedical Laboratories, Ed. 5 that refer to criteria for BSL1 and BSL2 laboratories.

7.1 How to write a safety protocol (SOP)

Each SOP must minimally include the following sections: (1) Hazard communication, (2) Safety procedures, (3) Emergency procedures.

The following steps should be performed prior to writing the SOP:

- Review laboratory protocols and identify potential hazards and perform a risk assessment. Are you using risk group 2 organisms, toxins, recombinant or synthetic DNA (e.g. insertion of an oncogene, potential to generate a replication competent virus, etc.)?
- Determine the types of exposure risk. Are you using sharps, generating potential aerosols, working with exposed animals?
- Develop a plan to minimize the risk of personnel exposure and release of the biohazardous agent. Examples: Work in BSC, use secondary containment during centrifugation, use PPE, provide immunizations?
- Identify the types of waste that will be generated and how it will be decontaminated and disposed. Are you using sharps, culture media, toxin waste, recombinant or synthetic DNA exposed animals?
- Develop a plan for routine clean-up in compliance with [Hazardous Waste Management Program](#).
- Include information from the Biological Safety Manual for emergency procedures involving a biohazardous spill or exposure

For work at BSL2 it is important to outline specific instances during protocols where consideration of biosafety is paramount. Examples of SOPs where safety is emphasized are bulleted below:

- Propagation of viruses/microorganisms
- Experiments that require PPE in addition to a lab coat and gloves
- Experiments that require manipulation of a BSL2 agent outside a biosafety cabinet
- How to properly vortex or sonicate a viable BSL2 agent
- How to safely centrifuge a sample containing BSL2 agents
- Safety concerning the handling of human or non-human primate primary cell lines or tissues
- Safety when injecting a research animal with a BSL2 agent

7.2 Safety protocol examples and templates

Examples and template SOPs can be downloaded and modified as needed at <http://research.musc.edu/resources/ori/ibc/sops>

8. Facilities Inspection

All facilities in which IBC registered agents will be used must be inspected. The biosafety inspection is in addition to the general laboratory inspection performed by OSHP. The BSO inspects all research areas where biohazardous agents will be used or stored, which may include the main laboratory, tissue culture rooms, and equipment rooms. The following are required:

- For initial lab inspections, the PI must be present at the time of inspection. For subsequent inspections, the PI must be available to sign the paperwork at the conclusion of the inspection.
- The presence of at least one laboratory representative possessing knowledge of the biological agents (recombinant or synthetic DNA/RNA, microorganisms or biotoxins) and procedures used in the laboratory.
- A copy of the signed laboratory safety protocols must be provided to the BSO.

The safety protocol must be signed by the individuals working in the laboratory, indicating that they have read, understand, and agree to follow the safety protocol and that they have received agent specific training as described in the MUSC Biosafety Policy. In some cases, when lab space is shared, it may be required to “cross-sign” SOP’s between laboratories to ensure hazard communication.

The MUSC Biosafety webpage (<https://horseshoe.musc.edu/university/risk-management/services/biosafety/setting-up-a-biosafety-level-2-laboratory>) serves as a guide for researchers setting up Biosafety Level 2 (BSL2) laboratories. Adherence to this guide will result in compliance with the CDC's guidelines (Biosafety in Microbiological and Biomedical Laboratories, ed. 5) and facilitate passing a lab inspection conducted by the BSO.

8.1 Biosafety Level 1 laboratory inspection

Biosafety Level 1 (BSL-1) is suitable for working with agents having no known or minimal hazard to laboratory personnel and the environment (including plants and other animals), such as molecular grade cloning strains of *E. coli*. It is important to remember that BSL-1 depends entirely upon good laboratory practice (see Section 2.3). The PI must ensure adequate training of laboratory personnel regarding duties, potential hazards and safety procedures, and exposure evaluation procedures, especially to at risk individuals (immunocompromised individuals, women of childbearing age). Such training should be conducted and documented on an annual basis (or more frequently in case of procedural or policy changes) even though laboratory inspections may be performed less frequently. A signed biosafety protocol can serve as documentation of this training. The BSO will inquire about access to facilities, PPE, practices for handwashing, decontamination, pipetting, use/disposal of sharps, liquid and solid waste handling, and emergency procedures. No special safety practices are identified at BSL-1.

8.2 Biosafety Level 2 laboratory inspection

Biosafety Level 2 (BSL-2) incorporates the requirements for BSL-1 and builds on them to create an environment that is suitable for work involving agents of moderate potential hazard to personnel and the environment (including plants and other animals). Laboratory procedures that generate aerosols may increase the risk and therefore are to be conducted in a biological safety cabinet and/or other primary containment equipment. BSL-2 facilities and procedures are those that are basic in a good quality laboratory working with microorganisms, genetic materials, cell/tissue cultures, and carcinogens. At BSL-2, plants or animals not involved in the work performed are not permitted in the facilities. Elements in addition to BSL-1 that are assessed during the BSL-2 safety inspection minimally include:

- Presence of BSL-2 placards bearing the universal biohazard sign on entrances to any work areas where experimentally infected materials or animals are present. The sign needs to include the agent being used and names and phone numbers of responsible individuals to be contacted in an emergency (24/7).
- Certified biosafety cabinets with HEPA filtered vacuum lines.
- Centrifugation with sealed rotors or safety cups to contain aerosols.
- Additional PPE may be required.

8.3 Considerations for animal research at ABSL-2

Use of animal facilities should be listed on the IBC registration. Animal facilities are inspected annually and do not require inspection as part of an individual lab inspection. During manipulations of BSL-2 agents, all precautions outlined in agent-specific protocols must be followed but additional considerations are required. A separate ABSL-2 safety protocol is required. Investigators may choose to perform procedures in certain ABSL-2 approved DLAR facilities. These rooms are shared and therefore hazard communication is critical. It is the PIs responsibility to ensure display of the ABSL-2 placard during the procedure to prevent unauthorized personnel from entering the procedure room. Signage must be removed once the area has been decontaminated. The BSO will review the ABSL-2 safety protocol and signage that will be used in procedure rooms, if applicable.

8.4 Considerations for clinical trials

The facilities utilized in clinical trials (in addition to research laboratories) may involve patient care rooms, the operating room, and/or the Investigational Drug Pharmacy. All listed procedure rooms and the IDS Pharmacy (if involved) will be inspected. Consideration has to be given to handling and storage of the material, which may arrive from a sponsor, preparation of the material for administration to the patient (who, where and how?), procedures of transport between locations (i.e. from IDS Pharmacy to patient or operating rooms), decontamination and disposal. The risk to various personnel (pharmacy, nurses, doctors, housekeeping etc.), the patient, as well as persons in contact with the patient post-administration (i.e. caretakers, family members) must be considered and addressed in the biosafety protocol. Since facilities are not exclusively used for the biohazardous substance administered as part of the clinical trial, careful consideration should be given to subsequent use of the facilities. The BSO is available to discuss these issues.

9. Decontamination

9.1 Purpose and methods of decontamination

Contamination is the introduction of microorganisms into tissues or sterile materials. Decontamination is disinfection or sterilization of infected articles to make them suitable for use (reduction of microorganisms to an acceptable level). Disinfection is the selective elimination of certain undesirable microorganisms in order to prevent their transmission. Disinfection reduces the number of infectious organisms below the level necessary to cause infection. Sterilization is the complete killing of all organisms.

Decontamination methods have always played a role in the control of infectious diseases. However, the most efficient means of rendering infectious diseases harmless (i.e., toxic chemical sterilization) may not be utilizable if harm to people or damage to materials is to be avoided. Mechanical decontamination involves measures to remove, but not necessarily neutralize an agent. An example would be filtration of water to remove *Giardia*. Chemical decontamination renders agents harmless by the use of disinfectants, which are usually in the form of a liquid, gas or aerosol. Chemical disinfectants can be harmful to humans, animals, the environment and/or materials. Rooms in fixed places are best decontaminated with gases or liquids in aerosol form (e.g., formaldehyde, vaporized hydrogen peroxide). This is usually combined with surface disinfectants to ensure complete decontamination.

9.2 Chemical decontamination

Chemical decontaminating agents can generally be split into two categories; chemical mixtures that are made to clean and disinfect surfaces and chemical mixtures that are made to do terminal disinfection of inanimate surfaces. Soap or detergent mixtures including disinfectants are made to clean dirty surfaces. These cleaners contain a soap or detergent to suspend gross contaminants into solution until they are rinsed off. A disinfectant is often added to help start the process of decontamination. Mixtures formulated to do terminal disinfection on inanimate surfaces contain no soap or detergents. These solutions are made to disinfect surfaces that are already clean. These agents might not be recommended for use on animals or human patients.

Contact time between surface and disinfecting chemical must be sufficient for effective disinfection. Variables that effect disinfection times are:

- The amount or concentration of the contaminant.
- The temperature (in general, colder temperatures require longer times than stated on the directions).
- The type of agent to be decontaminated.
- The dilution of the disinfectant.

Most disinfectants have directions that specify a dilution depending on the target agent to be disinfected and the type of surface to be disinfected. The directions for the disinfectant must be followed precisely for effective disinfection.

9.3 Autoclave decontamination

Autoclaving is a physical means of rendering an agent harmless through heat and steam exposures. Waste must be placed into an autoclavable bag. A secondary container sufficient to contain the waste in the event the primary bag/container fails must be used. The bag and the secondary container must be able to withstand temperatures from 250°F to 270°F. An autoclavable indicator (tape, etc.) that reacts to both duration and contact with steam and heat should be used to indicate effective decontamination. As a general rule, autoclaving should be done at 121°C/250°F for a minimum of 20 minutes at one atmosphere of overpressure (15 lbs. per square inch), depending on the size and density of the load. Dry heat is another physical means of rendering agents harmless. Exposing the agent to 160°C for two hours is usually effective.

Steam autoclaving may be used for decontamination, as long as:

- The waste does not have volatile or reactive organics that could react with heat and steam,
- The waste quantity does not exceed the capacity of the autoclave to decontaminate,
- The waste can be contained in some way such that it will not grossly contaminate the interior of the autoclave
- The waste is not radioactive.

It is suggested that autoclaves be dedicated to sterilization or decontamination, and not be used for both. If both decontamination and sterilization must be done with the same autoclave, then an empty cycle should be run between a decontamination cycle and a subsequent sterilization cycle to prevent residual cross-contamination. Cycle times and temperatures are determined by the load size and the agent to be decontaminated. A quality control run should be done to assure complete decontamination is taking place before assuming the load is safe for disposal. At least once a month a quality assurance run should be done to ensure that autoclaving is effective. Methods that only indicate an effective run after an appropriate contact time with heat and steam should be used, for example a biological indicator such as *Bacillus stearothermophilus*.

9.4 Equipment decontamination for maintenance/repairs/disposal

To minimize potential exposure of maintenance personnel to biohazards, building maintenance requires that equipment/rooms used for biohazardous materials must include a thorough description of the hazards that may exist. This requirement pertains to work performed by outside contractors as well as in house personnel. Because of the large variety of tasks performed by maintenance personnel, a biosafety risk assessment must be performed on a case-by-case basis. All laboratory equipment must be free of biohazardous materials prior to transport to MUSC Surplus or other destinations. It is the responsibility of the equipment owner to remove all known hazardous materials and to decontaminate the equipment with a 10% (v/v) solution of bleach. Once the equipment owner has deemed the item “safe” for transport, they must affix a signed MUSC OSHP [Transportation of Laboratory Equipment form](#) to the equipment. OSHP must be contacted for verification that decontamination has been completed.

9.5 Procedures for inactivation of toxins

Information about inactivation of selected toxins is provided in **Table 3** in Appendix I. For complete inactivation of T-2 mycotoxin and brevetoxin, it is recommended that all liquid samples, accidental spills and non-burnable waste be soaked in a solution of 2.5% sodium hypochlorite (NaOCl) with 0.25 N NaOH for four hours. It is further recommended that cages and bedding from animals exposed to T-2 mycotoxin or brevetoxin be exposed to 0.25% NaOCl and 0.025 N NaOH for four hours. Exposure to 1.0% NaOCl for thirty minutes is an effective procedure for laboratory solutions, equipment, animal cages, working areas and spills for inactivation of saxitoxin, tetrodotoxin, microcystin, palytoxin, ricin, botulinum toxin or staphylococcal enterotoxins (SEB). Increasing the concentration of disinfectant will not allow for shorter contact times.

10. Biohazardous waste

10.1 Types of waste

Contaminated laboratory waste refers to the waste that was in contact with recombinant or synthetic DNA, pathogens, or biological toxins in any type of laboratory work. The variety of wastes in this category includes culture dishes, devices used to transfer, inoculate, and mix cultures; and paper and disposable items that were in contact with biohazardous materials. Wastes may also include bloodborne pathogens and other potentially infectious materials. Contaminated laboratory waste frequently generated by research laboratories includes but may not be limited to:

- Culture dishes
- Pipettes
- Syringes or other sharps
- Tissue culture bottles and flasks
- Membrane filters in plastic dishes
- Collection bottles, cups and tubes from specimens of blood or bloody bodily secretions.
- Micro-titer plates used for hemagglutination testing complement fixation, or antibody titer testing.
- Slides and plates from immunodiffusion testing.
- Slides and cover slips from blood specimens or tissue or colony picking.
- Disposable gloves, lab coats, and aprons.
- Swabs, capillary tubes, and spreaders used to take or transfer samples containing pathogens.
- Centrifuge tubes

Contaminated wastes from the culturing and handling of pathogens in research laboratories should also be managed as infectious waste because they are usually contaminated with etiologic agents from pure cultures, often at high concentrations. In addition, there are the wastes that are generated in research applications of various biotechnologies (including recombinant or synthetic DNA). For example, biotechnologies are utilized in vaccine production, fermentation biology, cell biology and virology, microbiology, and other aspects of applied biology and applied microbiology. At this time, there is divergence of opinion among experts in the field about the extent and degree of the potential hazard posed by these wastes. Therefore, in the interest of safety, all biotechnological wastes from research work should be managed as biohazardous waste. If animals are used in research, their carcasses, body parts, fluids, bedding and other waste from animal rooms must be properly disposed (see section 10.2).

Equipment and equipment parts that are contaminated with etiologic agents and are to be discarded constitute a category of infectious waste. These wastes include equipment that was used in patient care, equipment that was used in medical laboratories, equipment that was used in research with etiological agents, and equipment that was used in the production and testing of various pharmaceuticals. Another example is the HEPA filter that is used in biological safety cabinets and in the ventilation systems of biological containment facilities, which should be handled as infectious waste.

10.2 Procedures for biohazardous waste disposal

The Medical University of South Carolina contracts with an outside vendor to provide for incineration of biohazardous waste. The direction and coordination of this effort has been assigned to the OHSP. The [Hazardous Waste Management Program](#) is also relevant to laboratories with IBC registrations. Generators are to segregate biohazardous waste from other waste as outlined below.

Liquid waste

- Liquid waste should be collected into containers containing bleach, so that the final volume of undiluted bleach is 10% (v/v). After 30 minutes of contact time, liquid waste should be discarded into the sink with copious amounts of water. Other agents may also be used, if approved by the IBC.

Solid waste

- Infectious/biological waste will be placed in a red three- (3) mil (1/1000 inch) polyethylene equivalent bag and sealed. When bagging, the top of the bag should be twisted tightly, doubled over and cinched tightly with tape.
- The preferred method of disposal for the majority of infectious waste from the laboratories is autoclaving.
- The bagged waste will then be placed into infectious/biohazards waste disposal carts that are provided by OHSP.

Sharps

Discarded sharps (*e.g.*, hypodermic needles, syringes, Pasteur pipettes, broken glass, scalpel blades) present the double hazard of potentially transmitting disease and inflicting injury. The disease potential is great if the sharp was used for work involving biohazards. Other contaminated sharps are generated in the inoculation of people or animals. Sharps also pose the hazard of physical injury through cuts or puncture wounds.

- All contaminated sharps must be disposed of in puncture resistant/leak-proof containers, which have been labeled as biohazardous.
- Before moving containers, they must be closed to prevent spillage or protrusion of contents.
- The sharps containers must then be placed in a sealable, leak proof secondary container.
- Sharps containers are then placed into the infectious/biohazards waste disposal carts that are provided by OHSP.

Animal waste

- Carcasses of animals must be placed into red biohazard bags (double bagged for ABSL-2) followed by disposal into dedicated necropsy freezers located within DLAR facilities.
- Animal bedding is discarded into dedicated dump stations located within animal facilities. Cages from ABSL-2 rooms require autoclaving before dumping bedding or entering the cage wash area. Investigators should check with DLAR supervisors on specific procedures.
- Generally waste generated in the animal facilities is handled by DLAR personnel or if applicable by Core Facility personnel.

When the infectious/biohazards waste disposal carts are full, Environmental Services, University Housekeeping, or DLAR personnel will transport the disposal carts to one of five MUSC storage areas. The storage areas are located at Children's Research Institute, the Strom Thurmond/Gazes Building, Sabin Street Autoclave Facility behind the Medical University Hospital, the Drug Discovery Building and at the Ashley River Tower. The outside vendor collects infectious/biohazards waste from these locations for subsequent incineration.

11. Transport and Shipping of Biohazardous Materials

Viable organisms should only leave the laboratory in a well-sealed primary (inner) and secondary (outer) container with a closable top (a test tube rack inside a tray or a tube in an ice bucket are not acceptable for transport). The exterior of the secondary container should be wiped down with disinfectant prior to leaving the laboratory so that it can be transported without wearing gloves.

MUSC personnel shipping or transporting biological materials off campus must be trained and certified to perform these functions in accordance with regulations set forth by the U.S. Department of Transportation (DOT) and the International Air Transport Association (IATA). The Department of Risk Management shall assist MUSC personnel in obtaining training to ship

biological materials and acquisition of permits for possession or transfer of such materials. Shipping infectious agents requires completion of the training module “Shipping Infectious Agents and Dry Ice” in My Quest.

Federal import, export and/or transport permits may be required for shipping etiological agents. The Principal Investigator is responsible for obtaining the proper permits for possession, use and transfer of biohazards. The Department of Risk Management can be contacted to provide assistance in obtaining the proper permits. Guidance is available at: <https://horseshoe.musc.edu/university/risk-management/services/biosafety/shipping-issues-related-to-biomedical-research-labs/permits-for-infectious-agents>

12. Emergency Procedures

12.1 Personnel contamination and research related illness

Personnel contamination may lead to research associated illness. To prevent or minimize risk, the following language steps must be followed and adopted as part of the biological safety plan:

IMMEDIATE ACTION WITHIN FACILITY

- SKIN (including open sores, wounds, animal bites, needle sticks): Wash immediately with antiseptic soap and a high volume of water for 5 minutes while applying friction. Control bleeding.
- MUCUS MEMBRANES (including eyes, nose, mouth): Rinse cautiously with water for 5-10 minutes. For eyes, remove contact lenses, if present, and continue rinsing. For accidental ingestion, rinse mouth, but do not swallow. Repeat rinsing of mouth multiple times.
- Contaminated clothing (including shoes) must be removed.

SEEK IMMEDIATE MEDICAL FOLLOW-UP (do not wait 24 hours)

Employees and students go to:

- Employee Health Services (during business hours: Monday-Friday, 7:30 am to 4 pm). Address/Location: 57 Bee Street, Charleston SC 29425; Phone: (843) 792-2991
- MUSC Emergency Room (after business hours). Address/Location: 96 Jonathan Lucas Street, Charleston SC 29425
- Be prepared to discuss the risks of the biohazardous agent with medical personnel.

REPORT EXPOSURE IMMEDIATELY to your supervisor or Principal Investigator and call the main number of the Department of Risk Management at 843-792-3604 to notify and/or request the Biosafety Officer. **Overt exposures involving recombinant or synthetic DNA require an immediate report to NIH OBA and a formal written report within 30 days (see section 13).** Certain types of Human Gene Transfer Research events must be reported on a more expedited basis. Please refer to [IBC Policies and Procedures](#) Section 8.5 Human Gene Transfer reporting

NOTIFY Employee Health Services within 24 hours by filing an ACORD First Report of Injury form at <https://www.carc.musc.edu/acord/>

12.2 Accidental spills

The spill response varies depending on the amount of biohazardous material involved and whether containment was lost. Spill response cue cards are attached in **Appendix II**. Laboratory personnel are strongly encouraged to post these spill response cue cards in their area and on equipment.

12.2.1 Small spills inside the BSC: First, lower the sash for 5 minutes to allow the blower to move aerosols through the HEPA filter. During this time, check to see if the spill is fully contained within the BSC, if any PPE has become contaminated, or if any breach of containment has occurred (*e.g.*, a splash where droplets have escaped the BSC and fallen on the floor). If there has been a breach of containment, follow procedures outlines for spill outside the BSC (12.2.3 or 12.2.4). Small spills (<25 ml) can be decontaminated by layering paper towels soaked in appropriate disinfectant on top of the spill, allowing 30

min. for the disinfectant to inactivate the agent, then depositing the paper towels in the biohazard waste bag in the BSC. If using bleach, residual bleach can be wiped off with paper towels sprayed with 70% ethanol, and the towels deposited in the biohazard waste bag.

IMPORTANT: Small spills inside the BSC that do not involve an exposure or injury, do not require notification of the IBC or Biosafety Officer, but do require notification of the PI, who will direct further training (*e.g.* retraining on pipetting techniques, or organization of materials and instruments in the BSC) to minimize the risk of recurrence. Note: a spill of media or buffer not containing the agent does not represent a biohazard, but paper towels used to wipe it up should be deposited in the biohazard bag in the BSC.

12.2.2 Large spills inside the BSC (spills over 25 ml, with likely splattering of droplets outside the BSC): Large spills should be treated more cautiously. Leave the BSC running. Remove gloves (or outer gloves, if double-gloved) before touching the door handle. Close the door to the room as you leave, remove PPE and any contaminated clothing (check the sleeves of your lab coat), and place it in sealable plastic container or a biohazard bag. Everyone in the room at the time of the spill should thoroughly wash their hands, using disinfectant soap. Notify the PI. Allow 20 min. for any potential aerosols to settle. Don clean PPE, re-enter the room, cover the spill with paper towels, soak with appropriate diluted disinfectant, starting at the perimeter and working inward toward the center. Allow 30 min. to inactivate the agent. Deposit soaked towels in biohazard waste. The interior of the BSC should be decontaminated by wiping down the walls, sash, and equipment with disinfectant. Autoclavable equipment (*e.g.*, racks, some pipettors, and tube containers) should be autoclaved, if feasible. If the spill has entered the BSC drain pan, more extensive decontamination must be performed. The drain pan should be emptied into a collection vessel containing disinfectant. A hose barb and flexible tube should be attached to the drain valve and be of sufficient length to allow the open end to be submerged in the disinfectant within the collection vessel. The drain pan should be decontaminated, flushed with water and the drain tube removed. After decontamination with corrosive disinfectants (*e.g.*, bleach), remember to wipe down the BSC with 70% ethanol to remove residual chemicals. If no overt exposure has occurred, and the spill was completely contained within the BSC, the Biosafety Officer does not need to be informed. The PI should review the incident to revise procedures to minimize the risk of recurrence.

12.2.3 Small spills outside the BSC. A small spill, in this circumstance, is defined as a spill with low potential to aerosolize, presents no inhalational hazard, and no endangerment to people or the environment. As a practical consideration, volumes less than 10 ml fall into this category. First, ascertain the extent of the spill. Simply dropping a 150 mm dish contained inside a closed secondary container does not constitute a spill outside the BSC, since there is no breach of containment—as long as the secondary container stays closed. If other personnel are present, alert them immediately. Keep in mind: spills generate aerosols. Quickly check to ascertain the extent of the spill: Is PPE (gloves, lab coat, pants cuffs, shoes) contaminated? Is bare skin exposed? Has liquid splashed over a large area? If shoes are visibly contaminated, decontaminate them with appropriate disinfectant, then evacuate the room, closing the door. Remove gloves (or outer gloves, if double-gloved) before touching the door handle. Remove any potentially contaminated PPE, place it in a biohazard bag, wash hands and face thoroughly. Post a sign on the door warning personnel not to enter. Allow 20 min. for aerosols to settle. During this time, call Risk Management (2-3604) to explain the nature of the accident and request the Biosafety Officer. Don fresh PPE, re-enter the room, cover the spill with paper towels, then soak them with disinfectant starting at the periphery and moving inward toward the center. Be sure to check for and decontaminate small splashes beyond the main affected area. Leave the soaked towels in place for 30 min. to inactivate the agent. Leave the room during this time. After the 30 min. inactivation time, transfer soaked paper towels to biohazard waste. Wipe up the residual spill with more paper towels. Give the area a final wipe-down with paper towels using the appropriate disinfectant. If there has been overt exposure (*e.g.*, actual contact of bare skin with biohazardous material follow emergency procedures as described in Section 12.1. **All Spills outside of the BSC that involve breach of containment, regardless of exposure, must be reported to the Biosafety Officer.**

12.2.4 Large spills outside the BSC. A large spill, in this circumstance, is defined as a spill that spreads rapidly, presents an inhalational hazard, endangers people or the environment, and/or involves personal injury or rescue and should be handled as an emergency. In practical terms, this might be a spill of more than 10 ml splattering over a large area, thus presenting the possibility of aerosolization and widespread contamination. If other personnel are present, alert them immediately. Keep in mind: spills generate aerosols. Ascertain the extent of the spill: possible overt exposure, splash on shoes or soles of shoes, contamination of PPE. If shoes are contaminated, disinfect them before evacuating the room (if shoes are extensively contaminated, you should remove them as you leave the room). After removing gloves (or outer gloves, if double-gloved), evacuate the room, closing the door as you leave. Remove PPE. Wash hands and face thoroughly. Post a sign on the door warning personnel not to enter. Allow 20 min. for aerosols to settle. During this time, call Risk Management (2-3604) to explain the nature of the accident and request the Biosafety Officer. If the spill is too difficult to manage alone, seek help from the OSHP Hazmat team and/or Biosafety Officer. Don fresh PPE, re-enter the room, cover the spill with paper towels, and soak the towels with appropriate disinfectant, working from the outside toward the center. Allow 30 min. for the biohazardous material to be inactivated. If there is any broken glass associated with the spill, pick it up with tongs or forceps, and transfer it to a biohazardous broken glass container. Pick up soaked paper towels, and transfer to a biohazard bag. Give the area a final wipe-down with paper towels using the appropriate disinfectant. If there has been overt exposure (e.g., actual contact of bare skin with biohazardous material follow emergency procedures as described in Section 12.1. **All Spills outside of the BSC that involve breach of containment, regardless of exposure, must be reported to the Biosafety Officer.**

12.3 Loss of containment

Loss of containment occurs when biosafety practices and procedures fail to prevent the exposure of laboratory personnel, the public, agriculture, and the environment from potentially hazardous biological materials. These may include accidental spills as outlined above (i.e. spills within the centrifuge, spills outside the BSC/BSL2 laboratory), accidental release of contaminated waste into the environment (i.e. disposal of liquid waste into sink without prior decontamination) and/or escape of transgenic/nontransgenic experimental animals. Loss of containment requires reporting to the supervisor/principal investigator, Biosafety Officer, and possibly to NIH as described in section 13.

13. Reporting Requirements for Incidents involving Recombinant or Synthetic Nucleic Acid Molecules

Under the NIH Guidelines reporting of incident and violations involving recombinant or synthetic nucleic acid molecules is articulated as a responsibility of the Institution, IBC, BSO, and Principal Investigator. Institutions have the discretion to determine which party should make these reports, and one report for each incident or set of information is generally sufficient. The preferred reporting mechanism pertaining to MUSC is outlined in Section 8 of the [MUSC IBC Policies and Procedures for Institutional Biosafety Committee](#).

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) states that "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" must be reported to NIH OBA within 30 days. Certain types of accidents must be reported on a more expedited basis. Spills or accidents in BSL2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA. These kinds of events might include skin punctures with needles containing recombinant or synthetic DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet. Failure to adhere to the containment and biosafety practices articulated in the NIH Guidelines must also be reported to OBA. Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported. OBA should be consulted if clarification, on whether the incident is reportable or not, is needed.

Incident reports should include sufficient information to allow for an understanding of the nature and consequences of the incident, as well as its cause. A detailed report should also include the measures that the institution took in response to mitigate the problem and to preclude its reoccurrence. The incident reporting template is found on the NIH OBA website. Depending on the severity of the incident, OBA staff may request additional information.

Adverse events in human gene transfer trials are subject to a separate set of reporting requirements. These are found in Appendices M-1-C-3 and M-1-C-4 of the NIH Guidelines. Serious adverse events that are unexpected and possibly associated with the gene transfer product should be reported to OBA within 15 calendar days of sponsor notification, unless they are fatal or life threatening, in which case they should be reported within 7 calendar days. Other serious adverse events should be reported to OBA as part of the Principal Investigator's annual report to OBA.

14. Violations

14.1 Existing protocols

The IBC has authority to withdraw or suspend protocol approval in response to violations of the NIH Guidelines, this MUSC Biosafety Manual, or [MUSC IBC Policies and Procedures for Institutional Biosafety Committee](#), including but not limited to:

- Failure to maintain an existing approved protocol or;
- Failure to complete required training or;
- Failure to adhere to safety and containment design and principles.

In general, upon notice of a deficiency, the PI is expected to implement corrective actions in a timely manner (see 14.3). With regard to research involving recombinant or synthetic nucleic acid molecules, failure to adhere to the containment and biosafety practices articulated in the NIH Guidelines must also be reported to NIH OBA. Reporting templates are available on the NIH OBA website.

14.2 Unapproved work activities

If it is discovered that a PI is conducting activities involving recombinant or synthetic DNA, microorganisms and biological toxins, select agents and agents of dual use research concern, for which he/she is not approved by the IBC, the IBC or BSO on behalf of the committee will notify the PI. The PI will be required to immediately submit an IBC registration and suspend all activities involving such agents until IBC approval has been obtained. With regard to research involving recombinant or synthetic nucleic acid molecules, failure to adhere to the containment and biosafety practices articulated in the NIH Guidelines must also be reported to OBA. Reporting templates are available on the NIH OBA website.

14.3 Protocol for remediating non-compliance with MUSC biosafety guidelines

The procedures outlined below are designed to ensure a swift and decisive response to issues of non-compliance with federal and MUSC Biosafety Guidelines. The desired outcome in all incidents of non-compliance is to obtain remediation by the PI or take administrative action within 30 days of discovery of non-compliance.

In case of non-compliance with MUSC Biosafety Guidelines, the following actions will be taken:

Upon notification of a non-compliance incident, the BSO or designee will:

- Contact the PI by both email and telephone. This email will outline the PI's responsibilities, instruct the PI of actions needed to remedy the non-compliance issue, advise the PI to take immediate action, and outline the risks associated with continued non-compliance. The PI will be given 7 days to remedy the situation and will also be directed to suspend the work in question until compliance is achieved.
- For repeated or multiple non-compliance incidents, the IBC Chairperson and the Associate Provost for Research Compliance and Regulatory Affairs will also be contacted and informed of the incident.

- For serious violations that put people or the environment at meaningful risk, University Risk Management has the authority to shut down the laboratory immediately.

If 7 days pass and non-compliance persists, corrective action is insufficient, or PI is non-responsive, the BSO or designee will:

- Send a second email to the PI, with copies going to the IBC Chairperson as well as the entire IBC committee, the Department Head/Chair, and the Associate Provost for Research Compliance and Regulatory Affairs. This email will reiterate the PI's responsibilities and the risks associated with continued non-compliance, and outline the actions needed to remedy the non-compliance. At this point, the PI will be given an additional 7 days to comply or face immediate suspension of the IBC registration.
- The Department Head/Chair will be contacted via telephone or in person to solicit assistance in obtaining compliance.

On the 14th day following notification of the incident, the following will occur if the issues of non-compliance have not been resolved:

- The BSO or designee will inform the Associate Provost for Research Compliance and Regulatory Affairs that the PI is still not in compliance.
- The Associate Provost for Research Compliance and Regulatory Affairs will send a final email notice of non-compliance to the PI, with copies going to the Department Head/Chair, the IBC Chairperson and the entire IBC committee, giving the PI 24 hours to become compliant or face immediate suspension of the IBC registration.

If non-compliance is still not addressed at the end of this period, the following will happen:

- If the PI has a currently approved protocol, the IBC will take immediate action to suspend all work under the protocol until compliance is achieved. A special meeting of the IBC will be called if necessary to execute this action.
- The Associate Provost for Research Compliance and Regulatory Affairs will take additional steps to ensure compliance from the PI or impose appropriate consequences. University Risk Management has the authority to shut down laboratory facilities.

14.4 Reinstatement of suspended protocols

A suspended protocol can be reinstated when the following occurs:

- The violation has been addressed/corrected to the satisfaction of the IBC and;
- The PI has submitted an explanation, in writing, to the IBC of his/her reasons for non-compliance with the MUSC Biosafety Guidelines and actions taken to prevent reoccurrence.
- The IBC will discuss reinstatement at the next regularly scheduled meeting following completion of the items above and a decision will be made about reinstating full approval of the protocol. In some cases, reinstatement of the protocol may be approved by a subcommittee consisting of at least two of the following: The IBC Chair, the IBC Vice Chair, and the BSO.
- The PI will receive a letter notifying him/her as to the decision.

Appendix I

Table 1. Aerosols Created by Common Laboratory Procedures.

Technique	Average colonies recovered from air during operations
Pipetting 10 ml culture into 1,000 ml broth	2.4
Drop of culture falling 12 in. (30 cm) onto:	
Stainless steel	49.0
Painted wood	43.0
Hand towel wet with 5% phenol	4.0
Re-suspending centrifuged cells with pipette	4.5
Blowing out last drop from pipette	3.8
Shattering tube during centrifuging	1183.0
Inserting hot loop into broth culture	8.7
Streaking agar plates	0.2
Withdrawing syringe and needle from vaccine bottle	16.0
Injecting 10 guinea pigs	16.0
Making dilutions with syringe and needle	2.3
Using syringe/needle for intranasal inoculation of mice	27.0
Harvesting allantoic fluid from 5 eggs	5.6

Survey of Viral and Rickettsial Infections Contracted in the Laboratory. National Cancer Institute, National Institutes of Health, Bethesda, MD: U.S. Department of Health, Education and Welfare. P. 29.

Table 2. Recombinant or synthetic DNA classification/registration criteria as interpreted by the MUSC IBC

Research	Classification	Minimum BSL	Example Activity
Cloning of insert genes from RG 2 agents (including mammals) into bacteria and yeasts	D2a	1	Cloning into RG1 molecular cloning strains of <i>E. coli</i> (K12, DH5alpha, BL21 and TOP10) or <i>S. cerevisiae</i>
Cloning of insert genes from RG 2 (including mammals), 3 or 4 agents into mammalian or insect cells	D2a	2	Transfecting plasmids into cultured mammalian or insect cells
Cloning into viral vectors not requiring a helper virus	D1a and either D2a (<i>in vitro</i>) or D4 (<i>in vivo</i>)	2	Cloning into Retroviral or Adenoviral vectors (classified as D1a) and either <ul style="list-style-type: none"> <i>In vitro</i> infection of cell lines (classified as D2a) <i>In vivo</i> infection of animals (classified as D4)
Cloning into viral vectors requiring a helper virus	D3a and either D2a (<i>in vitro</i>) or D4 (<i>in vivo</i>)	2	Cloning into Adeno-Associated Viral vectors (classified as D3a) and either <ul style="list-style-type: none"> <i>In vitro</i> infection of cell lines (classified as D2a) <i>In vivo</i> infection of animals (classified as D4)
Administering recombinant or synthetic DNA or cells modified with recombinant or synthetic DNA into animals	D4	2	Gene transfer into animals using plasmids or viral vectors Transfer of cells or organisms (including viral vectors) modified with recombinant or synthetic DNA into animals
Creating genetically modified animals	D4c	1	Includes knockout or transgenic animals. Note: Animals treated with viral vectors must be classified as D4, requiring BSL2 containment.
Propagating cultures modified with recombinant or synthetic DNA with volumes exceeding 10 liters	D6	2	Industrial scale protein expression experiments
Administering recombinant or synthetic DNA in to plants	D5	2	Cloning into plants
Administering recombinant or synthetic DNA in to humans	C1	2	Human gene transfer or gene therapy
Cloning of biological toxins	B1	2	Cloning of biological toxins into bacteria for protein expression
Transferring drug resistance into Risk Group 2, 3 or 4 microorganisms that do not acquire it naturally	A1a	2	Providing antibiotic resistance to pathogenic microorganisms that would impair medical intervention in the event of infection (<i>e.g.</i> creation of MRSA or antibiotic resistant tuberculosis or anthrax)

Table 3. Inactivation Procedures for Selected Toxins

Toxin	Autoclave (1 hour @ 121° C, liquid exhaust)	2.5% NaOCl + 0.25 N NaOH	1.0% NaOCl	2.5% NaOCl
Abrin (1)(8)	Yes	N/A	N/A	N/A
Botulinum Neurotoxin (1)(7)	Yes	Yes	Yes	Yes
Clostridium perfringens epsilon toxin (2)	Yes	N/A	N/A	N/A
Conotoxin (3)	contact Biosafety Officer			
Diacetoxyscirpenol (5)	No	Yes	No	Yes (3-5%)
Ricin (1)(7)	Yes	Yes	Yes	Yes
Saxitoxin (1)(7)	No	Yes	Yes	Yes
Shigatoxin & Shiga-like ribosome inactivating proteins (4)	Yes	Yes	Yes	Yes
Staphylococcal Enterotoxins (1)(7)	Yes	Yes	Yes	Yes
Tetrodotoxin (1)(7)	No	Yes	Yes	Yes
T-2 Toxin (1)(6)(5)	No	Yes	No	No

1. Wannemacher R.W. 1989. *Procedures for Inactivation and Safety Containment of Toxins*. Proc. Symposium on Agents of Biological Origin, U.S. Army Research, Dev. and Engineering Center, Aberdeen proving Ground, MD. pp. 115-122
2. Factsheets on Chemical and Biological Warfare, <http://www.cbwinfo.com/Biological/Toxins/Cper.html>
3. Factsheets on Chemical and Biological Warfare, <http://www.cbwinfo.com/Biological/Toxins/Conotox.html>
4. Factsheets on Chemical and Biological Warfare, <http://www.cbwinfo.com/Biological/Toxins/Verotox.html>
5. Factsheets on Chemical and Biological Warfare, <http://www.cbwinfo.com/Biological/Toxins/mycotoxins.html>
6. For complete inactivation of T-2 mycotoxin extend exposure time for liquid samples, spills, and non-burnable waste in 2.5% sodium hypochlorite and 0.25 N sodium hydroxide to 4 hr. Expose cages/bedding from animals exposed to T-2 mycotoxin to 0.25% sodium hypochlorite and 0.025 N sodium hydroxide for 4 hrs.
7. For inactivation of saxitoxin, tetrodotoxin, ricin, botulinum toxin, or staphylococcal enterotoxins, expose work surfaces, solutions, equipment, animal cages, spills to 10% sodium hypochlorite for 60 minutes
8. <http://www.inchem.org/documents/pims/plant/abruspre.htm>

(Adapted from the University of Pennsylvania Environmental Health and Safety website)

Allow at least a 60-minute chemical contact time for complete inactivation of toxin. Any procedure labeled “yes” is an approved procedure for inactivation of the toxin specified.

Appendix II – Forms

For Laboratory Safety Certification Statement please go to:

<https://horseshoe.musc.edu/~media/files/univ-files/risk-management-files/updated-forms/ppe-policy-appendix-ii.pdf?la=en>



Biosafety Level 2

Authorized Personnel Only

Hazard Identity

1. _____

4. _____

2. _____

5. _____

3. _____

6. _____

CONTACT

PHONE

Toxin Placard



WARNING

TOXIN IN USE

Authorized Personnel Only

Toxin Identity:

CONTACT

PHONE

MUSC OCCUPATIONAL SAFETY AND HEALTH PROGRAMS TRANSPORTATION OF LABORATORY EQUIPMENT

Purpose:

All laboratory equipment must be free of hazardous materials (i.e., biological, chemical, radiological) prior to transport to MUSC Surplus or other destinations. Appropriate removal of hazardous materials will protect both the movers and those receiving the items.

Laboratory equipment that needs an evaluation prior to transport includes, but is not limited to the following: refrigerators, freezers, centrifuges, incubators, chemical fume hoods, biological safety cabinets and other items potentially contaminated with hazardous materials.

Procedure:

It is the responsibility of the equipment owner to remove all known hazardous materials and to decontaminate the equipment with a 10% solution of bleach.

Once the equipment owner has deemed the item "safe" for transport, they must affix this signed document to the equipment. Occupational Safety and Health Programs must be notified at 2-3604 for signature and to verify decontamination has been completed. Not all items from the laboratory will need a hazard assessment, such as computers, chairs, bookshelves, etc. However, if the movers are concerned for any reason about an item which does not include this signed document, they may request one prior to transport.

Equipment Owner Declaration:

I have removed all known hazardous materials from this equipment. This includes surface decontamination (if applicable). To the best of my knowledge, this item is safe to transport and does not pose a hazardous materials risk to the movers or surplus personnel.

_____	_____
Print Name	Signature
_____	_____
Department	Phone
_____	_____
Date	Occupational Safety & Health Rep.

SPILL RESPONSE CUE CARDS

Cut out cue cards and post in a highly visible work area



SPILLS INSIDE THE BIOSAFETY CABINET

1. Make sure the cabinet continues to operate. Wait 5 min. to allow aerosols to be pulled through the HEPA filter.
2. Decontaminate the surfaces within the cabinet wearing protective clothing. Gently cover the spill with absorbent paper towels and apply the appropriate disinfectant starting at the perimeter and working towards the center. Wipe down back and sides within biosafety cabinet.
* Note: Examine drain pan for contents of the spill. Disinfect if needed.
3. Discard soaked paper towels in a biohazard bag. Wipe up residual fluids. Wipe down surfaces with 70% EtOH, discarding towels in a biohazard bag.
4. After completion allow cabinet blower to run for 10 minutes before resuming work.

SPILLS INSIDE AN INCUBATOR

1. Alert personnel in the vicinity.
2. Evacuate the room. Close door. Discard potentially contaminated PPE and remove any contaminated clothing. Wash hands thoroughly.
3. Notify PI.
4. Don fresh PPE: lab coat or gown, gloves, mask, eye protection.
5. Cover spill with paper towels.
6. Soak paper towels with appropriate disinfectant, from perimeter toward the center.
7. Allow 30 minutes of contact time.
8. Discarded towels go in biohazard bags. Pick up sharps with tongs & place in sharps container.
9. Wipe down spill area one final time with appropriate disinfectant.
10. Decontaminate water pan via autoclave.

SPILLS INSIDE A CENTRIFUGE

1. Shut the centrifuge off and do not open lid for 20 minutes to allow aerosols to settle.
2. Don protective equipment (lab coat, gloves, face shield/goggles).
3. Open the centrifuge lid and determine whether containment has been breached.
4. If there has been no breach of containment, spray rotor with 70% EtOH. Remove rotor and buckets, and safely transport to biosafety cabinet for decontamination. As a precautionary measure, decontaminate the centrifuge chamber.
5. If a breach of containment has occurred, i.e. rotor buckets are damaged, close centrifuge lid.
 - a. Alert personnel in the vicinity.
 - b. Evacuate room and wait 20 minutes
 - c. Meanwhile, notify Principal Investigator and Risk Management (843-792-3604).
 - d. If assistance is needed, request Biosafety Officer when calling Risk Management.
 - e. Open lid slowly and add paper towels.
 - f. Spray walls of chamber and rotor with 70% EtOH.
 - g. Close centrifuge lid for 30 min. contact time.
 - h. Finish centrifuge clean-up as for major spill outside the BSC. Transport rotor to BSC.
 - i. Open and decontaminate rotor/buckets in the BSC.

SPILLS OUTSIDE THE BIOSAFETY CABINET

Small Spill (<10 mL, localized to small area)

1. Alert personnel in the vicinity.
2. Check for contaminated clothing, including shoes. Decontaminate if necessary.
3. Evacuate the room. Close door. Discard potentially contaminated PPE, remove and decontaminate any contaminated clothing. Wash hands.
4. Notify Principal Investigator. Wait for 20 minutes to allow for room air exchanges to clear aerosols through room exhaust.
5. Don fresh PPE: lab coat or gown, gloves, mask, eye protection.
6. Cover spill with paper towels.
7. Soak paper towels with the appropriate disinfectant, from perimeter toward the center.
8. Allow 30 min. of contact time. Work can continue during contact time.
9. Discarded towels go in biohazard bags. Pick up sharps with tongs & place in sharps container.
10. Wipe down spill area one final time with appropriate disinfectant.

SPILLS OUTSIDE THE BIOSAFETY CABINET

Major Spill (>10 mL, localized to small area)

1. Alert personnel in the vicinity.
2. Check for contaminated clothing, including shoes. Decontaminate if necessary.
3. Evacuate the room. Close door. Discard potentially contaminated PPE and remove any contaminated clothing. Wash hands thoroughly.
4. Post warning sign: "DO NOT ENTER: Biological spill!"
5. Wait 20 min. Meanwhile, notify Principal Investigator and Risk Management (843-792-3604).
6. If assistance is needed, request Biosafety Officer when calling Risk Management.
7. Don fresh PPE: lab coat or gown, gloves, mask, eye protection.
8. Re-enter the room, cover spill with paper towels.
9. Soak paper towels with appropriate disinfectant, from perimeter toward the center.
10. Allow 30 min. of contact time. Work can continue during contact time.
11. Discarded towels go in biohazard bags. Pick up sharps with tongs & place in sharps container.
12. Wipe down spill area one final time with appropriate disinfectant.
13. With Principal Investigator, write up a report and submit to the Biosafety Officer.

TRANSPORT OUTSIDE THE BL-2 LABORATORY

1. Viable organisms should only leave the laboratory in a well-sealed primary (inner) and secondary (outer) container with a closable top (a test tube rack inside a tray or a tube in an ice bucket are not acceptable for transport)
2. The exterior of the secondary container should be wiped down with disinfectant prior to leaving the laboratory so that it can be transported without wearing gloves.
3. In the unlikely event of a spill, post someone to notify people in the immediate area. Follow the instructions for "spills outside a BSC". If the area cannot be isolated by closing doors, contact Risk Management for assistance with clean-up (843-792-3604) and Public Safety to help restrict access to contaminated areas (843-792-4196).