Simmons UNIVERSITY

SIMMONS UNIVERSITY BIOSAFETY MANUAL



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BIOSAFETY MANUAL ANNUAL REVIEW

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1.0 INTRODUCTION

The purpose of this manual is to serve as a resource for researchers and staff and to support and encourage their activities in a manner that:

- Protects all University personnel and visitors from laboratory-acquired infections;
- Maintains the security and integrity of specimens and other research materials;
- Provides environmental protection to minimize risks to those outside the laboratory and beyond the confines of the campus; and,
- Ensures compliance with existing Federal, State, and City health, safety, and environmental regulations and guidelines.

The main regulations covered in this manual are:

- <u>NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)</u>
- Biosafety in Biomedical and Microbiological Laboratories (BMBL)
- OSHA Bloodborne Pathogen Standard

No single document can address every contingency. When additional activity- or agent-specific information is required, EHS will assist investigators in developing and implementing appropriate practices to minimize the risk of laboratory infection or environmental contamination.

When required, the expertise of the Institutional Biosafety Committee or other resources may be called upon for additional input. Principal Investigators are responsible for seeking out these and other resources. They must also ensure that all personnel under their supervision are appropriately trained, informed of applicable regulations and guidelines and that they are capable, based on academic background and hands-on experience, of working within these regulations and guidelines.

Research laboratories and classes at Simmons University (Simmons) conduct various activities, which may have the potential to expose faculty, adjuncts, staff, students and visitors to biological materials. These activities may include but are not limited to the manipulation of cells, tissues, microorganisms, and animals.

To eliminate or reduce this potential exposure, the Simmons' Institutional Biosafety Committee (IBC) has developed this Biosafety Manual to outline the practices and procedures to provide a safe working and teaching environment for faculty, adjuncts, staff, and students.

1.1 Definitions

Administrative controls: changes in work procedures such as written safety policies, work practices, rules, supervision, schedules, and training with the goal of reducing the duration, frequency, and severity of exposures to hazardous materials or situations

Biohazardous Material - infectious agents or hazardous biologic materials that present a risk or potential risk to the health of humans, animals, or the environment. The risk can be direct through infection or indirect through damage to the environment. Biohazardous materials include certain types of recombinant DNA, organisms and viruses infectious to humans, animals, or plants (e.g., parasites, viruses, bacteria, fungi, prions, and rickettsia), and biologically active agents (e.g., toxins, allergens, and venoms) that can cause disease in other living organisms or cause significant impact to the environment or community. (CDC, 2011)

Biologic agents: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), infectious substance or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance capable of causing death, disease, or other biologic malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment (2).

Biologic materials: Any biologically derived materials or materials that contain biologic species, including bacteria, viruses, microorganisms, genetically modified organisms or microorganisms, or prions, including but not limited to cellular lines, DNA materials, tissues, organs, body fluids, biologic agents and toxins, allergens and cultured cells. Biologic materials are not necessarily pathogenic or hazardous.

Biologic waste: any biohazardous or non-biohazardous waste containing biologic material, including but not limited to blood and blood products, clinical specimens, pathological waste, animal carcasses and soiled bedding, cultures and stocks of microbial materials, sharps and other items that have been in contact with biohazardous materials, biotechnology byproduct effluents designated for disposal, and laboratory supplies, plastics, or glassware that have been in contact with biologic materials.

Biosecurity: the system to prevent unauthorized entry to laboratory areas, access to dangerous pathogens, or the unwarranted or accidental release of materials to the outside environment.

Containment: methods used to shield or protect personnel, the immediate work environment, and the community from exposure to hazardous, radiologic, chemical, or biologic materials.

Decontamination: The removing of chemical, biologic, or radiologic contamination from, or the neutralizing of it on, a person, object, or area (6).

Disinfection: the process of reducing or eliminating microorganisms from a surface or space.

Engineering controls: refers to methods to remove a hazard or place a protective barrier between the worker and the workplace hazard, which usually involves building design elements and specialized equipment.

Hazard communication: a written program that identifies the process for ensuring that information concerning hazards is transmitted appropriately to personnel, to include, but not be limited to, use of signage, symbols, container labels, material safety data sheets, and other written sources describing hazards of a material or space.

Hazard control: methods used to eliminate or reduce the potential for exposures to a hazard.

Medical surveillance program: the ongoing, systematic collection of health data that signal either biomarkers of exposure or early signs of adverse health outcomes from known biologic materials and toxicants in persons working with those materials. Includes a program for preemployment screening, ongoing monitoring, and postexposure management.

Primary barriers: specialized laboratory equipment with engineering controls designed to protect against exposure to hazardous laboratory materials, including, but not limited to, biologic safety cabinets, chemical fume hoods, enclosed containers, bench shields, animal cages, and engineered sharps injury-protection devices (e.g., safety needles, safety scalpels, and sharps containers).

Risk assessment: a process to evaluate the probability and consequences of exposure to a given hazard, with the intent to reduce the risk by establishing the appropriate hazard controls to be used.

Routes of exposure: paths by which humans or other living organisms come into contact with a hazardous substance. Three routes of exposure are breathing (inhalation), eating or drinking (ingestion), and contact with skin (dermal absorption).

Sterilization: the use of physical or chemical methods to completely destroy or eliminate all forms of microbial life.

Universal precautions: guidelines recommended by CDC for reducing the risk for transmission of bloodborne and other pathogens in hospitals, laboratories, and other institutions in which workers are potentially exposed to human blood and body fluids. The precautions are designed to reduce the risk for transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals, laboratories, and other institutions to the workers in these facilities (9).

1.2 Scope

This Biosafety Manual applies to all work with biological agents, and covers all personnel, regardless of employment status, including Faculty, Adjuncts, Staff, Students, Contractors, and any other personnel that may come in contact with biological material as part of their duties.



Figure 1 – Hierarchy of Controls

This Biosafety Manual applies to Simmons laboratories only and not to other department within Simmons, who may be exposed to biological materials. In addition, this document does not provide information regarding animal, select agent or toxin, and chemical safety since these topics are covered under separate documents.

The IBC will review this Biosafety Manual on an annual basis or when there is a change in operations associated with biological materials. The IBC will recommend to the Safety Committee whether or not to approve the biological material work and the revised Biosafety Manual. An official copy of the Biosafety Manual is located in the Building and Grounds Offices, Suite E-008, 300 The Fenway, Boston, MA 02115.

2.0 BIOLOGICAL SAFETY PROGRAM

2.1 Biological Use Authorization

All work with BSL-2 material must be authorized by the Institutional Biosafety Committee.

2.3 Human Pathogens

All work with Human Pathogens must be authorized by the Institutional Biosafety Committee

2.4 Recombinant and Synthetic Nucleic Acid Experiments

All work with rDNA at Biosafety Level 2 must be authorized by the Institutional Biosafety Committee.

2.6 Select Agents and Toxins

2.7 Research Animals

2.9 Risk Assessment and Mitigation

Biological materials are natural biocompatible materials that comprise a whole or a part of a living structure or biomedical device that performs, augments, or replaces a natural function. Biological materials are most often engineered for medical, biotechnology and pharmaceutical applications.

Many materials are considered biocompatible or biological materials including human derived, natural materials, laboratory support products, and application specific products.

2.10 Laboratory Signage and Labeling of Equipment

Door Signage Laboratory Equipment Signage

3.0 ACCIDENTS

3.1 **3.1 Emergency Procedures for Exposure Incidents**

Percutaneous Injury Splash to Face Exposure to Aerosols

4.0 BIOHAZARDOUS MATERIALS

- **Antibodies** Antibodies are specialized proteins. They are produced when an antigen is introduced into the body and they have the ability to combine with that antigen to destroy it.
- **Blood and plasma** Blood contains white and red blood cells which transport nutrients and removes wastes throughout the body. Plasma is the liquid part of the blood which contains antibodies and other proteins but does not contain cells. Blood and plasma can be donated and used in medical procedures.



Figure 2 – Blood Cells

• **DNA**-Deoxyribonucleic acid (DNA) is the nucleic acid that carries genetic information. It is found primarily in the nucleus of all living cells.

- Enzymes- Enzymes are proteins that cause or accelerate changes in other substances.
- **Peptides-** Peptides are molecules small enough to be synthesized from the constituent amino acid.
- **Proteins-** Proteins are large molecules composed or one or more chains or amino acids. They are required for the structure, function, and regulation of the body's cells, tissues and living organs.
- **RNA**-Ribonucleic acid (RNA) is similar to DNA but contains ribose instead of deoxyribose. RNA plays a critical role in protein synthesis.

4.1 2.2 Natural Materials

- **Hydroxyapatite** Hydroxyapatite is a natural mineral found in bone. It is also a naturally occurring ceramic material.
- Artificial tissue- Artificial tissue is the construction of tissue material outside of the body using several types of skin cells.
- **Bone and tissue-** Bone and tissue can also be collected from other living or once-living organisms such as cadavers, animals, and human donors.
- **Bio-polymers-** Bio-polymers are derived from renewable resources such as cellulosic plastics like cellulose acetate, starch plastics, and corn-derived plastics. They evolve to function as cellular components of the organism.
- **Starch** Starch is a carbohydrate found in plant tissues. It is an important nutrient and can be prepared as a white amorphous powder. Starch is a biodegradable material and can easily and inexpensively be converted into a bio-polymer.
- **Sugars** Sugar (sucrose saccharose) is a white crystalline carbohydrate found in many plants. Sugar is a potential scaffold material for stem cell transplantation.
- **Cellulose**-Cellulose is a long chain of linked sugar molecules. It is a natural polymer that gives wood its strength. It is a basic building block for many paper and textile products as well as a large selection of biopolymers.

4.2 2.3 Laboratory Support Products

• Cell culture growth media- Growth media is a gel or liquid that contains nutrients and components to support cell or microorganism growth. Different types of media are available for different types of cells.



Figure 3 – Cell Culture Media

- **Cell scaffolding-** Cell scaffolding is an artificial structure used to support three-dimensional tissue formation. They allow for cell attachment and for certain biological and mechanical forces to influence cell development. Cell scaffolding can be made from a variety of materials including collagen and polyesters. Scaffolding is a critical component in the field of tissue engineering.
- **Cell lines and cultures-** Cells can survive outside of an organism if grown and maintained in a special media. Cell lines are the cells grown from a sample. The process of growing microorganisms is called culturing.

5.0 **REGULATIONS AND STANDARDS**

International, federal, state, and local agencies have developed regulations and standards for protecting faculty, adjuncts, staff, and students and the general public from potential health hazards associated with the use of biological materials in laboratories. Regulations, such as the U.S. Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard (BBP), have the force of the law while those from other government agencies, the National Institutes of Health (NIH) or the Centers for Disease Control and Prevention (CDC) are recommended guidelines. In some cases, these recommended guidelines are referenced in the state and local regulations, which enables them to be enforced as a law.

5.1 3.1 International

Three agencies provide regulations and guidelines with regards to working with biological materials. They are the World Health Organization (WHO), International Air Transport Association (IATA), and the International Civil Aviation Organization (ICAO).

The WHO provides resources for faculty, adjuncts, staff, and students who are interested in working with biological materials aboard. Guidelines and regulations associated with the WHO only apply to Simmons if there is no existing federal, state, or local guideline or regulation. As of April 2015, the WHO guidelines, which are associated with disease and international travel, apply to Simmons.

The IATA/ICAO regulation is the Dangerous Good Regulation, which is the global reference for shipping dangerous goods by air and the only standard recognized by airlines. The requirements of this regulation apply when faculty, adjuncts, staff, or students want to ship a biological material via air. Additional information regarding this topic is provided in Section 11.0.

5.2 3.2 Federal

Occupational Safety and Health Administration

Faculty, adjuncts, and staff who come in contact with human blood and other bodily fluids are at increased risk for exposures to and infections from certain bloodborne pathogens (BBP): Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus. The U.S. OSHA BBP Standard, 29 Code of Federal Regulations (CFR) 1910.1030 was designed to eliminate or minimize the occupational exposures to blood and other bodily fluids and the risks for developing the infectious diseases associated with them.

Safe practices for studies involving biological materials and animals are provided in the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, which was issued by the U.S. Department of Health and Human Services (DHHS), NIH, and CDC. In addition, NIH has developed a guideline, which outlines the safe practices and procedures for studies involving the use of rDNA, which is entitled NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).

DHHS has established 42 CFR Parts 72 and 73 to provide the requirements when working with select agents and toxins. Refer to the Select Agent Policy for additional information.

Department of Agriculture

The U.S. Department of Agriculture (USDA) also established requirements when working with select agents and toxins under 7 CFR Part 331 and 9 CFR Part 121. Select agents and toxins are used at Simmons. The proper method to work with select agents and toxins is provided in the Select Agent Manual, which is a separate document.

U.S. Environmental Protection Agency

The U.S. Environmental Protection Agency (EPA) has approved certain disinfectants for certain biological materials. These disinfectants should be used for the corresponding biological material.

Postal Services and Public Health Services

The U.S. Postal Services (USPS) and U.S. Public Health Services (PHS) have restrictions on certain materials being shipped in the U.S.

5.3 3.3 Commonwealth of Massachusetts

The Massachusetts Department of Public Health (MADPH) issued the following regulations with regards to biological materials:

- 105 Code of Massachusetts Regulations (CMR) 480.000, Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code Chapter VIII)
- 105 CMR 300.000, Reportable Diseases, Surveillance, and Isolation and Quarantine

105 CMR 480.000 outlines the requirements for the management of biological waste. This regulation outlines what constitutes biological waste, how to treat the biological waste, and how to dispose of it properly. Overall, it is constant with the OSHA, NIH and CDC definition and procedures for handling biological waste. This topic is further discussed in Section 10.0.

The purpose of 105 CMR 300.000 is to list diseases dangerous to the public health as designated by the Department of Public Health and to establish reporting, surveillance, isolation and quarantine requirements.

5.4 3.4 City of Boston

In September 2006, the Boston Public Health Commission (BPHC) issued the Biological Laboratory Regulations. This regulation applies to entities working with biological materials requiring biosafety level 3 and/or 4 practices and procedures. As of April 2015, this regulation does not apply to Simmons since research and teaching laboratories are not working with these types of biological materials.

The BPHC has a recombinant Deoxyribonucleic Acid (rDNA) regulation, which requires institutions to register with them if they working with rDNA. Since Simmons' faculty are working with rDNA, Simmons filed a permit with the BPHC in 2022.

The Boston Fire Department (BFD) has a Laboratory Registration program, which requires laboratories working with biological materials to register with them. The registration is due between January 1st and April 1st each year. This registration is submitted by the Department of Buildings and Grounds to the BFD on an annual basis.

6.0 **RESPONSIBILITIES**

This section outlines the specific responsibilities associated with Simmons' Biosafety Program.

6.1 4.1 Biosafety Officer

The Biosafety Officer (BSO) is the primary intermediary between the faculty, adjunct, laboratory manager, or laboratory supervisor and the regulatory agencies. The BSO for Simmons is the Director of EH&S. She is responsible for:

- Managing the biosafety program.
- Implementing the biosafety program.
- Assisting laboratories in confirm to the applicable regulations and guidelines by providing training, laboratory inspections, and communication of program requirements.
- Inspecting laboratories, which require biosafety, on a periodic basis to review laboratory containment, procedures, records, and equipment. The frequency is determined by the results

of the previous inspection. Refer to the Laboratory Inspection Protocol, which is a separate document, for details.

- Summarizing the results of the laboratory inspections to faculty, adjuncts, laboratory managers, and/or laboratory supervisors.
- Reviewing research and teaching protocols proposed by faculty or adjuncts to determine the biosafety level. This will be accomplished using the Risk Assessment with regard to the absence of PPE.
- Reporting to the IBC the results of the review and recommending a biosafety level (BSL).
- Reporting to the IBC on the status of the biosafety program.
- Assisting faculty, adjuncts, laboratory managers, and laboratory supervisors, when needed, in addressing biosafety-related issues.
- Providing faculty, adjuncts, laboratory managers, or laboratory supervisors with a BSO letter explaining the requirements including BL associated with their work with biological materials once approved by IBC. If the work is not approved by the IBC, providing faculty, adjuncts, laboratory managers, or laboratory supervisors with a BSO letter explaining why it was not approved by IBC.
- Recommending emergency response procedures in the event of a biological spill or an exposure to a biological material.
- Acting as a liaison with regulatory agencies and the Institutional Animal Care and Use Committee.

6.2 4.2 Department Chairs

The Department Chairs:

- Assume responsibility for personnel engaged in the laboratory use of hazardous chemicals.
- Provide the BSO with the support necessary to implement and maintain the Biosafety Manual.
- After receipt of laboratory inspection reports from the BSO, meets with laboratory staff to discuss cited areas for improvement and to ensure timely actions to protect trained laboratory personnel and facilities and to ensure that the department remains in compliance with applicable codes, regulations, and standards of care.

6.3 4.3 Faculty, Adjunct, Laboratory Manager

The faculty, adjunct, and laboratory manager are responsible for implementation of the applicable biosafety practices and procedures in their laboratories. They MUST:

- Be trained in good microbiological techniques.
- Be aware of the potential health effects of the biological materials used in her or his laboratory, the appropriate biosafety level, and any other pertinent factors that will ensure the safety of laboratory staff and students and the surrounding community.
- Ensure that the appropriate equipment and facilities (e.g., engineering controls, personal protective equipment, and emergency equipment) are available for laboratory staff and students and that they are used properly.
- Arrange for appropriate training regarding the safe use of biological materials.

• Require laboratory staff and students adhere to biosafety requirements while working with biological materials.

If the faculty, adjunct, and/or laboratory manager conducts research involving the use of rDNA, (s)he agrees to maintain full compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, which includes the following responsibilities. Additional requirements found in the *NIH Guidelines*. Failure to comply with the *NIH Guidelines* could potentially affect all NIH-funded projects at Simmons, therefore, compliance with the *NIH Guidelines* is **mandatory**.

- Ensure that no research is conducted with biological materials prior to approval by IBC.
- Obtain IBC approval for rDNA research prior to initiation.
- Determine whether experiments are covered by *NIH Guidelines*.
- Ensure that the reporting requirements are fulfilled and be held accountable for any reporting lapses.
- Report any significant problems, violations of the *NIH Guidelines*, or any research-related accidents, illnesses, or potential exposures to the Biosafety Officer (BSO) and IBC.

NOTE: The BSO or a representative from the IBC will contact the NIH Office of Biotechnology Activities (OBA), and the Boston Public Health Commission.

- Instruct and train laboratory, staff and students in:
 - O Practices and techniques required to ensure safety.
 - o The procedures for dealing with accidents.
 - The instructions should be specific to the agents and materials used in the research project.
- Make available to laboratory staff protocols that describe the potential biohazards and the precautions to be taken with the biological materials to be used in the laboratory.
- Comply with the shipping requirements for rDNA molecules provided in the *NIH Guidelines*.

6.4 4.4 Laboratory Staff and Students

Laboratory staff and students are responsible for following the Simmons EH&S policies and procedures including biosafety policies and procedures and instructions from their faculty, adjunct, laboratory manager, laboratory supervisor, and/or BSO. In addition, they are required to:

- Comply with applicable international, federal, state, and local regulations and guidelines.
- Use safe microbiological techniques and laboratory practices.
- Inform the faculty, adjunct, laboratory manager, laboratory supervisor, and/or BSO regarding any potentially hazardous situations or conditions.
- Ensure the lab safety protocols are up-to-date and comply with applicable regulations.

6.5 4.5 Institutional Biosafety Committee

Simmons' Institutional Biosafety Committee (IBC) reviews and approves all research and teaching activities involving the use of hazardous biological (biohazardous) materials, on campus under the control of Simmons' faculty, adjuncts, students and staff. The committee works to ensure that all

projects and research involving biological materials or agents and the facilities used to conduct the projects and research, are in compliance with existing government regulations and applicable university policies.

The IBC functions to ensure that the University upholds its responsibility and obligations outlined by current government requirements described in the U.S. Department of Health and Human Services regulations and standards, the U.S. Department of Public Health, National Institute of Health's Guidelines for Research Involving Recombinant DNA Molecules, other NIH guidelines, the Centers for Disease Control and Prevention guidelines, the U.S. Department of Agriculture regulations, the U.S. Occupational Health and Safety Administration regulations and standards, the U.S. Department of Transportation regulations and standards, the United States Postal Service requirements, the World Health Organization regulations and standards, the International Air Transport Association and International Civil Aviation Organization regulations and guidelines, the Massachusetts Department of Public Health regulations and standards, Boston Fire Department regulations and standards, and the Boston Public Health Commission regulations and standards.

The IBC will meet at least once a semester, or when needed. A current list of members is provided in Appendix B. The IBC is responsible for the following with regards to biosafety.

- Assisting the university community in implementing university-wide biosafety policies and procedures while complying with applicable international, federal, state, and local regulations and guidelines.
- Approving proposed work with biological materials from faculty, adjuncts, and laboratory managers.
- Reviewing and approving this Biosafety Manual on an annual basis, at least, or when a change is made to this Biosafety Manual.
- Recommending to Simmons' Safety Committee on whether or not to approve work with biological materials. Also, recommending Simmons' Safety Committee to approve biosafety policies and procedures.

6.6 4.6 Safety Committee

Simmons' Safety Committee has three main purposes:

- Formulate policies and standard operating procedures (SOPs) governing laboratory safety, hazardous materials, laboratory processes, environmental protection, and occupational safety and health. Policies and SOPs may include but are not limited to manuals, procedures, and training presentations.
- 2. Recommend to the Colleges of Arts and Sciences (CAS) Dean policies and SOPs referenced above.
- 3. Monitor compliance at the University with respect to federal, state, and local regulations, University policy, and University SOPs pertaining to the above. The Safety Committee shall be responsible for:

• Recommending policies and procedures for occupational and environmental safety and compliance in laboratories and in other workplaces where hazardous materials are used, including

but not limited to education and training, inspection and compliance, containment, waste disposal, and occupational medicine,

- Reviewing the relevant safety and compliance programs on an annual basis or more frequently if requested by the CBBHS Dean.
- Recommending policy development or revision when deficiencies in the safety and compliance programs are noted,
- Reviewing incident reports submitted by the individual departments or Public Safety as well as any other information or issues pertaining to occupational and environmental safety and compliance in laboratories and in other workplaces where hazardous materials are used,
- Establishing subcommittees or ad hoc committees, as necessary, to carry out its overall responsibilities, and
- Maintaining a written record of actions taken by the Committee.

The IBC will report to the Safety Committee on biosafety matters. A current list of Safety Committee members is provided in Appendix B.

6.7 4.7 Department of Building and Grounds

The Department of Building and Grounds will assist in the testing and repairs to engineering controls, emergency equipment and other facility related equipment used to contain or eliminate biological hazards.

6.8 4.8 Talent and Human Capital Strategy and Public Safety

The Science Department, and Public Safety will assist with emergencies and exposures involving biological materials.

7.0 ROUTES OF EXPOSURE

There are four main routes of exposure that must be avoided when working with biological materials in the laboratory: percutaneous injuries, inhalation of aerosols, exposure to mucous membranes, and ingestion.

- 1. **Percutaneous Injuries:** Percutaneous injuries can result from needle sticks, cuts or abrasions from contaminated items. These exposures are particularly serious because of the potential forT immediate entry of the agent into a normally sterile bloodstream. All sharps items should be handled and disposed of as noted in Section 10.0.
- 2. Inhalation of Aerosols: Aerosols have the potential to be generated when biological materials are agitated in some manner. Some of these procedures include the use of vortexes, blenders and sonicators. Proper work practices must be implemented to minimize the aerosolization of all materials, especially whose main route of exposure is through inhalation (e.g., Adenovirus,

Vaccinia virus, Mycobacterium tuberculosis, etc.). Please see Section 8.0 for more information on how to minimize and contain aerosols.

- 3. Exposure to Mucous Membrane: Exposure of mucous membranes to infectious agents can lead to occupationally acquired infections. Mucocutaneous exposures can result from splashes to the eyes, nose or mouth, or by inadvertent inoculation via contaminated hands. A face shield should always be used if there is a likelihood of splash or splatter.
- 4. Ingestion: Accidental ingestion of biohazardous materials can result from improper personal hygiene in the laboratory. Food and drink are prohibited in all areas of the laboratory in which work is conducted using any biological or chemical material. Hands must be washed immediately if visible contamination occurs and always before leaving the laboratory.

8.0 **RISK ASSESSMENT**

8.1 **6.1 Minimum Requirements**

9.0 **BIOSAFETY LEVELS**

The different biosafety levels (BL) developed for microbiological and biomedical laboratories provide increasing levels of personnel and environmental protection. The recommended BL for a biological material represents the conditions under which the agent can be ordinarily handled safely. The CDC and the NIH have done this in their publication: BMBL. BMBL describes four BLs, comprised of level-specific laboratory practices and techniques, safety equipment and laboratory facilities.

NOTES: Simmons's laboratories are designed for biological materials requiring BL-1 practices and procedures. BL-3, and BL-4 practices and procedures are not permitted at Simmons.

9.1 7.1 Summary of BL-1 and BL-2

Table 1 provides a summary of BL-1 and BL-2 since BL-1 applies to Simmons's laboratories and BL-2 applies to common biological materials used in laboratories within an academic and research setting.

Table 1 – S	Table 1 – Summary of Biosafety Levels				
Biosafety	Examples of Biological Materials	Agent Properties	Laboratory Practices	Safety Equipment	
Level				(Primary Barrier)	
1	Escherichia coli strain K12 Lactobacillus	Not known to	Standard	Personal Protective Equipment (PPE)	
	acidophilus	consistently cause	Microbiological	including lab coats, gloves, close toed	
	Micrococcus leuteus	disease in healthy	Practices (Refer to	shoes, and eye protection, when	
	Neurospora cras	adults	Section 8.1)	needed	
	Pseudomonas fluorescens				
	Serratia marcescens				
	Chinese Hamster Ovary (CHO) cells				

2	Staphylococcus aureus Plasmodium cynomologi Trypanosoma cruzi Leishmania spp. Human cell lines	Associated with human disease; Potentially infectious human blood or bodily fluids	 BL-1 practices plus: Limited access Biohazard sign PPE Sharps precautions Biosafety Manual including waste procedures 	•	Biosafety cabinet or other engineering control to prevent exposure to aerosols and/or splashes PPE including lab coat, gloves, close toed shoes, eye protection, and face protection, when needed.
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9.2 7.2 Laboratory Facilities Requirements

In accordance with Section IV—Laboratory Biosafety Level Criteria of the BMBL, below are the Laboratory Facilities (Secondary Barrier) requirements for BL-1 and BL-2.

BL-1

- 1. Laboratories should have doors for access control.
- 2. Laboratories must have a sink for hand washing.
- 3. The laboratory should be designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.
- 4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
 - a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- 5. Laboratories windows that open to the exterior should be fitted with screens. BL-2
- 1. Laboratory doors should be self-closing and have locks in accordance with the institutional policies.
- 2. Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.
- 3. The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
- 4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
- 5. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
- 6. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

- 7. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.
- 8. Biosafety cabinets (BSCs) must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.
- 9. Vacuum lines should be protected with liquid disinfectant traps.
- 10. An eyewash station must be readily available.
- 11. There are no specific requirements for ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.
- 12. High-efficiency particulate air (HEPA) filtered exhaust air from a Class II BSC can be safely recirculation back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.
- 13. A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

10.0 LABORATORY PRACTICES

Guidelines evolved as a means of protecting microbiological workers based on published data and an understanding of the risks associated with manipulating various agents. These guidelines work on the premise that safe work sites result from a combination of engineering controls, management policies, work practices and procedures, and, occasionally, medical interventions.

In addition, each laboratory and studio should have a specific biosafety or operation manual that identifies the hazards that may be encountered, and which specifies practices and procedures designed to minimize or eliminate risks.

10.2 8.1 Standard Microbiological Practices

An important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required for handling such material safely. The faculty, staff member, laboratory manager, or laboratory supervisor is responsible for communicating the potential hazards and for providing or arranging appropriate training.

Below are the Standard Microbiological Practices as outlined in the BMBL:

1. The faculty, staff member, laboratory manager, or laboratory supervisor must enforce the institutional policies that control access to the laboratory.

- 2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- 3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
- 4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- 5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, faculty, staff members, laboratory managers, or laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries.
- 6. Precautions, including those listed below, must always be taken with sharp items. These include:
 - a. The use of needles, glass pipettes, glass slides and cover slips, scalpels and lancets should be kept to a minimum.
 - b. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
 - c. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - d. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - e. Minimize the use of sharps
- 7. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
- 8. Perform all procedures to minimize the creation of splashes and/or aerosols.
- 9. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Refer to Section 9.0.
- 10. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport. See Section 9.0.
 - a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
 - b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
- 11. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. The sign may include the name of the agent(s) in use, and the name and phone number of the faculty, staff member, laboratory manager, laboratory supervisor or other responsible personnel. Agent information should be posted in accordance with the institutional policy.
- 12. An effective integrated pest management program is required.
- 13. The faculty, staff member, laboratory manager, or laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary

precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider or personal healthcare provider for appropriate counseling and guidance.

In addition to the Standard Microbiological Practices, laboratory and studio personnel should:

- Know and understand the biology and infectious potential of the biohazards they handle;
- Handle all potentially infectious materials as if the biohazard is present;
- Develop safe operating procedures;
- Know the location of spill kits and emergency response equipment;
- Plan in advance for safe handling of accidents;
- Use disinfectants with proven efficacy against the specific biohazard you are handling;
- Work at the appropriate BL for the biological material you are handling;
- Accept full responsibility for your work;
- Complete any necessary training before you work with biohazards;
 Report all accidents to your supervisor; and
 Dispose of biohazards waste properly.

10.3 8.2 Personal Protective Equipment

Once a biological hazard has been identified, the faculty must ensure that their students are wearing the appropriate personal protective equipment (PPE) as the primary barrier of protection. PPE may include, but is not limited to face protection, lab coats and gowns, respirators, booties, and gloves. The laboratory managers deliver an initial training each academic year on laboratory safety to all students, student employees and faculty. Faculty members are responsible for ensuring and reinforcing students' compliance. Laboratory managers are responsible for ensuring and reinforcing student employees' compliance.

Appropriate PPE must be worn before handling potentially hazardous biological materials and removed immediately and replaced if gross contamination occurs. PPE must be removed before exiting the laboratory.

- 1. **Face Protection:** When splash or splatter of infectious substances or other biological materials is anticipated, appropriate face protection must be worn if work is performed outside a biological safety cabinet. Such equipment would include but is not limited to goggles, side-shielded safety glasses and chin length face shields.
- 2. Lab Coats and Gowns: Long sleeved lab coats or gowns must be worn to protect skin and street clothes from contamination. In circumstances when splash or splatter is anticipated, the garment must be resistant to liquid penetration. A cuffed lab coat or gown should be worn when working with potentially infectious materials. Long sleeved shirts and long pants or equivalent must be worn in the laboratory.

- 3. **Gloves:** Gloves should always be worn when handling biological materials. Disposable gloves provide an adequate barrier between the lab worker and biological materials. Gloves with extended arms, which cover the skin between the lab coat and glove, should be used when the biological material has the potential to be absorbed through the skin.
- 4. **Respirators:** When engineering controls (i.e. Biological Safety Cabinets) are not available to provide adequate protection against aerosolized agents or when mandated by federal regulations, respirators shall be worn. The Respiratory Protection Program requires that employees be medically cleared, fit-tested, and trained on proper usage and care before being allowed to wear a respirator. Please contact lab manager regarding Respirator training and fit testing.
- 5. **Disposable Booties/ Shoe-covers:** Close toed shoes should be worn to protect feet from contamination. When significant splash and splatter are anticipated, booties/ shoe-covers should be considered. Prior to exiting the laboratory, these must be removed and disposed of properly. Table 2 provides a summary on which PPE is required for which activity.

Table 2 – PPE Selection Guide by Task	
Task/Activity	PPE
Working with non-hazardous/non- infectious biological materials	Safety glasses or goggles when there is a splash hazard One pair of disposable gloves
Working with biological materials requiring BL1 practices and procedures	Laboratory coats Safety glasses or goggles when there is a splash hazard One pair of disposable gloves
Working with biological materials requiring BL2 practices and procedures	Laboratory coats Safety glasses, goggles, or face shield when there is a splash hazard Two pairs of disposable gloves

Table 2 – PPE Selection Guide by Task

10.4 8.3 Biosafety Cabinets

Biosafety cabinets (BSCs) are designed to contain aerosols generated during work with biological material through the use of laminar air flow and high-efficiency particulate air (HEPA) filtration. When combined with standard microbiological and laboratory practices, BSCs protect both laboratory personnel and the environment. **The primary purpose of a BSC is to protect laboratory personnel from exposures to biological materials.** The BSC also provides product protection to avoid contamination of the work, experiment, or process; and environmental protection from contaminants contained within the cabinet. *Types*

Three types of biological safety cabinets (Class I, II and III) are used in laboratories. These classes are based on the specific airflow within the BSC and on the locations of the HEPA filter within the cabinet. Table 3 provides the characteristics of the different types of BSCs.

Table 3 – Biosafety Cabinet Characteristics			
New NSF Classification, Adopted 2002	Previous NSF Classification	General Description	Use of Volatile Chemicals and/or Radionuclides

A1	Class II, Type A	70% air recirculated; 30% exhausted from a common plenum to the room; 75FPM intake; and	No
		may have biologically contaminated positive pressure plenum	
A2	Class II, Type A/B3	70% air recirculated; 30% exhausted from a common plenum to the room; 100FPM intake; and biologically contaminated plenum under negative pressure or surrounded by negative pressure	No
A2	Class II, Type B3	70% air recirculated; 30% exhausted from a common plenum to a facility exhaust system; 100FPM intake; and biologically contaminated plenum under negative pressure or surrounded by negative pressure	Νο
B1	Class II, Type B1	40% air recirculated; 60% exhausted from cabinet; exhaust air pulled through dedicated exhaust duct into facility exhaust system; 100FPM intake; and all biologically contaminated plenums are negative to the room or surrounded by negative pressure plenums	No
В2	Class II, Type B2	0% air recirculated; 100% exhausted from cabinet exhaust air pulled through dedicated exhaust duct into facility exhaust system; 100FPM intake; and all ducts and plenums are under negative pressure all contaminated ducts are under negative pressure or surrounded by directly exhausted negative pressure ducts or plenums	No
NOTES: 1. Inf <u>saf</u> 2. Un	ormation provided by E etycabinets) viewed on der no circumstances s	aker Company's webpage (<u>http://www.bakerco.com/introduction-biol</u> December 1, 2014. hould the chemical concentration reach the chemical's lower explosion	. <u>ogical-</u>

HEPA filters are typically composed of a pleated sheet of borosilicate fiber material that has been treated with a wet-strength water-repellant binder. These filters are specifically designed to remove particles equal and greater than 0.3 microns with an efficiency of 99.97%. This filtration will capture a majority of bacteria, spores, and viruses from the air.

BSCs are required to be tested and certified annually by technicians accredited by the National Sanitation Foundation (NSF). Additionally, BSCs will be certified when they are first installed and whenever they are moved, even to a nearby laboratory, because HEPA filters may be dislodged from their proper fitting during these moves. The technician certifies the BSCs in accordance with NSF International/American National Standards Institute Standard 49, *Biosafety Cabinetry: Design, Construction, Performance, and Field Certification.*

Class II, Type A2 BSCs are used at Simmons. Figure 4 demonstrates the airflow in a Class II, Type A2 BSC.



Figure 4 – Class II, Type A2 Airflow Diagram

NOTE: Picture obtained from NuAire's webpage on December 1, 2014.

Proper Use of Biosafety Cabinets

Start-up Procedure

- 1. If the unit has not been left running continuously, press the blower on/off switch. The yellow indicator light below the switch will light. Make sure that you have cabinet airflow by listening for blower sound.
- 2. Turn on the fluorescent light. The fluorescent light will not operate unless the ultraviolet light is turned off. Never leave the ultraviolet light on while there is anyone in the room unless view screen is fully closed.
- 3. Check to determine that the drain valve is in the closed position or the drain coupling is capped.
- 4. Wipe down the interior area of the cabinet with a surface disinfectant.

NOTE: Some disinfectants, such as bleach or iodine, may corrode or stain the steel surfaces. If this happens, thoroughly clean the surfaces afterward with a detergent and rinse with sterile water to prevent corrosion.

- 5. Place all materials to be used for the next procedure inside the cabinet on the solid work surface. Disinfect the exterior of these materials (by spraying them with ethanol) prior to placing them on the work surface.
- 6. Ensure an appropriate in-line filter (e.g., hydrophobic) and two flasks containing a proper disinfectant are installed for the vacuum line. Refer to Figure 5 for an example of this setup.



Figure 5 – Example of Aspiration Flask Set-up NOTE: Picture obtained from U.S. Department of Energy's webpage on December 1, 2014.

This combination will provide protection to the central building vacuum system vacuum pump, as well as to the personnel who service this equipment. Inactivation of aspirated materials can be accomplished by placing sufficient chemical decontamination solution such as bleach, into the flask to kill the microorganisms as they are collected. Once inactivation occurs, liquid materials can be disposed of as non-infectious waste down the sink.

- 7. Place a horizontal pipette discard trays containing an autoclave bag or an appropriate chemical disinfectant within the cabinet. Upright pipette collection containers placed on the floor outside the cabinet should not be used. The frequent inward/outward movement needed to place objects in these containers is disruptive to the integrity of the cabinet air barrier and can compromise both personnel and product protection.
- 8. Ensure operations are performed on the work surface at least four (4) inches from the inside edge of the front grille.
- 9. Ensure active work flows from the clean to contaminated area across the work surface. Bulky items such as biohazard bags, discarded pipette trays and suction collection flasks must be placed to one side of the interior of the cabinet.
- 10. Avoid using open flames. Open flames are rarely necessary in the near microbe-free environment of a BSC. An open flame creates turbulence that disrupts the pattern of HEPAfiltered air supplied to the work surface. When deemed absolutely necessary, touch-plate microburners equipped with a pilot light to provide a flame on demand may be used to help minimize internal cabinet air disturbance and heat build-up. The burner must be turned off when work is completed.
- 11. Follow proper disinfection and decontamination procedures for the BSC. Please see Section 9.0.
- 12. After your equipment is in place inside the cabinet, adjust the sliding view screen so it is open no higher than the correct access opening height (8" or 10"). An alarm will signal if you have exceeded the design opening. This is important to maintain proper airflow.
- 13. After the cabinet has run for at least three minutes with the window in the proper position, you are ready to begin.

Working in the BSC

- Hands and arms should be washed thoroughly with germicidal soap both before and after work in the cabinet. Operators are encouraged to wear long-sleeved gowns or lab coats with tightfitting cuffs and sterile gloves. This minimizes the shedding of skin flora into the work area and protects hands and arms from contamination.
- 2. Perform all work on the depressed area of the solid work surface. Work with a limited number of slow movements. Since all of the equipment you need is already in the cabinet, it will not be necessary to move your arms in and out through the air barrier.
- 3. Opening and closing doors in the laboratory should be kept to a minimum to prevent air disturbance which might interfere with cabinet airflow. Personnel should also avoid walking by the front of the cabinet while it is in use.
- 4. Avoid using floor-type pipette discard canisters. It is important that your used pipettes be discarded into a tray or other suitable container inside the cabinet. This reduces the temptation to move in and out of the work area unnecessarily.
- 5. Because of the restricted access, pipetting within the cabinet will require the use of pipetting aids.
- 6. Use aseptic technique. Procedures done with good technique and proper cabinet methods will not require the use of a flame.

NOTE: If, however, the BSO approves the use of flame after evaluating the circumstances, then a burner with a pilot light such as the "Touch-O-Matic" should be used. Place it at the rear of the work area where the air turbulence caused by the flame will have the least possible effect.

Flame disturbs the unidirectional airstream and also contributes to the heat load. If the cabinet blower is unintentionally turned off, the flame could also damage a filter. Tubing for a burner within the cabinet should be resistant to cracking or puncture. Material such as Tygon tubing is not acceptable for this use.

- 7. *Never operate your cabinet while the view screen alarm indicator is on.* The operating position of the sash provides either an 8" or 10" high access opening, depending on the design set at the factory. This restricted opening permits optimum operating conditions for the cabinet. Because operators will not all be the same height, it is suggested that the operator use a chair which may be adjusted for height.
- 8. After a procedure has been completed, all equipment which has been in contact with the research agent should be enclosed, and the entire surface decontaminated. Trays of discarded pipettes and glassware should be covered. The cabinet should then be allowed to run for at least three minutes with no activity so that the airborne contaminants will be purged from the work area. Next, make sure that all equipment is removed from the cabinet.
- 9. After you have removed all materials, culture apparatus, etc., decontamination of the interior surfaces should be repeated. Check the work area carefully for spilled or splashed nutrient which might support bacterial growth. Never use the cabinet to store supplies or laboratory equipment.

10. Recommended that the cabinet be left running continuously to ensure containment and cleanliness. If the user elects to turn the cabinet off at the end of a work session, the window should be closed completely. The sash alarm will be silenced when the window is in the closed position.

Key Points:

- **Store** equipment and supplies outside of the cabinet.
- Always leave the blower on.
- Set the view screen at the proper height.
- When possible, use pipetting aids.
- Avoid use of an open flame (e.g., Bunsen burner) within the cabinet unless the use has been specifically approved by a safety professional

10.5 8.4 Other Safety Equipment

Other safety equipment includes enclosed containers and other engineering controls designed to remove or minimize exposures to biological materials.

Eppendorf Microcentrifuge

1. Open lid of the instrument and remove the top of the rotor as shown.





2. Place samples in a slot making sure the rotor is balanced while rotating (if 2 samples, place 1 across from the other)



3. Close the rotor and lock it in place by turning it clockwise until a clicking noise is heard.



4. Close the lid of the instrument and adjust duration and speed (rpm or rcf) of rotation.



- 5. Press start button to begin sample spin.
- 6. Once spinning is complete, the lid should automatically open. If not, press the open button. *Facility Design*

Properly designed labs and animal facilities can provide protection for persons working inside and outside of the laboratory, as well as persons and animals in the community surrounding Simmons. Basic

facility design includes separation of the laboratory or animal room from public access and the availability of a sink for hand washing. If the risk of airborne transmission is high, additional design features, such as specialized ventilation systems, filtering of exhaust air, airlock entrances and controlled access zones may be necessary.

11.0 DISINFECTION, DECONTAMINATION, AND STERILIZATION

A basic knowledge of disinfection and sterilization is crucial for biosafety in the laboratories. Since heavily soiled items cannot promptly be disinfected or sterilized, it is equally important to understand the fundamentals of cleaning prior to disinfection (pre-cleaning). In this regard, the following general principles apply to all known classes of microbial pathogens.

Specific decontamination requirements will depend on the type of experimental work and the nature of the biological materials being handled. The generic information given here can be used to develop both standardized and more specific procedures to deal with biohazard(s) involved in a particular laboratory. Contact times for disinfectants are specific for each material and manufacturer. Therefore, all recommendations for use of disinfectants should follow manufacturers' specifications.

11.1 9.1 Definitions

Many different terms are used for disinfection and sterilization. The following are among the more common in biosafety:

- Antimicrobial An agent that kills microorganisms or suppresses their growth and multiplication.
- Antiseptic A substance that inhibits the growth and development of microorganisms without necessarily killing them. Antiseptics are usually applied to body surfaces.
- **Biocide** A general term for any agent that kills organisms.
- Chemical germicide A chemical or a mixture of chemicals used to kill microorganisms.
- **Decontamination** Any process for removing and/or killing microorganisms. The same term is also used for removing or neutralizing hazardous chemicals and radioactive materials.
- **Disinfectant** A chemical or mixture of chemicals used to kill microorganisms, but not necessarily spores. Disinfectants are usually applied to inanimate surfaces or objects.
- **Disinfection** A physical or chemical means of killing microorganisms, but not necessarily spores.
- **Microbicide** A chemical or mixture of chemicals that kills microorganisms. The term is often used in place of "biocide", "chemical germicide" or "antimicrobial".
- **Sporocide** A chemical or mixture of chemicals used to kill microorganisms and spores.
- Sterilization A process that kills and/or removes all classes of microorganisms and spores.

11.2 9.2 Cleaning Laboratory Materials

Cleaning is the removal of dirt, organic matter and stains. Cleaning includes brushing, vacuuming, dry dusting, washing or damp mopping with water containing a soap or detergent. Dirt, soil and organic

matter can shield microorganisms and can interfere with the killing action of decontaminants (antiseptics, chemical germicides and disinfectants).

Pre-cleaning is essential to achieve proper disinfection or sterilization. Many germicidal products claim activity only on pre-cleaned items. Pre-cleaning must be carried out with care to avoid exposure to infectious agents. Materials chemically compatible with the germicides to be applied later must be used. It is quite common to use the same chemical germicide for pre-cleaning and disinfection.

11.3 9.3 Disinfection

Laboratory personnel use one of the following:

- A 10% sodium hypochlorite (i.e., bleach) solution for disinfecting laboratory surfaces. Sodium hypochlorite is an effective disinfectant against the biological materials, which are being used and/or stored at Simmons.
- A 70% alcohol solution to disinfect the working surfaces of the BSC. If a 10% sodium hypochlorite solution is used in a BSC then it is rinsed with a water solution prior to the alcohol solution. Sodium hypochlorite is not recommended for BSC disinfection since it may erode the stainless steel.

In addition	to sodium hypochlorite and alcohols, there are other disinfectants available for use at
Simmons.	Types of disinfectants and their uses are summarized in Table 4.

Table 4 – Types of Disinfectants and Uses			
Disinfectant	Final Concentration	Effective	Ineffective
Sodium hypochlorite: Clorox™	1:10	Bacteria, some spores, viruses, TB, HIV	Some spores
Chlorine dioxide: Clidox [®] -S	1:3:1 or 1:18:1 (check with manufacturer)	Bacteria, spores, viruses, TB	
Alcohols: ethanol, isopropyl alcohol	70%	Bacteria, most viruses	Spores, TB
Formaldehyde: Formalin®	Depending on biological material; Follow manufacturer's recommendations	Bacteria, spores, viruses, TB	Prions
Quaternary ammonium compounds: Quatricide®	Depending on biological material; Follow manufacturer's recommendations	Bacteria, spores, viruses, TB	
NOTES:			

1. The use of a brand name does not imply recommendation.

- 2. TB means tuberculosis.
- 3. HIV means Human Immunodeficiency Virus.

11.4 9.4 Decontamination of BSC

To decontaminate Class II cabinets, equipment that independently generates, circulates and neutralizes formaldehyde gas is available. Alternatively, the appropriate amount of paraformaldehyde (final concentration of 0.8% paraformaldehyde in air) should be placed in a frying pan on an electric hot plate.

Another frying pan, containing 10% more ammonium bicarbonate than paraformaldehyde, on a second hot plate is also placed inside the cabinet. The hot plate leads are plugged in outside the cabinet, so that operation of the pans can be controlled from the outside by plugging and unplugging the hot plates as necessary. If the relative humidity is below 70%, an open container of hot water should also be placed inside the cabinet before the front closure is sealed in place with strong tape (e.g. duct tape). Heavy gauge plastic sheeting is taped over the front opening and exhaust port to make sure that the gas cannot seep into the room. Penetration of the electric leads passing through the front closure must also be sealed with duct tape.

BSC decontamination will occur prior to moving a BSC to another location within Simmons or disposing of the BSC. Simmons will hire a contractor to perform this process to decontaminate the BSCs.

11.5 9.5 Hand-washing/Hand Decontamination

Whenever possible, suitable gloves should be worn when handling biological materials. However, this does not replace the need for regular and proper hand-washing by laboratory personnel. Hands must be washed after handling biological materials and animals, and before leaving the laboratory.

In most situations, thorough washing of hands with ordinary soap and water is sufficient to decontaminate them, but the use of germicidal soaps is recommended in high-risk situations. Hands should be thoroughly lathered with soap, using friction, for at least 10 seconds, rinsed in clean water and dried using a clean paper or cloth towel (if available, warm-air hand-dryers may be used).

Foot- or elbow-operated faucets are recommended. Where not fitted, a paper/cloth towel should be used to turn off the faucet handles to avoid re-contaminating washed hands.

Alcohol-based hand-rubs may be used to decontaminate lightly soiled hands when proper hand-washing is not available.

11.6 9.6 Autoclaving

Saturated steam under pressure (autoclaving) is the most effective and reliable means of sterilizing laboratory materials and biological materials. Laboratory personnel at Simmons use the autoclave to sterilize laboratory equipment and biological waste.

Autoclave Operation

Autoclaves work by denaturing biological materials with superheated steam. Dry heat is not as effective. Example: It takes 12 minutes to kill most spores with steam at 121 degrees Celsius (°C), while 6 hours are required for dry heat at 121°C. As a result, it is important that biological materials and contaminated equipment come in contact with the steam within the autoclave's chamber. This is accomplished in two ways:

- 1. Cut a hole in the autoclave bag.
- 2. Place approximately 200 milliliters of water into the bag before sealing.

Simmons has two gravity displacement autoclaves in the MCB Wing, Science Building. Figure 6 provides a diagram how these autoclaves work.



Figure 6 – Autoclave Diagram NOTE: Picture obtained from University of North Carolina's webpage on December 1, 2014.

TO OPERATE:

- 1. IMPORTANT: Make sure the drain valve is closed. Make sure the drain valve is closed. Fill bottom of the sterilizer chamber with approximately 6 quarts of water or just below ledge at bottom of door opening.
- 2. **LOAD STERILIZER:** Use proper sterilizer loading procedures when placing materials in sterilizer chamber. All solid containers or instruments must be placed so that water or air will not be trapped in them.
- 3. **CLOSE DOOR:** Grasp handle, and holding it in vertical position, pull door down until bottom of door rests in the bottom of door opening. Then rotate handle forward, engaging the lower curved portion under the horizontal rod in the casting at the bottom of the door opening. Push handle all the way down and back until door is locked securely in position.

4. DETERMINE CORRECT STERILIZATION TIME:

NOTE: In no case should the timer be set to less than 15 minutes.

Sterilization will not be accomplished in less than 15 minutes exposure time.

TIME	ITEMS
(MINUTES)	
15	Glassware, needles (unwrapped), pipettes, and tubing glass
20	Flasked solutions (75-250mL) and rubber gloves
30	Brushers in dispensers, flasked solutions (500mL-1000mL), and syringes
45	Flasked solutions (1500-2000mL)

- 5. **TURN TIMER:** Located at upper right front of sterilizer. Select desired length of sterilizing period. This turns power supply on and starts the cycle after pressure-temperature combination has been reached. Amber pilot light indicates that the timer is running.
- 6. When the sterilizer chamber reaches the selected temperature, the timed exposure cycle will begin. When the exposure cycle is completed, the electric supply will be opened automatically. When the chamber pressure gauge located at the top of the control housing reads "0", the door may be opened. (Release handle and let go to avoid possible contact with remaining steam.) When opening the door, allow a few seconds for steam to escape from chamber before opening completely.

TO MAINTAIN - DAILY CLEANING PROCEDURE (AT THE END OF EACH DAY):

- 1. IMPORTANT: Sterilizing chamber must be cleaned and drained daily
- 2. DRAIN sterilizing chamber completely
- 3. ADD approximately 3 quarts of water to cavity
- **4. ADD** a small portion of a mild detergent to the water in the cylinder. NOTE: If a soft cloth or brush used with the detergent does not completely remove the surface film, a NYLON soap pad should be used.
- 5. After washing a thorough rinse with clean soft water is IMPERATIVE. Dry cylinder and leave door OPEN overnight.

Autoclave Testing and Validation

Each treatment of biological waste is tested by the laboratory manager using autoclave tape. Autoclave tape changes color when it reaches a certain temperature, typically 121°C. It is important to note that autoclave tape only indicates that a critical temperature was met. The tape does not indicate the length of time at the desired temperature or whether steam was produced during the autoclave run.

On a quarterly basis as required by the MADPH for biological waste, the laboratory manager tests and validates each autoclave to ensure it is operating properly and effectively killing the biological materials in each load. This is accomplished through the use of a commercial spore test kit. This kit uses ampoules containing a bacterial species that is tolerate to high temperatures and a color indicator solution. The ampoules are placed in the middle of the autoclave bag and incubated for two days at 56°C. If spores grow, the color changes, which indicates that the autoclave did not sterilized the contents of the autoclave bag. If spores do not grow, then there is no color change and the autoclave procedure is adequate.

Biological Waste Treatment

The MADPH regulation, 105 CMR 480.000, requires that if an autoclave is used to treat biological waste, each load must be logged with the date of treatment, the quantity of the waste treated, the type of waste, process parameters (e.g., time, temperature) and the signature of the operator. This log is posted adjacent to the autoclave and completed by the laboratory manager, who is responsible for treating the biological waste. A hyperlink to this log is available in Appendix D of this document.

Below is the process for treating biological waste in the autoclaves:

- The below process is an excerpt from 105 CMR 480 and is required of all institutions. The IBC has the right to develop their own internal process with regard to this as long as the standards are met.
- Place biological waste into a clear autoclave bag. It is recommended that no biohazard symbol should be visible. Do not use red or orange biohazard bags to autoclave biohazard waste as these bags cannot be disposed of as regular trash.
- Label autoclaved waste bags non-infectious with the supporting information. To meet this requirement, the laboratory manager or students will label the outer black trash bag with the words:

-Non-infectious and Non-hazardous
-Treated in accordance with MADEP and MADPH regulations
-Date Treated: with the treatment date (MM/DD/YYYY),
-Simmons University - Boston, MA.

In addition, a placard with the following words will be placed inside the black trash bag to meet the MADPH recommendations for biological waste:

-Generator: Simmons University – Boston, MA

-Contact Name: ____

-Contact Phone Number: _____

-Biological Waste (Please Specify Agent):_____

-Date Rendered Non-infectious (MM/DD/YYYY), sterilized via Autoclave

Helpful Tips

Failure to effectively sterilize an autoclave load can be due to either a mechanical problem with the equipment or operator error. Laboratory personnel must report mechanical problems to the laboratory manager. Operator errors are generally due to insufficient steam circulation and penetration due to:

- Autoclaving for too short of a time for the size and configuration of load
- Using an autoclave bag that is too large for the autoclave
- Filling bags more than 3/4 full
- Closing bags before autoclaving
- Not having enough liquid in bottom of bag to create steam and force air out
- Placing material in plastic container that does not allow efficient heat transfer
- Placing material in plastic container with high sides that does not allow effective steam penetration

NOTE: DO NOT autoclave plastic unless it is rated as autoclavable. Do not exceed the temperature that the material is rated. Melted plastic releases fumes, ruins autoclave surfaces and clog chamber drains.

12.0 DISPOSAL OF BIOLOGICAL WASTE

12.1 10.1 Definition

The MADPH defines medical or biological waste as *"Waste that because of its characteristics may cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible illness; or pose a substantial present potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed.*

The following types of waste are identified and defined as medical or biological waste, and shall be subject to the requirements of 105 CMR 480.000:

- 1. Blood and Blood Products: Discarded bulk human blood and blood products in free draining, liquid state; body fluids contaminated with visible blood; and materials saturated/dripping with blood. Blood and Blood Products shall not include: feminine hygiene products.
- 2. Pathological Waste: Human anatomical parts, organs, tissues and body fluids removed and discarded during surgery, autopsy, or other medical or diagnostic procedures; specimens of body fluids and their containers; and discarded material saturated with body fluids other than urine. Pathological waste shall not include: Teeth and contiguous structures of bone without visible tissue, nasal secretions, sweat, sputum, vomit, urine, or fecal materials that do not contain visible blood or involve confirmed diagnosis of infectious disease.
- 3. Cultures and Stocks of Infectious Agents and their Associated Biologicals: All discarded cultures and stocks of infectious agents and their associated biologicals, including culture dishes and devices used to transfer, inoculate, and mix cultures, as well as discarded live and attenuated vaccines intended for human use, that are generated in:
 - a. Laboratories involved in basic and applied research;
 - b. Laboratories intended for educational instruction; or
 - c. Clinical laboratories
- 4. Contaminated Animal Waste: Contaminated carcasses, body parts, body fluids, blood or bedding from animals known to be:
 - a. Infected with agents of the following specific zoonotic diseases that are reportable to the Massachusetts Department of Agricultural Resources, Bureau of Animal Health pursuant to 105 CMR 300.140: African swine fever, Anthrax, Avian influenza – H5 and H7 strains and any highly pathogenic strain, Bovine spongiform encephalopathy (BSE), Brucellulosis, Chronic wasting disease of cervids, Foot and mouth disease, Glanders, Exotic, Newcastle disease, Plague (Yersinia pestis), Q Fever (Coxiella burnetti), Scrapie, Tuberculosis,

Tularemia (Francisella tularensis); or

b. Infected with diseases designated by the State Epidemiologist and the State Public Health Veterinarian as presenting a risk to human health; or

- c. Inoculated with infectious agents for purposes including, but not limited to, the production of biologicals or pharmaceutical testing.
- 5. Sharps: Discarded medical articles that may cause puncture or cuts, including, but not limited to, all needles, syringes, lancets, pen needles, Pasteur pipettes, broken medical glassware/plasticware, scalpel blades, suture needles, dental wires, and disposable razors used in connection with a medical procedure.
- 6. Biotechnology By-Product Effluents: Any discarded preparations, liquids, cultures, contaminated solutions made from microorganisms and their products including genetically altered living microorganisms and their products."

Laboratory personnel at Simmons generate cultures and stocks of biological materials, contaminated animal waste, and sharps. Animal waste is discussed in Simmons's Animal Safety Manual and will not be discussed in this manual.

Biological waste at Simmons may be disposed of in four ways:

- 1. Designated biohazard waste box,
- 2. Designated sharps containers,
- 3. Chemical disinfection, which is discussed in Section 9.0, or
- 4. Sterilization via autoclave, refer to Section 9.0.

12.2 10.2 Solid Biological Waste

Solid biological waste is placed into a cardboard box lined with two red biohazard waste bags. Each box is labeled with the universal biohazard symbol. See Figure 7. When constructing the cardboard box, ensure that the U.S. DOT arrows are pointing towards the ceiling. Tape the bottom of the box with 2-inch shipping tape. Place the label identifying the waste generator information on the pre-printed label location on the box.

Once the cardboard box is ready for disposal, contact the biohazard waste company for disposal. When the cardboard box is picked up by the disposal company, a person trained in biohazard waste must sign the Shipping Tracking form. Refer to Section 12.0 for details regarding training. The MADPH requires that off-site shipments of biohazard waste be documented using a form provided by them. A hyperlink to the form is provided in Appendix D. Please refer to the Exposure Control Plan for additional information on the Biological Hazard Label.



Figure 7 – Universal Biohazard Symbol NOTE: Picture obtained from OSHA's webpage on December 1, 2014.

When a biological waste box is between two-thirds (2/3) and three-quarters (3/4) full, each bag must be hand-tied by gathering and twisting the neck of the bag. Then, close the cardboard box and ensure that no red bag is visible once closed. Once closed, tape the cardboard box using two-inch shipping tape. The laboratory manager will contact the biohazard waste company for disposal.

NOTES: DO NOT OVERFILL THE BOX. The weight limit for carrying the box is 55 pounds.

12.3 10.3 Liquid Waste

Liquid biological waste must be rendered non-infectious by steam sterilization or chemical disinfection prior to sink disposal. If chemical disinfection is selected, a chlorine bleach solution may be added to the liquid waste container (e.g., aspiration flask) so that the **final** solution concentration of bleach will be 10%. Contact time should be at least 30 minutes prior to sink disposal for bleach.

NOTES: If bleach is not adequate disinfectant for the biological material, an U.S. EPA approved disinfectant must be used for the biological material. Ensure the proper contact time prior to disposal.

Prior to sink disposal, the treated liquid biological waste should be tested for pH to ensure it is within the permissible range (5.5 - 12.0 standard units) under the Massachusetts Water Resource Authority discharge permit. If the pH is within this range, the treated solution should be poured down the sink drain while running tap water to minimize possible plumbing damage due to corrosive effects of the disinfectants. Autoclaving solutions containing bleach is not permitted due to the potential for production of toxic chlorine gas.

12.4 10.4 Biological and Chemical Waste

The first step when dealing with biological and chemical waste disposal is to render the biological waste as non- infectious through disinfection. Do not select a chemical, which will react with the chemical in the biological and chemical waste. Contact the laboratory manager or Director of EH&S if you have any questions.

12.5 10.5 Sharps

To prevent exposure to biological materials and injuries from sharps, place needles, **Pasteur pipettes**, syringes, suture needles, scalpels, and razor blades into a sharps container immediately after use. Large volumetric/serological pipettes or other items that have the potential to puncture the red biohazard bag should also be placed into a sharps container. Any material that contains or contained chemicals (including chemical residue) shall never be placed in a sharps container.

Sharps containers are red, leak-proof, rigid, puncture-resistant, and shatter-proof containers that are marked with the universal biohazard symbol (see Figure 5) and the "Biohazard" in a contrasting color. Place sharps containers in convenient locations near work areas so they will be used after sharps' use.

Containers should be sealed when they are three-quarters (3/4) full or when they reach the fill line on the sharps containers. Full sharps containers must be sealed with two-inch shipping tape and placed into the biohazard waste box or autoclaved in accordance with Section 9.0. If a sharps container is placed into a biohazard waste box, please ensure that the SHARPS box is checked off on the side of the cardboard box. Refer to the Simmons University Regulated Medical Waste Program for additional information.

12.6 10.6 Broken Glassware

Place clean broken glassware into the standard recycling boxes for glassware. Contaminated broken test tubes or other glassware must be placed into the sharps containers. Contact the laboratory manager or Director of EH&S if you have any questions.

13.0 SHIPPING OF BIOLOGICAL MATERIALS

Import, export, and interstate transport of biological materials are subject to requirements and laws from PHS, DOT, USDA, USDA, and USPS regulate the transport of hazardous materials by rail, air, vessel, and public highway. The guidelines and regulations of the IATA/ICAO also apply when shipping substances by air. Import permit and export permit requirements are regulated by the Bureau of Customs, the Department of Commerce, CDC, and USDA.

Faculty, staff members, or laboratory managers, who may be shipping biological materials internationally or within the U.S., must receive shipping training **PRIOR TO SHIPPING** to comply with these international and federal regulations and guidelines. This training will include information on:

- Properly packaging, labeling and marking the shipment;
- Accurately completing the paperwork;
- Making advance arrangements as needed with the recipient and the carrier; and
- Obtaining any permits needed to import or export biological materials.

Individuals who fail to comply with the regulations may have their shipments refused by airlines or other carriers. They are also at risk for the fines and/or jail terms.

NOTE: It is illegal to carry infectious or other hazardous materials on an airplane. For example, if you visit another lab and want to bring an infectious substance back to your lab, you CANNOT take it on an airplane. You must ship it using a certified carrier such as DHL or Federal Express.

In addition, carriers have specific requirements so prior to shipping a biological material, so it is important to contact your carrier prior to shipping the biological material.

14.0 TRAINING

Biosafety training is required for all individuals, faculty, adjunct, staff, or student, prior to the start of any work in a laboratory or classroom with biological materials. These trainings are mandated by OSHA and

other regulatory agencies including the NIH and CDC. Faculty members are responsible for providing students with information regarding the biological materials present in the laboratory or classroom. Faculty members should work with the BSO to schedule any other necessary trainings. The BSO will deliver a holistic training on working with hazardous materials prior to each semester with the other Laboratory Manager. All faculty and student employees are required to attend.

The following additional trainings are required which can be arranged through the BSO or Director EH&S.

- INITIAL BIOSAFETY TRAINING upon hire or within 30 days at Simmons.
- ANNUAL REFRESHER BIOSAFETY TRAINING.
- U.S./IATA SHIPPING TRAINING prior to shipping biological materials
- **REFRESHER U.S./IATA SHIPPING TRAINING** once every two years unless there is a change in the regulations and guidelines, which warrants re-training.

Additional training, provided by the faculty, adjuncts, laboratory manager, or laboratory supervisor should be specific to the activities conducted in the laboratory or classroom. It should include:

- 1. Biological health risks posed by experimental procedures conducted in laboratory or classroom.
- 2. Biological waste training and proper disposal methods for biological materials.
- 3. The existence and location of all areas in the laboratory or classroom that are specified for only certain procedures.
- 4. The selection and use of personal protective equipment appropriate for tasks to be completed in the laboratory or classroom.
- 5. The proper use of engineering controls and equipment used with biological materials to prevent exposures and spills.

15.0 EMERGENCY RESPONSE

15.1 13.1 Biological Spill

Below is the procedure for biological spills:

- Evacuate the area immediately. Turn off heat sources and equipment, if you are able to do it safely, and close all the doors and windows behind you.
- Call Public Safety immediately at 617-521-1111. If needed, Public Safety will notify 911.
- Try to describe the conditions and identify the material, if known. DO NOT attempt to clean up the spill.
- Follow all instructions from Public Safety officers and other local emergency responders about evacuating or sheltering in place.
- Notify others in the area about the spill.

- If a hazardous material spills/splashes on skin or eyes, flush the affected area immediately with water from an eyewash station or a drench shower for at least 15 minutes or until help arrives.
- If the spill or release occurs outdoors, move upwind from the spill location.

15.2 13.2 Medical Emergency

In case of a medical emergency:

- Notify Public Safety at 617-521-1111 and 911immediately.
- Follow all instructions from Public Safety officers and other local emergency responders.
- Don't move an injured person unless you are able to do so safely and they face a greater danger by not moving.
- Protect yourself and others; be aware of your surroundings.
- Remain with the injured until medical personnel arrive.
- Administer first aid if you are trained and feel comfortable.
- Automated external defibrillators (AEDs) are available for use in the Holmes Sports Center and Health Services.
- Avoid contact with blood or bodily fluids.
- Keep area clear for medical personnel.

16.0 IMMUNIZATION and MEDICAL RESTRICTIONS

Certain biological materials require personnel working with them to receive immunizations and/or have medical restrictions.

16.1 14.1 Hepatitis B Vaccine

Under the OSHA BBP Standard, a HBV vaccine is recommended for anyone working with human blood, body fluids, or tissues. OSHA requires that the vaccine be offered free of charge to employees who have the potential for occupational exposure. Those employees declining vaccination will be asked to sign the OSHA declination indicating that HBV vaccine has been offered and refused. Any questions should be directed to the laboratory manager, BSO, or Director of EH&S. Please consult the Exposure Control Plan for additional information on the Hepatitis B Vaccine.

16.2 14.2 Other Medical Restrictions

Restrictions or recommendations will be made on an individual basis after discussion with either an occupational medicine practitioner or the affected individual's personal physician.

Examples of some conditions that might warrant special precautions are infection, immunosuppressive conditions, or drug therapy that suppresses the immune system. Therefore, anyone who has any of the above-mentioned conditions is encouraged to inform their personal physician about any issues that prevent them from being able to work in a laboratory with biological materials.

17.0 BIOSECURITY

Since the publication of the 4th edition of BMBL in 1999, significant events have brought national and international scrutiny to the area of laboratory security. These events, including the anthrax attacks on U.S. citizens in October 2001 and the subsequent expansion of the United States Select Agent regulations in December 2003, have led scientists, laboratory managers, security specialists, biosafety professionals, and other scientific and institutional leaders to consider the need for developing, implementing and/or improving the security of biological agents and toxins within their facilities.

Doors associated with the laboratories, which are storing and using biological materials, at Simmons are locked at all times. Only faculty, adjuncts, staff, and students, who are authorized to enter the laboratories, have access to the laboratories via keys and to the floors via card access.

21.0 MEMBERS OF THE INSTITUTIONAL BIOSAFETY COMMITTEE 22.0

Bruce Gray Jane Lopilato Jyl Richards Tracy Machcinski Chair, Biology Associate Professor, Biology Senior Lab Manager, CNBHS Biology Lab Manager

MEMBERS OF THE SAFETY COMMITTEE

Michael Berger	Associate Professor, Chemistry and Physics
Edie Bresler	Associate Professor of Practice, Art and Music
Colleen Kiely	Associate Professor, Art and Music
Jane Lopilato	Associate Professor, Biology
Jyl Richards	Senior Lab Manager, CNBHS
Jennifer Roecklein-Canfield	Department Chair, Chemistry and Physics
Tracy Machcinski	Biology Lab Manager

23.0 RISK ASSESSMENT



APPENDIX B

APPENDIX C

28.0 MADPH BIOLOGICAL WASTE FORMS HYPERLINKS

Massachusetts 105 CMR 480

<u>105 CMR 480.00: Minimum requirements for the management of medical or biological waste (State</u> <u>sanitary code chapter VIII) | Mass.gov</u>

References used in the Creation of this Manual

Indiana University Biosafety Manual

Iowa State Biosafety Manual

University of Kentucky Biosafety Manual