Biosafety Manual
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1. PURPOSE AND SCOPE

Boise State University is committed to ensuring activities involving biohazardous materials are conducted safely and measures are in place to protect the public, employees, students, and environment from exposure to these materials.

The Biosafety Manual applies to all activities involving biohazardous materials at the University, and was developed with the following references in mind:

- Guidelines for Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition and all subsequent revisions.
- Idaho Division of Building Safety Bloodborne Pathogens, Section 330
- U.S. Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens, 29 CFR 1910.1030
- Boise State University Biosafety Policy (5080)
- Boise State University Bloodborne Pathogens Exposure Control Plan

2. RESPONSIBILITIES

2.1. Boise State University

The University is committed to providing a safe environment for its employees, students, and visitors and protecting the surrounding community. The University is responsible for providing sufficient resources to protect individuals who may be exposed to biohazardous materials and to minimize environmental impact from these materials.

2.2. Dean, Chair, and Research Center Director

Each Dean, Chair, and Research Center Director is responsible for ensuring Principal Investigators (PI), Instructors, and Supervisors under their purview adhere to applicable regulatory requirements and University policies, and each PI has received Institutional Biosafety Committee approval for activities requiring IBC review.

2.3. Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee (IBC) consists of representatives from across the University as well as the community. The committee’s activities are coordinated by the Office of Research Compliance. The committee’s primary responsibility is to review laboratory work involving biohazardous materials. These reviews are conducted to assess the risk of handling these materials and help to ensure adequate safeguards are in place to protect employees, students, visitors and the surrounding community. The IBC also helps ensure compliance with regulatory and University requirements.
2.4. Biosafety Officer (BSO)
The Biosafety Officer, a member of Environmental Health and Safety, consults with researchers on the safe use of biological materials in the laboratory, provides program oversight, and guides waste disposal practices.

2.5. Principal Investigator (PI), Instructor, and Supervisor
Each PI, Instructor and Supervisor carries direct responsibility for the work and those performing the work under their control. They must ensure applicable work has been granted IBC approval prior to beginning and suitable safeguards are available and used to protect lab workers, visitors, and those outside the lab. These safeguards shall include, but are not limited to: training on hazards and procedures, engineering controls, administrative controls, personal protective equipment, and emergency response.

2.6. Laboratory Worker
Laboratory workers are responsible for completing applicable training, being aware of the hazards with their work, and following instructions, protocols, and procedures including University policies and programs. A student or volunteer may be considered a laboratory worker.

2.7. Visitors
Visitors entering areas where biological materials are stored or handled must comply with the PI, Instructor, or Supervisor’s requirements for the area.

3. RISK ASSESSMENT
A risk assessment is the process to identify and assess the hazards and risks of a process. This process is a tool to minimize risk and identify safer work practices. The risk assessment will need to include all aspects of the project, from the initial development, through the actual work, and appropriate disposal.

3.1. Identify all known risks that could occur as result of your project.
Risk by definition is an uncertain future event which could adversely affect the outcome.

3.2. Determine the likelihood that the risk could occur.
What controls are in place to decrease the risk, this includes engineering controls, administrative controls including vaccines and personal protective equipment. Place the risk and probability into categories of high, medium and low.

3.3. Rate the Risk Impact
This is the potential effect that a risk could have on the organization, people, environment, reputation or funding.
- High: Serious impact
- Medium: Significant impact
- Low: Less significant impact
The combination of likelihood and impact gives us the value for each risk factor.

3.4. Evaluate

For those risks that are determined to be inherent to the process you will need to develop specific procedures to limit the exposure and safely complete the task.

Risk assessments involving biological material often include: pathogenicity, epidemiology, host range, infectious dose, mode of transmission, communicability, immunization, availability of treatment, prophylaxis, risk group classification, and risk to the environment.

4. INCIDENT REPORTING

All incidents, near miss events and personal injuries need to be reported. If an emergency occurs immediately dial 911 from any phone and summon emergency responders. The 911 operator will be asking for the street address of your building. Please refer to the sign on the outside of your door. This will indicate the exact street address of your building. You will also need to give them the floor and room number. Stay on the line with the emergency operator, they will ask additional questions to ensure we receive the appropriate level of response.

If the situation is moderate, you may call campus dispatch at 426-6911 and they will help you determine the appropriate level of response necessary.

Incidents involving personal injury need to be reported immediately to the Risk Management Department. Employees must fill out the Supervisor’s Accident Report form located on Risk Management’s website. All employee work related incidents are managed by St. Luke’s Occupational Health during work hours or the St Luke’s emergency room for after-hours incidents. Map to St Luke’s Occupational Health Clinic Students who are
injured will need to follow up with their personal physician or student health services. Please use the Incident/Accident Injury Report Form and return to Risk Management.

For all near miss events, spills, theft, and minor injuries, please use Report Exec which is an online tool for collecting information to help mitigate risk we find on campus.

5. PROTOCOL REQUIREMENTS
The University uses a protocol system to review and approve activities involving biohazardous materials to help ensure adequate controls are used to protect lab workers, staff, the public and the environment. Principal Investigators are required to submit protocols to the IBC for review. The PI must receive IBC approval of the protocol prior to beginning work. Additional information regarding protocol requirements and the IBC are available on the IBC website. If the work involves animals or human subjects, additional protocols will be necessary with requirements stipulated by the appropriate committee(s) – Institutional Animal Care and Use Committee (IACUC) or one of the University’s Institutional Review Board.

6. EXPOSURE CONTROLS
Control mechanisms are necessary to minimize exposure and must be based upon a risk assessment. Exposure controls are typically sought in the following order

6.1. Eliminate/Alternate/Reduce
The best way to minimize exposure to a hazard is to eliminate it altogether. Find a safer alternative for the activity, or reduce the scale of the experiment. The hazard may stem from the material or procedure, and it is important to consider both. It is important to determine if an alternate procedure, use of an attenuated strain, or reduction in scale could be used to eliminate or reduce the risk and attain the same results.

6.2. Facility Design
Facility design refers to the design and construction of the laboratory space. It serves as a barrier to protect occupants. Facility design hinges on the risks of exposure and characteristics of the infectious agent. All University laboratories are considered biosafety level 1 or biosafety level 2 laboratories. Most facilities at these levels only require design features to minimize direct contact with the material. This may include separating handling facilities; locating biosafety cabinets away from doors, high traffic areas, and ventilation supply sources; non-porous surfaces for easy decontamination, hand washing equipment, limited access, and decontamination facilities. Additional guidance can be found in the latest version of the Center for Disease Control & Prevention’s Biosafety in Microbiological and Biomedical Laboratories publication as well as the University’s Architectural and Engineering Services Design Guidelines.
6.3. Engineering Controls

Engineering controls are essentially various types of equipment used to minimize contact with a hazard. Common engineering controls for biological materials include biosafety cabinets, sharps containers, centrifuge safety cups, and vacuum line High Efficiency Particulate Air (HEPA) filters.

6.3.1. Biosafety Cabinet

A biosafety cabinet (BSC) is an important engineering control to capture airborne material to protect workers and the environment. Some biosafety cabinets provide protection of the material being handled from contamination. Each BSC uses High Efficiency Particulate Air (HEPA) filters to capture airborne material. Biosafety cabinets are available in three classes:

- **Class I** – protects the worker and environment, not the material.
- **Class II** – protects the worker, environment, and the material.
- **Class III** – glove box style cabinets used for highly infectious materials.

Class II BSCs are the most common on campus, and most, if not all, return HEPA filtered air to the room. HEPA filters do not adequately absorb volatile organics so these vapors would be exhausted into the room. Work requiring a biosafety cabinet while using volatile organic solvents must be conducted in a BSC fully exhausted to the outdoors. Currently, Boise State does not have any fully exhausted BSCs.

Each BSC must be certified annually and each time it is relocated prior to use to ensure it is operating properly and providing adequate protection.

BSC containment can be affected by air currents in the room; therefore, they should be located away from supply ducting, high traffic areas, and at least 10 feet from any door.

Some laboratories on campus use laminar flow hoods (PCR hood) to protect their work from contamination. These units provide no worker protection and are not considered a biosafety cabinet.

6.4. Administrative Controls

6.4.1. Training

Laboratory workers require varying levels of training dependent upon the materials they may contact and their duties. General awareness training typically covers broad topics of biosafety to help inform laboratory workers regarding the risks and controls needed to safely handle biohazardous materials. The University requires all PIs, Instructors, Supervisors, and Laboratory Workers complete applicable online biosafety training provided by CITI. For additional information about the CITI program, log on information, and training requirements please refer to the Office of Research Compliance website. Additional laboratory safety training is required by Environmental Health, Safety and Sustainability.
The PI, Instructor or Supervisor must ensure their laboratory workers receive lab-specific training to communicate specific procedures and hazards of the laboratory.

It is essential the PI, Instructor and Supervisor ensure compliance with training and maintain training records.

6.4.2. Work Practices

6.4.2.1. Universal Precautions
Universal precautions is the principle that all blood and body fluids are treated as infectious. Safeguards need to be designed to prevent the transmission of blood-borne diseases, respiratory conditions, or dermal conditions within the lab. Precautions may include specific recommendations for where the work will be completed and specific use of gloves, lab coats, masks and protective eye wear. Appropriate use of these methods will help to protect individuals working in the lab, and prevent cross contamination to others leading to increased infection control.

6.4.2.2. General Work Practices
Specific procedures may be written for high risk tasks occurring in the lab. For all other tasks, safe work practices must be followed. These practices should include but are not limited to:

- Appropriate personal protective equipment (PPE)
- No food or drink in the lab
- Aisles clear and benchtops uncluttered
- Life Safety Equipment in good working order and accessible
- All workers are compliant with their required training
- Limit cross contamination potential
- Waste is managed appropriately
- All materials are well labeled, including full chemical names not formulas
- Emergency signs are posted and visible
- Biological sharps are stored in red rigid containers, when 2/3rd full can be discarded in the biohazardous waste storage room
- Non-biological sharps such as pipette tips are placed in rigid containers, taped closed and discarded in the regular garbage
- Vacuum lines need to be protected from biohazardous pathogens and toxins. The lines shall be protected with liquid disinfectant traps and high efficiency particulate air (HEPA) filters, which are checked routinely and appropriately maintained

6.5. Personal Protective Equipment (PPE)
Personal protective equipment (PPE) is worn to minimize exposure to potential hazards and must be worn when handling hazardous materials or performing potential hazardous activities in the laboratory. Appropriate PPE is based upon the potential hazards and risks associated with those hazards. It is considered last line of defense in the hierarchy of
controls. Common PPE used includes lab coats, gloves, ANSI rated safety glasses, goggles, and face shield.

7. DECONTAMINATION AND WASTE DISPOSAL

7.1. Decontamination
Lab surfaces must be decontaminated after work to minimize cross contamination to lab workers and areas within and outside the lab. Decontamination procedures will differ per lab dependent on the work being conducted. Disinfection and sterilization are methods of decontamination used to reduce microbial contamination to render an item or area "safe". Cleaning may also be regarded as a decontamination method as it too can remove microorganisms from a soiled surface.

The use of chemical disinfectants is a widespread and important control technique in biological laboratories. Where microorganisms and other potentially infectious biological materials are handled, University laboratories must routinely use chemical disinfection to decontaminate surfaces and equipment, and disinfect spent culture fluids.

Microorganisms vary in their susceptibility to chemical disinfectants. Please contact EHS if you have questions regarding disinfectant selection.

7.2. Waste Disposal
All waste must be treated appropriately, and no waste is treated the same. Please refer to the Guidance Document for waste disposal best practices for all waste generated in your lab.

The University’s current biohazardous waste vendor will only autoclave waste. None of the biohazardous waste that leaves campus is incinerated.

7.2.1. Mixed Wastes
Mixed wastes are waste streams containing biohazardous waste with hazardous (chemical) waste and/or radioactive material waste. These waste streams are typically extremely expensive to dispose. Each lab must make significant effort to eliminate and minimize mixed waste streams. In some instances, the biological waste may be disinfected resulting in only a hazardous or radioactive waste, but care must be taken to ensure use of a compatible disinfectant.

Each lab must consult with EH&S prior to generating any mixed wastes.

8. SPILL CLEAN-UP
Personnel are responsible for following guidance in the University’s Immediate Actions for Emergencies on Campus – Hazardous Materials. After the event please enter the information into Report Exec.
Laboratories must have chemical spill kits available suited to the chemicals and quantities in their particular laboratories. Basic supplies should consist of appropriate absorbents, equipment, and PPE. A basic supply list is available on the EH&S website. If necessary, contact EH&S for assistance determining adequate supplies.

9. TRANSFER OF MATERIAL

9.1. Shipping
The shipment of biological materials involves varying degrees of packaging, documentation, and training dependent upon the material, quantity, method of shipment and destination. Shipments improperly prepared or those containing undeclared dangerous goods may result in hefty fines.

Persons who perform any classification, packaging, labeling or documentation of these types of shipments must be properly trained in accordance with the Department of Transportation and International Aviation Transportation Association regulations prior to their involvement with any of the above activities. Environmental Health and Safety is available to help determine classification, packaging, and documentation requirements as well as assess training needs, and in many cases, provide training.

9.2. Permits and Licenses
Biological materials could require permits and/or licenses to transfer them. Permitting or licensing requirements are dependent upon the material being transferred, the shipment’s origin and destination, and a multitude of international, federal, and state entities. It is imperative any necessary licenses and permits be obtained prior to shipment. At a minimum it will ensure the package makes it to its destination in a timely manner. In certain cases a shipment of restricted materials or a shipment to restricted countries could result in fines and/or imprisonment. Environmental Health and Safety can assist with determining required documentation, but depending upon the complexity, it may be necessary to involve a customs broker.

9.3. Material Transfer Agreement
A material transfer agreement (MTA) may be necessary for incoming or outgoing transfers of biological materials to be used for research purposes that have potential intellectual property value. A MTA delineates who owns the original material and any derivatives/progeny that may result from the additional research. It can also outline limits regarding the use of the material. The Division of Research processes MTA requests. Additional information and the MTA Request Form are available on the MTA webpage.
10. DEFINITIONS

Biohazardous materials
Infectious agents or biological materials potentially hazardous to humans, animals, or other forms of life.

Biosafety Levels (BL)
Categories of containment levels based upon a procedure’s risk assessment taking into consideration the agent’s risk group, facility design, work activities, etc. The BMBL outlines standard practices, special practices, safety equipment, and laboratory facilities for each biosafety level.

Bloodborne pathogen
Pathogens present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). (From 29 CFR 1910.1030(b)

Decontamination
A process for reducing the amount of biohazardous materials to an acceptable level. Disinfection and sterilization are forms of decontamination.

Disinfection
Significant reduction or complete elimination of pathogenic organisms to acceptable levels. Other organisms may survive.

Recombinant DNA (Nucleic Acids)
Molecules constructed outside a living cell by joining natural or synthetic DNA/RNA segments to DNA/RNA molecules that can replicate in a living cell.

Risk Groups (RG)
The NIH Guidelines define the following risk groups that must be used in the risk assessment process.

Risk Group 1 (RG1)
Agents not associated with disease in healthy adult humans

Risk Group 2 (RG2)
Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available

Risk Group 3 (RG3)
Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk)

Risk Group 4 (RG4)
Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)

Select Agents
Biological agents and toxins regulated by the United States Department of Agriculture (USDA) and/or the Centers for Disease Control and Prevention (CDC) that have the
potential to pose a severe threat to public, animal or plant health, or to animal or plant products.

**Sterilization**

Destruction of all living organisms including spores