# Biosafety Manual

Fitchburg State University
160 Pearl Street
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Revised May 2026

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# List of Abbreviations and Acronyms

BBP - Bloodborne Pathogens
BL - Biosafety Level
BMBL - Biosafety in Microbiological and Biomedical Laboratories
BSC - Biological Safety Cabinet
CDC - Centers for Disease Control and Prevention
CFR - Code of Federal Regulations
CMR - Code of Massachusetts Regulations
DNA - Deoxyribonucleic Acid
DOT - U.S. Department of Transportation
EH&S - Environmental Health and Safety
FDA - U.S. Food and Drug Administration
FSU - Fitchburg State University
GMO - Genetically Modified Organism
HEPA - High Efficiency Particulate Air
HIV - Human Immunodeficiency Virus
IACUC - Institutional Animal Care and Use Committee
IATA - International Air Transport Association
IBC - Institutional Biosafety Committee
LAA - laboratory animal allergies
NIH - National Institutes of Health
OSHA - U.S. Occupational Safety and Health Administration
PHS - U.S. Public Health Service
PI - Principal Investigator
PPE - Personal Protective Equipment
rDNA - Recombinant DNA
USDA - U.S. Department of Agriculture
WT - Wild-type
°C - Degrees Celsius

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| Useful Links |
|---|
| Fitchburg State Exposure Control Plan |
| NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) April 2024 |
| NIH/CDC Biosafety in Microbiological and Biomedical Laboratories 6th Edition |
| OSHA Bloodborne Pathogen Standard |

# 1.0 Introduction

## 1.1 Background

Work with blood, tissues, cells, microorganisms, and animals comprises a wide variety of routine activities in many research and teaching laboratories. Exposures to potentially infectious materials during many of these activities can present underestimated health hazards to researchers and students and may place them at increased risk for infections from bacteria, fungi, viruses, viral vectors, recombinant or synthetic nucleic acid molecules, and biological organisms containing recombinant or synthetic nucleic acid molecules.

Biosafety is defined as a group of practices and procedures designed to provide a safe environment for individuals who work with potentially hazardous biological materials. The primary goal of biosafety is to eliminate exposures to these materials through the use of containment. The term containment refers to safe methods for managing potentially infectious materials work or classroom environments. Containment includes both primary containment (e.g., good microbiological techniques and safety equipment) and secondary containment (e.g., the design and operation of the facility).

Two government agencies, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), have developed the biosafety guidelines that provide the foundation for this manual. They are designed to protect people working with biological materials and individuals in the surrounding community and are described in two publications.

The first is the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ( NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) April 2024 ). The second is the 6th Edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL), which is published jointly by the CDC and the NIH (NIH/CDC Biosafety in Microbiological and Biomedical Laboratories 6th Edition) the most recent edition was published in 2020.

These two publications classify work with biological agents into four distinct biosafety levels (BLs). Each of these levels is matched with progressively restrictive practices and laboratory design features that reduce health risks from exposures to potentially hazardous biological agents. These levels are further discussed in Section 3.

## 1.2 Regulations

Federal, state, and local agencies have developed regulations for protecting workers and the general public from the potential health hazards associated with the use of biological agents. Some of these regulations, such as those from the U.S. Occupational Safety and Health Administration (OSHA), have the force of law while those from NIH and CDC are recommended guidelines. As part of the grant application process, many federal and private granting agencies require applicants to certify that they adhere to all federally mandated requirements and suggested guidelines.

### 1.2.1 Federal

Employees and students who come in contact with human blood or other human bodily fluids are at increased risk for exposure and infections from bloodborne pathogens (BBP), such as human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C virus. The OSHA Bloodborne Pathogens Standard (Title 29 Code of Federal Regulations [CFR] Section 1910.1030) was designed to eliminate or minimize occupational exposure and the risk of developing infectious diseases associated with blood and other bodily fluids. All staff and students who work with human tissues, cells, blood and other bodily fluids must adhere to the OSHA BBP Standard (OSHA Bloodborne Pathogen Standard).

The use of Universal Precautions is a key element of any BBP program and must be followed at all times. All human blood, fluids, or cells and tissues that contain these fluids, are considered BL2. Universal Precautions means that all samples of blood or other human materials are treated as potentially infectious. For example, blood from any source, including HIV-seronegative control donors, must be handled as potentially infectious. Employees must be trained on laboratory safety, chemical spills, general hazard communication, and bloodborne pathogen safety including Universal Precautions techniques, at orientation and on an annual basis. Online trainings through Vector LMS/Safe Colleges will be assigned by the Environmental Health and Safety (EH&S) Officer. For more information, call 978-665-4801.

Safe practices for studies involving the use of recombinant or synthetic nucleic acid molecules are governed by the NIH Guidelines. It is Fitchburg State University policy that all laboratories comply with these Guidelines, which are law in the City of Fitchburg.

### 1.2.2 Commonwealth of Massachusetts

Regulations from the Commonwealth of Massachusetts (Title 105 Code of Massachusetts Regulations [CMR] Part 480.000—Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste State Sanitary Code Chapter VIII (105 CMR 480.00: Minimum requirements for the management of medical or biological waste (State sanitary code chapter VIII)) primarily focus on the management of biological waste. The principal issues deal with what constitutes biological waste and how to dispose of it properly. Overall, the state statutes agree with the NIH and CDC definitions of biological waste.

### 1.2.3 City of Fitchburg

All rDNA work conducted in the City of Fitchburg is subject to regulations outlined in the Code of the City of Fitchburg, Chapter 68, “Biotechnology, Regulation of”. At Fitchburg State University, these regulations are enforced by the EH&S Office and the Institutional Biosafety Committee (IBC). In general, the requirements set forth in the city code agree with NIH and CDC guidelines. Further information can be found at City of Fitchburg Code Chapter 68 Regulation of Biotechnology.

## 1.3 Institutional Biosafety Committee

The IBC is a committee made up of faculty, technical staff and community representatives, and the purpose of the IBC is to conduct specific review and oversight of biological research activities in compliance with the following guidelines and regulations:

- NIH—NIH Guideline for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) April 2024
- U.S. Occupational Safety and Health Administration—OSHA Bloodborne Pathogen Standard 1910.1030 OSHA Bloodborne Pathogen Standard
- Massachusetts Department of Public Health—Medical Waste Regulation 105 CMR 480.00: Minimum requirements for the management of medical or biological waste (State sanitary code chapter VIII)
- Code of the City of Fitchburg—Regulation of Biotechnology City of Fitchburg Code Chapter 68 Regulation of Biotechnology

### 1.3.1 IBC Membership Requirements

The IBC must have a minimum of 5 members and must have the following composition:

- At least two community (non-affiliated) members who are:
    - Not affiliated with the institution
    - Not immediate family of an affiliated person
    - Represent community interests in health and environmental protection

- At least one member with expertise in biosafety

- Members with appropriate scientific expertise
    - Experience in recombinant/synthetic nucleic acid research
    - Knowledge of containment practices
    - Ability to assess risk to public health and the environment

- Members with additional expertise as needed
    - Plant, animal, or human gene transfer expertise (if applicable)
    - Occupational and Environmental Health and Safety

- All members of the Institutional Biosafety Committee (IBC) are granted full voting rights and are authorized to cast votes on all matters brought before the committee during official meetings.

### 1.3.2 Required training for IBC Committee Members

All members of the IBC Committee will be required to demonstrate completion of the CITI collaborative training modules within the past 36 months. These modules include:

- Responsible Conduct in Research

- Biosafety/Biosecurity (BSS) Research Faculty/IBC Members

### 1.3.3 Registering Research Projects and Teaching Activities with IBC

All biological research and teaching activities involving the use of microbes, human and nonhuman primate materials, biological toxins, and recombinant or synthetic nucleic acid molecules must be registered with the IBC. Registrations for research and teaching activities involving human and nonhuman primate materials, biological toxins, and recombinant or synthetic nucleic acids must be submitted every three years or whenever changes occur. Please contact the Dean of Health and Natural Sciences for information about how to register a protocol with the IBC.

Each completed registration will be reviewed by the IBC Chair who may request additional information or clarification from the submitter or PI. Once the review is complete, the submission will be reviewed to determine if the research can be administratively approved. If the research or teaching activity falls under Sections III-A through III-D of the NIH Guidelines, it must be

reviewed at a convened meeting of the IBC. Additionally, research with pathogens or toxins is typically reviewed at a convened meeting.

## 1.4 Responsibilities

The following section outlines the specific responsibilities associated with the biosafety program.

### 1.4.1 Principal Investigator

PIs are responsible for implementation of all applicable biosafety procedures and practices in their laboratories. They must ensure that appropriate equipment and facilities are available for laboratory members and are used properly. Each principal investigator must be aware of the potential adverse health effects of the biological materials used in his or her laboratory, the appropriate BL, and any other pertinent factors that will ensure the safety of members of the laboratory and the surrounding community. They must also arrange for appropriate employee training regarding the safe use of potentially hazardous biological agents and require that all employees handling BBP receive the annual training mandated by OSHA.

In addition to the above, when research involves the use of recombinant or synthetic nucleic acid molecules, the principal investigator (PI) agrees to abide by the NIH Guidelines. Under the NIH Guidelines, the PI has a number of specific responsibilities, including the following:

- Ensure that IBC is notified prior to beginning any work with biological materials.
- Conduct an initial risk assessment of all hazards associated with the laboratory's work with biological materials.
- Report any significant problems, violations of the NIH Guidelines, or any laboratory-related accidents, illnesses, or potential exposures to the EH&S Office. The EH&S Office should be contacted immediately, as there may be additional reporting requirements to outside agencies. There is an incident report form in Appendix B.
- Instruct and train laboratory staff and students in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents. Instruction may be required when procedures are changed, new procedures are implemented, or when accidents occur. This instruction should be specific to the agents and materials used in the research project.
- Make available to all laboratory staff and students protocols that describe the potential biohazards and the precautions to be taken with the agents to be used.
- Submit an annual report to the IBC to include the following information:
    - IBC protocol number(s)
    - Project title(s)
    - PI name and lab location(s)
    - Any changes in research scope or objectives

- Any changes in protocol
- List of agents/materials used
- Current lab personnel working under the protocol
- Confirmation that all personnel have completed required training
- Summary of any spills, accidents/injuries, containment breaches

Additional responsibilities of the PI when working with recombinant or synthetic nucleic acid molecules are located in the NIH Guidelines (NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) April 2024). Failure to comply with the NIH Guidelines by one PI could affect all NIH and NSF-funded projects at Fitchburg State University; therefore, compliance is absolutely mandatory.

### 1.4.2 Teaching Laboratories

Teaching laboratories present unique biosafety considerations due to the presence of students who may have limited laboratory experience and varying levels of training. The following requirements establish minimum standards to ensure a safe learning environment and compliance with institutional and regulatory expectations.

- Any use of recombinant or synthetic nucleic acid molecules, microbes, human and nonhuman primate materials, and biological toxins must be registered with the IBC.

- Only biological agents and procedures approved by the Institutional Biosafety Committee (IBC) may be used.
  - Protocols involving the use of Risk Group 1 agents do not require review by the IBC and will be administratively approved by the IBC Chair.
  - Protocols involving the use of Risk Group 2 agents will be reviewed by the IBC Chair and given initial approval so that work may be started, pending review by the full IBC.
  - Use of Risk Group 3 or higher agents is strictly prohibited in teaching laboratories.

- Teaching laboratories must be under the direct supervision of a qualified instructor or designated laboratory staff member at all times when biological materials are in use.

- Instructors are responsible for enforcing all safety rules and ensuring proper laboratory conduct.

- Instructors must ensure students demonstrate understanding of safety procedures before beginning work.

- All protocols must be reviewed and approved prior to implementation if required.

- All spills, exposures, injuries, and near-misses must be reported immediately to the instructor.

- Instructors must ensure appropriate first aid, containment, and notification procedures are followed.

- Incidents must be documented and reported in accordance with institutional reporting requirements.

### 1.4.3 Staff and Student Responsibilities

Staff and students are responsible for following university health and safety policies and the procedures and instructions from their PIs, Professors, and the EH&S Office. They need to comply with all NIH, CDC, and OSHA regulations, use safe laboratory practices, and inform the PI, instructor, laboratory supervisor, or EH&S Office regarding any potentially hazardous situations or conditions.

### 1.4.4 Biosafety Officer

Because Fitchburg State University conducts only BSL-1 and BSL-2 research and does not perform research requiring BSL-3/4 containment or large-scale recombinant DNA work, a Biosafety Officer is not required under the NIH Guidelines. However, the IBC designates the IBC Chair and EH&S Officer to support the IBC and oversee biosafety compliance.
These responsibilities include:

### 1.4.5 IBC Chair

- Managing the biosafety program and implementation of IBC policies and procedures.The IBC Chair will work with the Dean of Health and Natural Sciences, the EH&S Officer, and a credentialed consultant (if needed) to implement the program.

- Acting as the liaison between IBC, Institutional Animal Care and Use Committee (IACUC), and researchers.

- Screening research protocols proposed by PIs and submitting to IBC for approval. The IBC Chair will determine whether more information is necessary and, if so, will communicate this need to the PI. Once the revised application is complete, the IBC Chair completes a risk assessment for the IBC summarizing the salient characteristics of the study and recommending an appropriate BL to reviewers and/or the full committee.

- Reporting to the IBC on the program status

- The IBC Chair will be given the results of biosafety inspections and will be responsible for communicating the results to individual laboratories.

- Providing advice on safe methods for new procedures.

### 1.4.6 EH&S Officer

- Assisting laboratories in conforming to pertinent regulatory guidelines and IBC policies by providing training, facility inspection, and communication of program requirements.
- Making annual inspections of laboratory containment, procedures, records, and equipment for laboratories using biological agents or toxins.
- The EH&S Officer will contract for training and facility inspections from a third party in conjunction with the Dean of Health and Natural Sciences.
- Providing advice on safe methods for new procedures.
- Recommending emergency response procedures in the event of an infectious spill or an exposure to a biological material, or directing affected employees to the EH&S or a credentialed consultant for assistance.
- Summarizing the results of the biosafety inspections of laboratories in biosafety reports.

# 2.0 Hazard Analysis/Risk Assessment

In order to determine which practices and procedures are required when working with biological materials, a risk assessment should be conducted. At a minimum, the risk assessment should include the following:

- Pathogenicity and infectious dose of the biological material
- Consideration of the outcome of an exposure
- Natural route of exposure
- Other routes of exposure (parenteral, airborne, ingestion, etc.)
- Stability of biological material in the environment
- Concentration of biological material and amount to be manipulated
- Presence of a suitable host
- Information available from animal studies and reports of laboratory-acquired infections or clinical reports

- How the biological material will be used (concentration, sonication, aerosolization, centrifugation, etc.)

- Any genetic manipulation of the organism that may extend the host range of the agent or alter the agent's sensitivity to known, effective treatment regimens

- Local availability of effective prophylaxis or therapeutic interventions

PIs are responsible for conducting an initial risk assessment of their work with biological materials. They will include the results of this risk assessment in their IBC registration.

## 2.1 Limited Information

There are situations when the information is insufficient to perform a risk assessment. For these situations, the following conservative approach must be used:

- Universal precautions must be followed, and barrier protections applied (gloves, gowns, eye protection), regardless of the origin of the samples.

- BL2 will be the minimum requirement for the handling of specimens.

## 2.2 Biological Expression Systems

Since biological expression systems consist of vectors and host cells, consider the following:

- The expression of DNA sequences derived from pathogenic organisms may increase the virulence of the organism.

- Inserted DNA sequences are not well characterized, e.g., during the preparation of genomic DNA libraries from pathogenic microorganisms

- Gene products may have potential pharmacological activity

- Gene products may code for toxins

## 2.3 Genetically Modified organisms

When a PI proposes to work with genetically modified organisms (GMOs), they should consider the characteristics of donor and recipient/host organisms. In addition, s/he should consider whether or not the GMO is more hazardous than the wild-type (WT) organism. For example, if GMO is a pathogen, has the genetic modification increased the virulence or expanded the tropism of the organism? Is the GMO hardier than the WT organism? What are the potential consequences if the GMO was released into the environment outside the lab? This information should be included in the risk assessment.

## 2.4 Human blood and bloodborne pathogens

Human blood, body fluids, tissues, and materials that may be contaminated with these materials, are considered potentially infectious. Any laboratory activity that includes the collection or manipulation of these materials must be conducted using Universal Precautions. Transportation of these materials through common-use or non-laboratory areas should be done in such a way as to securely contain the material and minimize or eliminate the chance of spills or accidental release.

# 3.0 Working With Animals in the Laboratory

## 3.1 Introduction

Working with animals in a laboratory setting can present risks from infections and injuries to all personnel. Personnel working with laboratory animals must be aware of the potential risks and implement measures to prevent injury or illnesses related to laboratory animal use. The purpose of this section is to communicate the risks involved with laboratory animal use and the protective procedures in place. All activities involving the use of vertebrate animals conducted by Fitchburg State University faculty, staff, or students, or sponsored, in part or in whole, by Fitchburg State must be reviewed and approved by the IACUC before the work begins.

All handling and use of animals must be conducted safely, humanely, and in full compliance with all IACUC policies and procedures. Any hazardous or non-compliant behavior or work conditions regarding the use of animals needs to be reported to the Animal Care Facility Manager, Attending Veterinarian/Director, or the IACUC.

## 3.2 Allergies

Allergic reactions to animals are among the most common adverse health effects associated with the care and use of animals in biomedical research. The development of laboratory animal allergies (LAA) commonly begins with the inhalation of animal allergens, such as dander and urinary proteins. Skin and eye contact with allergens can also result in symptoms. Although most animal allergens are found in urine, dander, hair, serum, and saliva, coexisting allergies and tobacco smoking can exacerbate the development of LAA. All possible measures or controls must be implemented to decrease or eliminate the exposure of personnel to allergens when working with laboratory animals.

Symptoms of LAA can range from minor to life threatening. Rhinitis (runny noses), conjunctivitis, asthma or other breathing difficulties, fever, skin rashes or bumps (atopic dermatitis), and gastrointestinal disorders can all be the result of LAA. Be aware that symptoms can be delayed up to 12 hours after animal exposure. Promptly report any suspicious clinical symptoms to your healthcare provider.

Guidelines for working with animals are summarized as follows.

- Wear required personal protective equipment (PPE) at all times when working with animals.
- Do not wear PPE outside of the animal facility.
- Wear gloves at all times when handling animals.
- Do not distribute animal bedding in your immediate work environment. All cage cleaning procedures should be performed in a manner that prevents bedding debris from entering the work environment. Change bedding in a biological safety cabinet (BSC) or fume hood.
- Ensure that animal cages are properly closed and that static microisolator cage lids properly fit.
- Do not overpopulate animal cages.
- Conduct work with animals in a BSC when required and whenever possible.
- When work cannot be conducted in a BSC, conduct work with animals in well ventilated areas and see facility supervisor.
- Clean and disinfect all equipment after use.
- Wash hands frequently and always after handling animals (even when wearing gloves).
- Avoid touching your face when working with animals.
- Keep work areas clean.
- Keep animal cages and transport containers properly covered at all times.
- Do not handle common items (i.e., door knobs) with gloved hands that have had animal contact.
- Do not house any animals overnight in any research laboratory.
- All animals must be purchased from well-established commercial vendors
- All wild-caught animals must be obtained, handled, and transported in full compliance with applicable institutional, federal, and state regulations. This includes prior review and approval by the Institutional Animal Care and Use Committee (IACUC), as well as adherence to all relevant permitting requirements and wildlife collection laws.

## 3.3 Zoonoses

Zoonoses are diseases that are communicable from lower animals (e.g., rats and mice) to humans under natural conditions.

### 3.3.1 Mice

No known risk of zoonotic diseases is known to be caused by usual animal care and handling exposures to the microbial flora of laboratory-reared mice. Two diseases of concern when working with wild mice are lymphocytic choriomeningitis virus and hantavirus. Laboratory animals at Fitchburg State are known to be free from these diseases and the Animal Health Monitoring program evaluates these agents on a regular basis.

### 3.3.2 Rats

No known risk of zoonotic diseases results from typical exposure to the microbial flora of laboratory-reared rats. Two diseases of concern when working with wild rats are hantavirus and rat-bite fever. Laboratory animals at Fitchburg State are known to be free from hantavirus and the Animal Health Monitoring program evaluates for the virus on a regular basis.

Rat-bite fever is caused by two bacteria, Streptobacillus moniliformis and Spirillum minor. These bacteria are present in the upper respiratory tract and mouths of rats. Rats are asymptomatic, as the bacteria do not cause disease in them. Commercial vendors have virtually eliminated these bacteria from their animals.

## 3.4 Bites and Scratches

Bites and scratches are hazards associated with all animals. A thorough understanding of species-specific behaviors and habits is the best preventative measure against bites and scratches. All personnel handling animals are required to go through species-specific training according to the requirements set forth by the IACUC and the Animal Facility's Policies and Procedures.

Injured and sick animals and certain strains of mice and rats may display unusually high levels of aggression towards one another and towards humans. When working with these animals, even experienced handlers must exercise caution. Diseases such as rat-bite fever are transmitted through bites and scratches. All bite wounds and scratches should receive immediate first aid; an evaluation for more extensive medical care may be needed. Please report all bites and scratches, and seek proper medical care. Also report such incidents to the EH&S Office, as in some cases reports must be filed within 30 days to the NIH.

## 3.5 Work with unmonitored animal populations

In addition to the hazards listed above, there are specific safety and regulatory issues associated with the collection and manipulation of unmonitored animal populations such as wild fish, insects, birds, reptiles or mammals. Since the prevalence of infectious disease in these

populations is not consistently recorded or monitored, field work may expose students or researchers to disease-bearing insects and animals.

Wild animals may carry a variety of diseases that can affect humans and/or other animals. The specific pathogens will depend on the type of animal and the location in which it is being collected. Prior to handling any wild animals or samples from these animals, a risk assessment must be conducted by the PI, in conjunction with the EH&S Office, to determine what hazards may be present and how these hazards can be minimized or eliminated. PIs must describe these risks and preventative measures to their students and employees prior to sending them to areas where these hazards may be present.

Permits from state or federal agencies may be required to collect wild animals or specimens from wild animals. These permits must be obtained by the PI prior to any field collection.

## 3.6 Responsibilities

### 3.6.1 Institutional Animal Care and Use Committee

The IACUC will review all animal care and use protocols to ensure a safe working environment for laboratory personnel. The IACUC will work with animal facility staff to ensure that the animal care and use program complies with current regulations and standards.

### 3.6.2 Principal Investigator

The PI is responsible for ensuring that research is conducted in accordance with university policies and safe laboratory practices. The PI is responsible for completing all appropriate hazardous agent protocols (chemical and biological hazards) and the IACUC protocol prior to the start of the research. If field collection of animals will occur, the PI is responsible for obtaining all required permits and ensuring that they are up-to-date, and for identifying any hazards associated with these animals or the area in which they're collected and addressing these hazards with students and employees. The PI and/or a designee is responsible for obtaining necessary safety equipment and maintaining awareness of safety policies and procedures.

### 3.6.3 Laboratory Staff

Laboratory staff members are responsible for conducting all animal work in a safe and humane manner in accordance with university policies and safe laboratory practices. The staff member is responsible for informing the PI, animal facility management, laboratory supervisor, IACUC, or EH&S Office regarding any potentially hazardous situations or conditions. The staff member is also responsible for reporting any work-related injuries or incidents in accordance with university policies.

# 4.0 Biological Research Involving Plants

Biosafety principles and regulations also apply to work with plants and plant pathogens. Steps must be taken to ensure that plant pathogens, exotic or invasive plants, transgenic plants, etc. are properly contained and are not released into the environment. All plant experiments must be designed to prevent the release of viable seeds, spores, microorganisms, etc. from the research area.

The creation and study of transgenic plants is subject to the NIH Guidelines, and all work with transgenic plants or plant pathogens must be registered with the IBC. In addition, other permits may be required to work with plant pathogens or exotic plants. Prior to field collection of any plants, ensure that any required permits have been obtained and are current.

# 5.0 Principles of Biosafety

The BMBL classifies work with biological agents into four distinct BLs that have increasingly restrictive practices and facilities. Each BL designation is based on the potential health risks for individuals handling the biological materials. The four BLs and the associated risks for individuals and community members are summarized in Table 5.1.

**Table 5.1** Biosafety Level Classifications for Biological Agents

| Biosafety Level | Risk Group | Examples |
|---|---|---|
| BL1 | Individual risk: LOW<br>Community risk: LOW | *Escherichia coli* K12 (laboratory strain)<br>Adeno-associated viruses |
| BL2 | Individual risk: MODERATE<br>Community risk: LOW | *Streptococcus*<br>*Staphylococcus*<br>Human blood and OPIM<br>Adenoviruses<br>Most retroviral and lentiviral vectors |
| BL3 | Individual risk: HIGH<br>Community risk: MODERATE | Mycobacterium tuberculosis<br>West Nile virus |
| BL4 | Individual risk: HIGH<br>Community risk: HIGH | Ebola virus |

Appendix A contains specific information drawn from the BMBL concerning BL1 and BL2.

## 5.1 Biosafety Levels 1 and 2

Laboratory work at Fitchburg State University is conducted using BL1 and BL2 containment and procedures. BL1 is applicable to work involving well-characterized agents not known to consistently cause disease in healthy adult humans; these agents present minimal potential health hazards to laboratory personnel and the surrounding community. BL2 is recommended for work involving agents that present moderate potential health hazards to laboratory personnel and the surrounding community. BL2 includes all of the practices and procedures of BL1 and then builds upon these guidelines. Table 5.2 provides a brief summary of the BL criteria for BL1 and BL2.

**Table 5.2** Summary of Biosafety Level Criteria for BL1 and BL2

| Biosafety Level | Agents | Practices | Safety Equipment (Primary Barriers) | Facilities (Secondary Barriers) |
|---|---|---|---|---|
| BL1 | Not known to consistently cause disease in healthy adults | Standard Microbiological Practices | Personal protective equipment (PPE) includes laboratory coats; gloves; eye protection as needed | Open bench top, sink required |
| BL2 | Associated with human disease. Potential hazards from percutaneous injury, ingestion, and mucous membrane exposure. | BL1 practices, plus:<br>● Limited access<br>● Biohazard signs<br>● PPE<br>● Sharps precautions<br>● Biosafety manual that defines any biological waste decontamination policies | ● Primary barriers include Class I or II biosafety cabinets or other physical containment devices for all manipulations of agents that cause splashes or aerosols of infectious materials.<br>● PPE includes laboratory coats; gloves; safety glasses | BL1, plus:<br>● Method of decontamination (i.e., chemical or autoclave) must be available. |

BL biosafety level

# 6.0 Laboratory Practices

## 6.1 Personal Protective Equipment

PPE is an essential element in laboratory safety and must be provided to all lab members. The selection of appropriate PPE is done through a risk assessment. PPE may include, but is not limited to:

- Gloves
- Laboratory coats
- Safety glasses with side shields
- Prescription safety glasses with side shields
- Goggles
- Face shields/masks
- Sleeve covers
- Shoe covers
- Respiratory protection
- Other site-specific personal protective equipment

At a minimum, anyone working in the lab shall wear gloves and a laboratory coat whenever handling biological agents, cells and tissues. Safety glasses with side shields, goggles, or a face shield shall be worn when manipulating these materials in such a manner that droplets could form and/or materials splashes could occur, or if the agent in use can be transmitted through ocular exposure. The best practice is to wear safety glasses with side shields at all times while

present in the laboratory. Laboratory personnel should wear other PPE (apron, face shield, mask, etc.) as needed or required to prevent potentially infectious materials from reaching their clothes, skin, eyes, mouth, or other mucous membranes. PPE must be removed prior to leaving the work area and placed in designated areas. PPE must be treated as biohazard waste when discarded. If PPE is not disposable, PPE shall be cleaned and disinfected before and after use.

## 6.2 Biological Safety Cabinets

BSCs provide a primary level of containment for working safely with potentially hazardous biological materials. When combined with good microbiological practices, BSCs can protect both laboratory personnel, the material in use, and the environment.

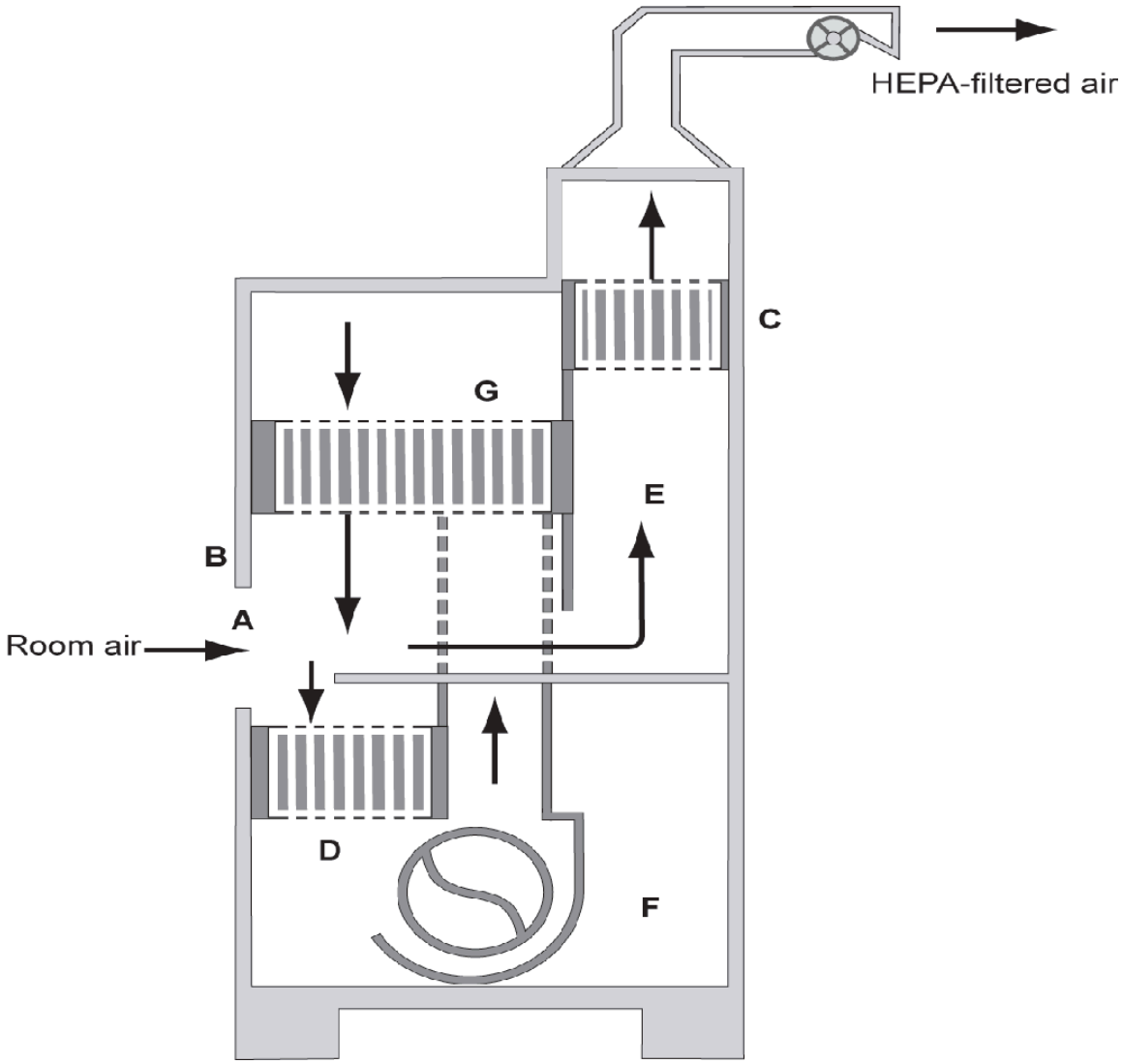
Class II A2 BSCs are the type most commonly found in laboratories. BSCs are designated as Class I, II, or III based on specific airflow patterns within the BSC and on the locations of high efficiency particulate air (HEPA) filters within the unit (Table 6.1). HEPA filters are usually composed of a pleated sheet of borosilicate fiber material that has been treated with a wet-strength water-repellant binder. These filters are 99.97% efficient which means that they remove 99.97% of the particles from the air. Because it is difficult to disperse or aerosolize single viral particles and because of the particle collection mechanisms of HEPA filters, particles larger and smaller than a filter's most penetrating size are collected with greater efficiency. This filtration level will capture a majority of bacteria, spores, and viruses from the filtered air. Figure 6.1 illustrates typical airflow patterns in a BSC.

**Table 6.1** Biological Safety Cabinet Characteristics[1]

| NSF Class and Type | Previous NSF Class and Type | Face Velocity (linear ft/min) | Airflow Pattern | Use of Volatile Toxic Chemicals and Radionuclides |
|---|---|---|---|---|
| A1 | II, A | 75 | 70% of intake air recirculated; 30% exhausted from a common plenum to the room. Plenum contaminated with biological materials under positive pressure. | No |
| **A2** | **II, A/B3** | **100** | **70% of intake air recirculated; 30% exhausted from a common plenum to the room. Plenum contaminated with biological materials under negative pressure or surrounded by negative pressure.** | **Yes (small amounts[2])** |
| B1 | II, B1 | 100 | 40% of intake air recirculated; 60% exhausted from cabinet; exhaust air pulled through dedicated exhaust duct into facility exhaust system. All plenums contaminated with biological materials are negative to the room or surrounded by negative pressure plenums. | Yes (small amounts[2]) |
| B2 | II, B2 | 100 | No intake air recirculated; 100% exhausted from cabinet. Exhaust air pulled through dedicated exhaust duct into facility exhaust system. All ducts and plenums are under negative pressure; all ducts contaminated with biological materials are under negative pressure or surrounded by directly exhausted negative pressure ducts or plenums. | Yes (small amounts[2]) |

NSF National Sanitation Foundation
ft/min feet per minute

[1] Information from The Baker Company.
[2] Under no circumstances should the chemical concentration approach the lower explosion limits of the compound.




(Figure taken from Biosafety in Microbiological and Biomedical Laboratories, Fifth Edition, 2009)

Figure 6.1 The Class II, Type B1 Biological Safety Cabinet (classic design)
(A) front opening; (B) sash; (C) exhaust HEPA filter; (D) supply HEPA filter; (E) negative pressure dedicated exhaust plenum;
(F) blower; (G) additional HEPA filter for supply air.
Note: The cabinet exhaust needs to be hard connected to the building exhaust system.

Implementation of the following procedures will ensure optimal operation of a BSC:

- Front and rear grills must be free of clutter to allow proper air intake.
- Sash should not be raised above the specified level, unless you are moving materials into or out of the cabinet prior to or after working.
- Make all attempts to avoid the use of flames such as a Bunsen burner within a BSC. Open flames disrupt airflow, leading to product and personnel contamination. The heat from open flames will damage the HEPA filter in the BSC and can lead to uncontrolled fire within the laboratory.
- Certification must be performed annually and whenever the BSC is moved or repaired.

BSCs are required to be tested and certified annually by qualified technicians. Additionally, BSCs will be certified when they are installed and whenever they are moved, even to a nearby laboratory, because the HEPA filters may be dislodged from their proper fitting during these moves. Please contact the EH&S Office for additional information about BSC certifications.

## 6.3 Disposal of Biological Waste

### 6.3.1 Biological Waste

Biological waste may be disposed of in one of three ways:

- Designated biological waste box
- Chemical disinfection
- Steam sterilization/autoclave

PIs will work with laboratory technicians to ensure that an appropriate disposal method is used for the biological agents in use in the laboratory.

Potentially infectious solid waste and solid waste containing rDNA must be disposed of in designated biological waste boxes. Each box is labeled with the universal biohazard symbol (Figure 6.2) and is lined with two red plastic bags to reduce the likelihood of leakage.

When a biological waste box is between two-thirds (2/3) and three-quarters (3/4) full, the two bags must be individually sealed. The box must be sealed with two-inch-wide tape. **Do not overfill the boxes.** Boxes that leak any liquid or that weigh more than 55 pounds will not be removed for disposal.

The biological waste vendor removes full, closed boxes. Contact the EH&S Office for more information about biological waste collection.

Figure 6.2 Universal Biohazard Symbol

Liquid biological and rDNA waste must be rendered non-infectious by steam sterilization or chemical disinfection prior to sink disposal. If chemical disinfection is selected, full-strength household chlorine bleach may be added to the waste container, such as an 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.

**Note:** If bleach is not an adequate disinfectant for the biological agent in use, an alternative disinfectant must be selected that is effective against the agent in use. Ensure the proper contact time is met prior to disposal.

Prior to sink disposal, the pH of the disinfected solution must be checked to ensure that it is within the permissible pH range under the Massachusetts Water Resources Authority discharge permit (5.5 – 12.0 standard units). If it is within this range, then sink disposal should be done while the water is running in order to minimize possible plumbing damage due to the corrosive effects of the disinfectants. Autoclaving solutions containing bleach **is forbidden** due to the potential for production of toxic chlorine gas.

### 6.3.2 Biological/Chemical Waste

Disinfect the infectious material with chemical disinfectant and dispose of as chemical waste. Select chemical disinfectants carefully because some disinfectants can react with chemicals. Contact the EH&S Office with any questions.

## 6.4 Sharps Management

Some of the most serious accidents in biological laboratories are those caused by puncture wounds through skin (percutaneous exposures). All objects that can puncture skin are designated as sharps and require special disposal treatment. Examples of sharps include hypodermic needles, glass Pasteur pipettes, razor blades, broken glass, and suture needles. Massachusetts regulations classify any item that may cause punctures or cuts as a sharp, even if it is not contaminated with biological materials. Sharps must be disposed of separately from all other waste streams, and sharps containers cannot be mixed with other biological waste. All filled disposable sharps containers must be placed into a larger reusable sharps container.

Federal regulations concerning sharps primarily focus on work with human bodily fluids. Research work conducted with animals only is not required to utilize engineered sharps; however, it is recommended that engineered devices be used whenever practical. Because the

majority of laboratory biohazard injuries are due to hypodermic needles, special attention has focused on their use and disposal. Some guidelines include:

- Minimize use of needles and syringes.
- Do not bend, shear, or break needles.
- Do not recap needles.
- Do not remove needles from syringes.
- Discard the entire syringe-needle combination in a sharps container.
- Be careful during cleanup; some sharp items may be hidden in the waste materials.
- If you do stick yourself, wash the area and then get medical attention immediately.

In 2001, in response to the Needlestick Safety and Prevention Act, OSHA revised the BBP Standard 29 CFR 1910.1030. The revised standard clarifies the need for employers to select safer needle devices and to involve employees in identifying and choosing these devices. The updated standard also requires employers to maintain a log of injuries from contaminated sharps. Further information can be found at OSHA Bloodborne Pathogen Standard. Laboratories are required to evaluate the use of safety needles whenever possible, and if feasible, select safety needles for use. Please refer to the Exposure Control Plan for details.

### 6.4.1 Sharps Disposal

To protect yourself and others from injury from sharps, place all needles, Pasteur pipettes, syringes, suture needles, scalpels, and razor blades into standard sharps containers. Large volumetric/serological pipettes, or other items that can puncture biohazard red bags should be disposed of in Sharps Boxes, regardless of whether they are contaminated with a biological material. **Please do not dispose of sharps that may contain mercury or other metals in sharps containers. Contact EH&S for proper disposal.** Sharps containers must be red, fluorescent orange or orange-red leak-proof, rigid, puncture-resistant, shatterproof containers that are marked prominently with the universal biohazard warning symbol and the word “Biohazard” in a contrasting color. Place sharps containers in convenient locations near work areas so they will be used. **Do not overfill the sharps containers.** Containers should be sealed when they are three-quarters (3/4) full and should not contain any non-sharps waste. All filled disposable sharps containers need to be placed into a larger reusable sharps container.

Figure 6.3 Sharps Container

### 6.4.2 Broken Glassware Disposal

Place clean broken glassware into the standard recycling boxes for glassware. Contaminated broken test tubes or other glass items may be placed directly into sharps containers.

### 6.4.3 Pasteur Pipettes Disposal

Pasteur pipettes are a special case because Massachusetts law requires that they be considered as sharps waste no matter what their previous use. Discard glass Pasteur pipettes directly into sharps containers; do not use cardboard broken glassware boxes. Plastic pipettes and serological pipettes that could puncture the red waste bags should also be disposed of in sharps containers.

## 6.5 Disinfection and Decontamination

Disinfection and decontamination are terms that are often used interchangeably, but they each have specific definitions. Disinfection is a chemical or physical treatment that destroys most biological agents, except spores. Decontamination refers to a chemical or physical treatment that destroys most biological agents to a low level, but not necessarily zero. A number of disinfectants are commonly used in laboratory settings, particularly to wipe down surfaces to remove infectious agents. Types of disinfectants and their uses are summarized in Table 6.2.

**Table 6.2** Summary of Disinfectants and Their Uses

| Disinfectant | Final Concentration | Effective On | Ineffective On |
|---|---|---|---|
| Sodium Hypochlorite Bleaches: e.g., Clorox™* | 1:10 | Bacteria, some spores, viruses, TB†, HIV | Some spores |
| Chlorine Dioxide: e.g., Clidox®-S* | *1:18:1~ (disinfection) or *1:3:1~ (sterilizing solution) | Bacteria, spores, viruses, TB | |
| Alcohols (ethanol, isopropanol) | 70% | Bacteria, most viruses | Spores, TB |

**Table 6.2** Summary of Disinfectants and Their Uses

| Disinfectant | Final Concentration | Effective On | Ineffective On |
|---|---|---|---|
| Quaternary Ammonium Compounds: e.g., Quatricide®* | Follow manufacturers' directions for dilutions | Bacteria, spores, viruses | |

TB tuberculosis
HIV human immunodeficiency virus

* The use of brand names does not imply a recommendation.
† Use 1/5 dilution.
~ Please check the manufacturers' directions for specific dilutions.

## 6.6 Autoclaving Procedures

Autoclaves work by denaturing biological molecules with superheated steam; dry heat is not nearly as effective. For example, it takes 12 minutes to kill most spores with steam at 121 degrees Celsius (°C), while 6 hours are required with dry heat at the same temperature.

As a result, anything that does not come in contact with steam inside the autoclave may not be adequately decontaminated. The potential for inadequate decontamination becomes a greater concern when sealed biohazard bags are placed in an autoclave. There are two simple solutions: 1) cut open the bag, or 2) place about 200 milliliters of water in the bag before sealing.

Typically, bags (24-inch x 36-inch) of solid plastic waste take from 45 minutes to one hour to reach sterilizing temperatures throughout its contents.

In the research laboratory setting, the target organisms to be killed are usually known and they are usually heat sensitive. In practice, the same autoclave is used for sterilizing laboratory materials and waste. If sterilized materials are subsequently determined to be contaminated, it is an indication that the autoclave is not working properly.

The following tips will help prevent injury and property damage when using the autoclave.

- Do not overfill containers. Leave the top third as empty expansion space.
- Use only vented closures. Bags and other containers must have openings to allow for steam to penetrate.
- Place contaminated materials in autoclave bags. Place bags inside plastic or metal trays when autoclaving.
- Use only containers designed for sterilization. Use plastic or metal trays.

- When placing containers in the autoclave, please leave room for steam to circulate. Do not fill the autoclave too tightly as this will not allow for proper sterilization.

Bottles should be cool to the touch before attempting to remove them. Do not place hot bottles directly on a room temperature or cool surface. Tighten screw caps when the liquid is completely cooled.

### 6.6.1 Autoclave Testing and Validation

Massachusetts regulations 105 CMR 480 requires that if you use an autoclave for the treatment of infectious waste, each load must be logged with the date of the treatment, the quantity of the waste treated, the type of waste, process parameters (e.g., pressure temperature) and the signature of the operator. Examples of log-sheets are located at the Massachusetts Department of Public Health website: Massachusetts Department of Public Health Medical or Biological Waste Record-Keeping Log

Massachusetts regulations 105 CMR 480 requires autoclaves used for decontaminating biological waste must be tested quarterly to ensure that they are operating properly and killing the biological organisms in each autoclave load. The preferred method to check your autoclave is to test it with a commercial spore test system. This system uses ampoules containing a bacterial species called Bacillus stearothermophilus that is tolerant to high temperatures and a color indicator solution. The ampoules are autoclaved under realistic conditions, such as in the middle of a bag of waste, and then incubated for two days at 56 °C. If the spores grow, a color change will occur indicating inadequate sterilization in the autoclave. If there is no growth, no color change occurs and the autoclaving procedure is adequate. It is important to note that autoclave tape indicates only that a critical temperature was reached; it does not indicate the length of time at the desired temperature or whether steam was present.

The following paragraphs are the specific requirements as stated in 105 CMR 480.150:

*(B) The methods which rely on heat shall be evaluated for each load or cycle by using a recording thermometer, thermocouple, parametric monitoring device, thermal indicator strip, or by an equivalent method approved in writing by the Department.*

*(C) For any wastes that are rendered noninfectious by chemical disinfection, the chemical used shall be of demonstrated efficacy, as determined by the Department, against the challenge testing target or indicator organism and registered with:*

> *(1) The U.S. Environmental Protection Agency, Office of Pesticide Programs pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and*
>
> *(2) The Massachusetts Department of Agricultural Resources, Pesticide Bureau.*

*(D) All parametric monitoring equipment utilized in conjunction with any approved disinfection methods, including autoclaves, shall be calibrated at a minimum annually, by an individual who has received training from the manufacturer in the operations and maintenance of the equipment.*

*(E) Quarterly qualitative (growth/no growth) biological challenge testing shall be conducted during standard operations for all approved disinfection methods including autoclaves, but not incineration. Specifically:*

*(1) Testing shall consist of spore strips or a retrievable alternative medium approved by the Department, which contain a 1.0 x 104 minimum challenge population of a bacterial indicator organism that is most resistant to any aspect of the treatment technology as outlined in the most recent medical waste treatment technology guidelines established by The State and Territorial Association on Alternative Treatment Technologies (STAATT) or its successor The International Society of Analytical Analysis of Treatment Technologies (IStAATT).*

*(2) Testing methodologies including the number, type and locations shall be in accordance with manufacturer's guidelines and procedures approved by the Department;*

*(3) Analytical testing results (growth/no growth) should demonstrate a minimum bacterial spore reduction of 4 log 10;*

*(4) When a 4 log 10 bacterial spore reduction has not been demonstrated (results indicate bacterial growth), an operations and mechanical systems assessment shall be conducted by a qualified individual who has received training from the manufacturer in the operations and maintenance of the equipment. Appropriate corrective actions shall be implemented, when warranted, including but not limited to mechanical adjustments and when applicable, recalibration of all parametric monitoring devices followed by re-treatment of the waste and additional challenge testing to confirm the effectiveness of any implemented corrective action;*

*(5) In accordance with 105 CMR 480.500(B)(1)(f), the analytical test results shall be documented on the required record-keeping log form for medical or biological waste treated on site in conjunction with the date and all applicable corresponding process parameter results.*

*(6) When implemented, corrective actions pursuant to 105 CMR 480.150(E)(4) shall be documented in detail, including the date, name of the individual implementing the corrective actions and a description of the work performed, on the back of the applicable record-keeping log form for medical or biological waste treated on-site.*

*(7) All analytical test results shall be retained in the required record-keeping log for a period of three years.*

## 6.7 Spill Management

The following procedures are recommended for the management of small spills of blood, bodily fluids, or other potentially infectious materials. If a large volume of biological material is spilled, or if equipment malfunctions while processing biological materials, call the EH&S Office for immediate consultation on implementing appropriate measures to contain the spill.

- Wear gloves and proper protective clothing. Heavyweight, puncture-resistant, utility gloves are recommended to be worn over disposable latex or nitrile gloves. If the spill contains broken glass or other sharps, these should be removed and discarded without contact with the hands. Rigid sheets of cardboard used as a "pusher" and "receiver" may be used to handle such objects and should be discarded into an appropriate biohazard container. If the spill is large and/or there is a potential of contaminating the worker's shoes, water-impermeable shoe covers should be worn.

- Absorb the spill. Because most disinfectants are less active, or even ineffective, in the presence of high concentrations of protein that are found in blood and serum, the bulk of the spilled liquid should be absorbed prior to disinfection. Absorb the spilled material with disposable absorbent material (e.g., paper towels, gauze pads, or tissue paper wipes). If the spill is large, granular absorbent material may be used to absorb the liquid. Absorbent granular material, such as an Isolyzer, containing a chemical that releases chlorine upon wetting is commercially available. The efficacy of such material for disinfection is not known and, therefore, should not be relied upon to disinfect a spill. After absorption of the liquid, all contaminated materials should be discarded as biological waste.

- Clean the spill site of all visible spilled material using an aqueous detergent solution. Any household detergent may be used. The intent is to dilute the spilled material, lyse red blood cells, and further remove proteins from the contaminated area. Absorb the bulk of liquid prior to disinfection to prevent dilution of the disinfectant. The use of a disinfectant detergent is not necessary.

- Disinfect the spill site using an appropriate intermediate to high-level hospital disinfectant, such as a dilution of household bleach (see Table 3.1). Flood the spill site or wipe down the spill site with disposable towels soaked in disinfectant to make the site "glistening wet."

- Note: If bleach is not an effective disinfectant against the material, then you are required to use an EPA-approved disinfectant. Ensure the proper contact time prior to disposal.

- Rinse the spill site with water to remove any noxious chemicals or odors. Dry the spill site to prevent slipping.

- Dispose all disposable materials used to decontaminate the spill into a biological waste container. Handle the material in the same manner as other infectious waste.

### 6.7.1 Management of Small Spills

The following procedures are recommended for the management of small spills of blood, body fluids, or other potentially infectious materials in the laboratory or in a biosafety cabinet.

- Put on protective clothing (laboratory coat, gloves, face and eye protection, and shoe covers) and assemble clean-up materials (disinfectant, autoclavable container or bag, forceps, and paper towels).
- If the spill has occurred in a biosafety cabinet, keep the cabinet turned on.
- Cover the spill with absorbent materials such as paper towels. Carefully pour or spray the affected area with a disinfectant, such as a fresh 10% bleach solution.
- Pick up any broken glass with forceps and place in an approved sharps container.
- Let disinfectant sit for 30 minutes.
- Soak up the disinfectant and spill with paper towels.
- Discard all clean-up materials in a biological waste box. Autoclave any reusable items, such as laboratory coats.
- Wash hands and exposed skin areas thoroughly with soap and water.

### 6.7.2 Management of Large Spills

A large volume spill is defined as any release of biological material that cannot be safely managed by routine laboratory personnel using standard spill kits and procedures, or that presents an increased risk of exposure due to volume, aerosolization, or agent hazard level.

A spill shall be considered large if any of the following conditions apply:

- Volume exceeds 1000 mL of liquid biological material
- The spill results in actual or potential aerosol generation (e.g., dropped containers, centrifuge incidents)
- The spill occurs outside of primary containment (e.g., outside a biosafety cabinet)
- The material involves Risk Group 2 or higher agents or potentially infectious human materials

- The spill impacts a large surface area or porous materials (e.g., carpet, upholstery, paper)
- The spill occurs in a public or common area (e.g., hallway, elevator, shared space)
- The spill requires evacuation, restricted access, or specialized PPE beyond standard lab PPE
- Laboratory personnel are untrained, uncomfortable, or unable to safely clean the spill

Contact the EHS manager and follow approved spill procedures for a large volume biological spill in the laboratory area, in a BSC, or if equipment malfunctions while processing biological materials.

# 7.0 Immunizations, Medical Restrictions, and Reporting of Injuries/Illnesses

Work with certain biological materials may require personnel working with them to receive immunizations and/or have medical surveillance.

Personnel working with certain biological materials or the potential for exposure are recommended to receive immunizations for protection. Certain conditions may also require additional protective equipment.

## 7.1 Hepatitis B Vaccine

Under the OSHA BBP Standard, hepatitis B vaccine is recommended for all employees working with human blood, body fluids, or tissues. It is provided free of charge to employees with the potential for occupational exposure to human materials. Those employees declining vaccination will be asked to sign the OSHA waiver indicating that hepatitis B vaccine has been offered and refused. Any questions about the vaccination program should be directed to the EH&S Office.

## 7.2 Pregnancy

Several infectious agents are known to affect embryonic development. Women of childbearing age should be aware of the risks associated with studies using these agents. Men or women living with women of childbearing age should also know of the risks and should be especially careful not to bring infectious agents home on clothing or other contaminated items.

For an infectious agent to affect embryonic development, the infectious agent must be transmitted to the child. In some cases, transmission is via the blood through the placenta. The following is a partial list of infectious organisms thought to have some adverse effects on human embryo and fetal development:

- Rubella virus
- Herpes simplex virus
- Varicella virus
- HIV
- Listeria monocytogenes
- Toxoplasma gondii

This list is not all inclusive. Please contact the EH&S Office for further information.

Infections caused by the following biological agents can cause birth defects in animals, but have not yet been shown to be teratogenic in humans:

- Influenza virus
- Mumps virus
- Parainfluenza type 2

This list is not all-inclusive. Prior to pregnancy, it would be best to discuss with your medical provider any infectious agents or chemicals you may have contact with in your work area. You may also contact the EH&S Office for further information.

- Women who wish to become pregnant, or who become pregnant while working in laboratories are encouraged to consult with their personal healthcare provider regarding additional precautions recommended while working with infectious materials. The EH&S Office can be contacted for precautions when working with hazardous chemical or biological materials during pregnancy.

## 7.3 Other Medical Restrictions

Examples of some conditions that might warrant special precautions when working in a laboratory setting are immunosuppressive conditions, allergies, or drug therapy that suppresses the immune system.  Employees are encouraged to discuss any medical concerns or contraindications to working in a laboratory with their medical provider.

## 7.4 Reporting of Injuries/Illnesses

All workplace injuries and illnesses must be reported to the EH&S Office and injured or ill employees and students should report to Healthcare Alliance Hospital immediately. This will ensure that the injured or ill person is provided with the appropriate medical care and ensure that any necessary reports are filed with the IBC, as well as the City of Fitchburg and the NIH, in a timely fashion.

# 8.0 Shipping and Receiving Procedures for Biological Specimens

Import, export, and interstate transport of biological materials are subject to requirements and laws from several federal agencies. The U.S. Public Health Service (PHS), U.S. Department of Transportation (DOT), U.S. Department of Agriculture (USDA), and U.S. Postal Service, regulate transport of hazardous materials by rail, air, vessel, and public highway. The guidelines and regulations of the International Air Transport Association (IATA) and International Civil Aviation Organization also apply when shipping substances by air. Import/Export Permit requirements are regulated by the Bureau of Customs; the Department of Commerce, CDC, and USDA require permits for certain agents.

The PHS defines etiological agents as viable microorganisms that cause disease in humans; infectious substances are those substances that contain etiologic agents. This terminology is used by the DOT and IATA. Diagnostic specimens are anything that the shipper reasonably believes to contain an infectious substance. Diagnostic and infectious specimens are regulated by the USDA, U.S. Food and Drug Administration (FDA), PHS, and IATA. Biological product means a product prepared in accordance with regulations that govern the manufacture of vaccines, reagents, or all viruses, serums, toxins, etc. intended for use in the diagnosis, treatment, or prevention of diseases in humans or animals. Biological products are regulated by the USDA, FDA, PHS, DOT, and IATA.

Laboratory staff can receive awareness level training from the EH&S Office for the shipment of hazardous materials. Individuals packaging specimens/hazardous materials for shipment must also receive function-specific training. The training is required every two years or when there is change in the regulations. Any biohazardous materials that are being shipped must only be done so by someone who has completed the DOT/IATA training. For assistance regarding training and other requirements for the legal shipping of hazardous materials, please contact the EH&S Office.

The required type of packaging, labeling, and documentation depend on the biohazardous material being shipped, how it is being shipped, and where it is being shipped. Specific packaging requirements for various biological agents should be reviewed by the principal investigator to ensure compliance with all regulatory requirements. Please be aware that anyone who ships restricted items improperly and without authorization may be subjected to fines and/or incarceration.

For more information of DOT Research and Special Programs Administration Office of Hazardous Materials Safety regulations (49 CFR 100-185) please refer to U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration; for more information about shipping packaging materials, go to the Inmark Saf-T-Pak® website Inmark Life Sciences .

# 9.0 General Laboratory Safety and Biological Safety Inspections

All laboratories are inspected on a routine basis, with BL2 laboratories being inspected at least annually. Laboratory inspections are typically scheduled beforehand to ensure the visit to the laboratory does not create a disruption; however, the EH&S Office reserves the right to perform unannounced inspections. The surveyor will review any non-compliant conditions observed, and make recommendations for improvement. An unannounced site visit may occur anytime to make certain that all conditions are corrected.

# Appendix A - Laboratory Biosafety Level Criteria

## Laboratory Biosafety Level Criteria

The following is excerpted from the *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) Sixth Edition*. Biosafety Levels 1 and 2 will be highlighted, since no work requiring Biosafety Level 3 or 4 containment will be performed at Fitchburg State University.

**Section IV—Laboratory Biosafety Level Criteria**

The essential elements of the Biosafety Levels 1–4 are standard microbiological practices, special practices, safety equipment, and laboratory facilities as discussed in Section III; these elements apply to activities involving infectious microorganisms, toxins, and laboratory animals. The four levels are organized in ascending order by the degree of protection provided to personnel, the environment, and the community. Special practices address any unique risks associated with the handling of agents requiring increasing levels of containment. Appropriate safety equipment and laboratory facilities enhance worker and environmental protection.

The features of each Biosafety Level (BSL) are summarized in Table 1 of this section. Adjustments to the containment levels described are based on an assessment of all risks, as detailed in Section II. Each facility ensures that worker safety and health concerns are coordinated with the Institutional Biosafety Committee (IBC), or equivalent resource, and/or other applicable institutional safety committee(s) and that all hazards are addressed as part of the protocol review process. Additional occupational health information is provided in Section VII.

**Biosafety Level 1**

Biosafety Level 1 (BSL-1) is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans and that present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open benchtops using standard microbiological practices. Special containment equipment or facility design is not generally required but may be used as determined by appropriate risk assessment. Laboratory personnel receive specific training in the procedures conducted in the laboratory and are supervised by a scientist with training in microbiology or a related science. The following standard practices, safety equipment, and facility specifications are recommended for BSL-1.

## A. Standard Microbiological Practices

1. The laboratory supervisor enforces the institutional policies that control safety in and access to the laboratory.

2. The laboratory supervisor ensures that laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained. Personnel receive annual updates and additional training when equipment, procedures, or policies change. All persons entering the facility are advised of the potential hazards, are instructed on the appropriate safeguards, and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.

3. Personal health status may affect an individual's susceptibility to infection and ability to receive available immunizations or prophylactic interventions. Therefore, all personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance. See Section VII.

4. A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated, as necessary.

a. The safety manual contains sufficient information to describe the biosafety and containment procedures for the organisms and biological materials in use, appropriate agent-specific decontamination methods, and the work performed.

b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.

5. A sign is posted at the entrance to the laboratory when infectious materials are present. Posted information includes: the laboratory's Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE requirements, general occupational health requirements (e.g., immunizations, respiratory protection),

and required procedures for entering and exiting the laboratory. Agent information is posted in accordance with the institutional policy.

6. Long hair is restrained so that it cannot contact hands, specimens, containers, or equipment.

7. Gloves are worn to protect hands from exposure to hazardous materials.
    a. Glove selection is based on an appropriate risk assessment.
    b. Gloves are not worn outside the laboratory.
    c. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
    d. Do not wash or reuse disposable gloves, and dispose of used gloves with other contaminated laboratory waste.
8. Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.

9. Persons wash their hands after working with potentially hazardous materials and before leaving the laboratory.

10. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in laboratory areas. Food is stored outside the laboratory area.

11. Mouth pipetting is prohibited. Mechanical pipetting devices are used.

12. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements. Whenever practical, laboratory supervisors adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions are always taken with sharp items. These include:

    a. Plasticware is substituted for glassware whenever possible.

    b. Use of needles and syringes or other sharp instruments is limited in the laboratory and is restricted to situations where there is no alternative (e.g., parenteral injection, blood collection, or aspiration of fluids from laboratory animals or diaphragm bottles). Active or passive needle-based safety devices are to be used whenever possible.

        I. Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick.

II. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.

III. If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle (e.g., loading syringes in one room and injecting animals in another), a hands-free device or comparable safety procedure must be used (e.g., a needle remover on a sharps container, the use of forceps to hold the cap when recapping a needle).

IV. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible.

c. Non-disposable sharps are placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

d. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.

13. Perform all procedures to minimize the creation of splashes and/or aerosols.

14. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly trained and equipped to work with infectious material. A spill procedure is developed and posted within the laboratory.

15. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method, consistent with applicable institutional, local, and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport: a. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label. b. Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations.

16. An effective integrated pest management program is implemented. See Appendix G.

17. Animals and plants not associated with the work being performed are not permitted in the laboratory.

**B. Special Practices**

None required.

**C. Safety Equipment (Primary Barriers and Personal Protective Equipment)**

1. Special containment devices or equipment, such as biosafety cabinets (BSCs), are not generally required.

2. Protective laboratory coats, gowns, or uniforms are worn to prevent contamination of personal clothing.

3. Protective eyewear is worn by personnel when conducting procedures that have the potential to create splashes and sprays of microorganisms or other hazardous materials. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use.

4. In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens.

**D. Laboratory Facilities (Secondary Barriers)**

1. Laboratories have doors for access control.

2. Laboratories have a sink for handwashing.

3. An eyewash station is readily available in the laboratory.

4. The laboratory is designed so that it can be easily cleaned.
    a. Carpets and rugs in laboratories are not appropriate.
    b. Spaces between benches, cabinets, and equipment are accessible for cleaning.

5. Laboratory furniture can support anticipated loads and uses.
    a. Benchtops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    b. Chairs used in laboratory work are covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

6. Laboratory windows that open to the exterior are fitted with screens.

7. Illumination is adequate for all activities and avoids reflections and glare that could impede vision.

**Biosafety Level 2**

Biosafety Level 2 (BSL-2) builds upon BSL-1. BSL-2 is suitable for work with agents associated with human disease and pose moderate hazards to personnel and the environment. BSL-2 differs from BSL-1 primarily because: 1) laboratory personnel receive specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

The following standard and special practices, safety equipment, and facility specifications are recommended for BSL-2.

**A. Standard Microbiological Practices**

1. The laboratory supervisor enforces the institutional policies that control safety in and access to the laboratory.

2. The laboratory supervisor ensures that laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained. Personnel receive annual updates and additional training when equipment, procedures, or policies change. All persons entering the facility are advised of the potential hazards, are instructed on the appropriate safeguards, and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.

3. Personal health status may affect an individual's susceptibility to infection and ability to receive available immunizations or prophylactic interventions. Therefore, all personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance. See Section VII.

4. A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated as necessary.

a. The safety manual contains sufficient information to describe the biosafety and containment procedures for the organisms and biological materials in use, appropriate agent-specific decontamination methods, and the work performed.

b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.

5. A sign incorporating the universal biohazard symbol is posted at the entrance to the laboratory when infectious materials are present. Posted information includes: the laboratory's Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE requirements, general occupational health requirements (e.g., immunizations, respiratory protection), and required procedures for entering and exiting the laboratory. Agent information is posted in accordance with the institutional policy.

6. Long hair is restrained so that it cannot contact hands, specimens, containers, or equipment.

7. Gloves are worn to protect hands from exposure to hazardous materials.

a. Glove selection is based on an appropriate risk assessment.
b. Gloves are not worn outside the laboratory.
c. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
d. Do not wash or reuse disposable gloves, and dispose of used gloves with other contaminated laboratory waste.

8. Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.

9. Persons wash their hands after working with potentially hazardous materials and before leaving the laboratory.

10. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in laboratory areas. Food is stored outside the laboratory area.

11. Mouth pipetting is prohibited. Mechanical pipetting devices are used.

12. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements. Whenever practical, laboratory supervisors adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions are always taken with sharp items. These include:

a. Plasticware is substituted for glassware whenever possible.

b. Use of needles and syringes or other sharp instruments is limited in the laboratory and is restricted to situations where there is no alternative (e.g., parenteral injection, blood collection, or aspiration of fluids from laboratory animals or diaphragm bottles). Active or passive needle-based safety devices are to be used whenever possible.

i. Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick.

ii. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.

iii. If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle (e.g., loading syringes in one room and injecting animals in another), a hands-free device or comparable safety procedure must be used (e.g., a needle remover on a sharps container, the use of forceps to hold the cap when recapping a needle).

iv. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible.

c. Non-disposable sharps are placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

d. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.

13. Perform all procedures to minimize the creation of splashes and/or aerosols.

14. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly

trained and equipped to work with infectious material. A spill procedure is developed and posted within the laboratory.

15. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method, consistent with applicable institutional, local, and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport:

a. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label.

b. Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations.

16. An effective integrated pest management program is implemented. See Appendix G.

17. Animals and plants not associated with the work being performed are not permitted in the laboratory.

**B. Special Practices**

1. Access to the laboratory is controlled when work is being conducted.

2. The laboratory supervisor is responsible for ensuring that laboratory personnel demonstrate proficiency in standard microbiological practices and techniques for working with agents requiring BSL-2 containment.

3. Laboratory personnel are provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.

4. Properly maintained BSCs or other physical containment devices are used, when possible, whenever:

a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.

b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotors or centrifuge safety cups with loading and unloading of the rotors and centrifuge safety cups in the BSC or another containment device.

c. If it is not possible to perform a procedure within a BSC or other physical containment device, a combination of appropriate personal protective equipment and administrative controls are used, based on a risk assessment.

5. Laboratory equipment is decontaminated routinely; after spills, splashes, or other potential contamination; and before repair, maintenance, or removal from the laboratory.

6. A method for decontaminating all laboratory waste is available (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

7. Incidents that may result in exposure to infectious materials are immediately evaluated per institutional policies. All such incidents are reported to the laboratory supervisor and any other personnel designated by the institution. Appropriate records are maintained.

C. Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Protective laboratory coats, gowns, or uniforms designated for laboratory use are worn while working with hazardous materials and removed before leaving for non-laboratory areas (e.g., cafeteria, library, and administrative offices). Protective clothing is disposed of appropriately or deposited for laundering by the institution. Laboratory clothing is not taken home.

2. Eye protection and face protection (e.g., safety glasses, goggles, mask, face shield or other splatter guard) are used for manipulations or activities that may result in splashes or sprays of infectious or other hazardous materials. Eye protection and face protection are disposed of with other contaminated laboratory waste or decontaminated after use.

3. The risk assessment considers whether respiratory protection is needed for the work with hazardous materials. If needed, relevant staff are enrolled in a properly constituted respiratory protection program.

4. In circumstances where research animals are present in the laboratory, the risk assessment considers appropriate eye, face, and respiratory protection, as well as potential animal allergens.

D. Laboratory Facilities (Secondary Barriers)

1. Laboratory doors are self-closing and have locks in accordance with the institutional policies.

2. Laboratories have a sink for handwashing. It should be located near the exit door.

3. An eyewash station is readily available in the laboratory.

4. The laboratory is designed so that it can be easily cleaned.

a. Carpets and rugs in laboratories are not appropriate.

b. Spaces between benches, cabinets, and equipment are accessible for cleaning.

5. Laboratory furniture can support anticipated loads and uses.

a. Benchtops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.

b. Chairs used in laboratory work are covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

6. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they are fitted with screens.

7. Illumination is adequate for all activities and avoids reflections and glare that could impede vision.

8. Vacuum lines in use are protected with liquid disinfectant traps and in-line HEPA filters or their equivalent. See Appendix A, Figure 11. Filters are replaced, as needed, or are on a replacement schedule determined by a risk assessment.

9. There are no specific requirements for ventilation systems. However, the planning of new facilities considers mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.

10. BSCs and other primary containment barrier systems are installed and operated in a manner to ensure their effectiveness. See Appendix A.

a. BSCs are installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs are located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.

b. BSCs can be connected to the laboratory exhaust system by either a canopy connection (Class IIA only) or directly exhausted to the outside through a hard connection (Class IIB, IIC, or III). Class IIA or IIC BSC exhaust can be safely recirculated back into the laboratory environment if no volatile toxic chemicals are used in the cabinet.

c. BSCs are certified at least annually to ensure correct performance, or as specified in Appendix A, Part 7.

# Appendix B - Incident Report Form

# Incident Report Form

**Date:** _____ **Time of Incident:** _____
**Location of Incident:** _____
**Name:** _____ **Phone#:** _____
**Person Initiating Call to EH&S:** _____ **Phone #:** _____
**Brief Characterization of Incident:**

_____

**Describe the Incident:**

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_____
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_____
_____

**Response Summary:**

_____
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**Recommended Corrective/Preventive Action:**

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_____

**Comments:**

_____
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_____

**EH&S Responder:** _____

**Date/Time of Resolution:** _____

□ ***Check here if this requires further action by P.I.***

**Signature of Person Filling Out Report:** _____

# Appendix C - Annual Biosafety Manual Review Certification Form

# Institutional Biosafety Committee (IBC)

Annual Biosafety Manual Review Certification

**Institution:** _____
**Department / Program:** _____
**Biosafety Level(s):** ☐ BSL-1 ☐ BSL-2 ☐ Other: _____
**Manual Title:** _____
**Manual Version / Date:** _____

Review Requirement and Regulatory Basis

This certification documents the **annual review** of the institutional Biosafety Manual in accordance with:

- **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**, which require institutions to ensure that biosafety policies and procedures are **current and appropriate** for the research conducted; and
- **CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* (BMBL)**, which recommends that biosafety manuals be **reviewed periodically and updated as necessary** to reflect current practices, hazards, and regulatory requirements.

The Institutional Biosafety Committee (IBC) conducts a **formal review at least annually**, and additionally whenever significant changes occur (e.g., new agents, procedures, facilities, equipment, incidents, or regulatory updates).

Scope of Review

The IBC has reviewed the Biosafety Manual for:

- ☐ Applicability to current teaching and research activities
- ☐ Alignment with assigned biosafety levels and risk assessments
- ☐ Compliance with NIH Guidelines and BMBL recommendations
- ☐ Roles and responsibilities (PI, lab personnel, EHS, IBC)
- ☐ Training, exposure response, medical surveillance, and incident reporting procedures

Review Outcome (check one)

☐ **Approved – No Changes Required**
☐ **Approved with Revisions** (see summary below)
☐ **Deferred – Revisions Required Prior to Approval**

**Summary of Revisions (if applicable):**

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Certification

By signing below, the Institutional Biosafety Committee certifies that it has completed the required annual review of the Biosafety Manual and that the manual is **current, accurate, and appropriate** for the biological research and instructional activities conducted at this institution.

**Date of IBC Review: _____**
**Next Scheduled Annual Review (no later than): _____**

IBC Approval

**IBC Chair (Name): _____**
**Signature: _____**
**Date: _____**

**Biosafety Officer / EHS Representative (Name): _____**
**Signature: _____**
**Date: _____**

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*This certification shall be retained with IBC records and made available upon request during inspections, audits, or regulatory reviews.*

| Year of Review | Summary of Changes | Effective Date |
|---|---|---|
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