University of Maryland, Baltimore County Institutional Biosafety Manual



Environmental Safety and Health University of Maryland, Baltimore County 1000 Hilltop Circle Baltimore, MD 21250 (410) 455-2918

> November 2020 Revised January 2024

Directory of Service and Emergency Providers

Emergency Contact	24/7
UMBC Police	(410) 455-5555
Emergency Services	911, Also notify UMBC Police

Services Contact	Mon-Fri 7am-4pm	After Hours
UMBC Environmental	(410) 455-2918	(410) 455-5555
Safety and Health	<u>esh@umbc.edu</u>	
(ESH)		
Retriever Integrated	(410) 455-2542	(410) 455-3230
Health (RIH)	<u>rih@umbc.edu</u>	
Office of Research	(410) 455-2737	<u>compliance@umbc.edu</u>
Protections and	<u>compliance@umbc.edu</u>	
Compliance (ORPC)		
University of Maryland,	(410) 706-7055	(410) 706-7055
Baltimore EHS		
UMBC Facilities	(410) 455-2550	(410) 455-2550
Management Work		
Control		
Contracted Janitorial	(410) 455-2701	(410) 455-2550
Services		
Campus Information	(410) 455-1000	(410) 455-1000
Center (CIC)		

*Off campus locations: Use 911 in the event of an emergency

Incident Reporting

- 1. Follow the appropriate incident response as outlined in your laboratory specific Standard Operating Procedures (SOPs) Once the incident is stable, **immediately notify**:
 - a. The Principal Investigator, Laboratory Manager or Supervisor, or Instructor.
 - b. The Building/Facility Manager.
 - c. The Office of Environmental Safety and Health (5-2918 or <u>esh@umbc.edu</u>).
- 2. The reporting individual should complete a <u>Laboratory</u> <u>Incident Report Form</u> found on safety.edu and submit it to the Office of Environmental Safety and Health at <u>esh@umbc.edu</u>
- 3. The Office of Environmental Safety and Health will conduct a follow up investigation and contact all required parties.
- 4. It is important to note that if an incident involves exposure to any recombinant or biohazardous material, immediate reporting is required by the NIH.
- 5. If an injury has occurred the employee should complete the <u>Employee's Report of Work-Related Injury</u> form and the employee's supervisor should complete the <u>Supervisor's</u> <u>Report of Work-Related Injury</u> form found on <u>https://safety.umbc.edu/forms/</u>

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LIST OF ABBREVIATIONS AND ACRONYMS

- **BBP** Bloodborne Pathogens
- **BL** Biosafety Level
- BMBL Biosafety in Microbiological and Biomedical Laboratories (most current edition)
- **BSC Biological Safety Cabinet**
- **BSO Biosafety Officer**
- CBP U. S. Customs and Border Protection
- CDC Centers for Disease Control and Prevention
- CFR Code of Federal Regulations
- CITI Collaborative Institutional Training Initiative
- COMAR Code of Maryland Regulations
- DNA Deoxyribonucleic Acid
- DOT U. S. Department of Transportation
- DURC Dual Use Research of Concern
- EHFR Elastomeric Half Face Respirators
- EPA U.S. Environmental Protection Agency
- ESH Environmental Safety and Health
- FDA U.S. Food and Drug Administration
- GMMO Genetically Modified Microorganism
- HEPA High Efficiency Particulate Air Filter

IACUC - Institutional Animal Care and Use Committee

- IATA International Air Transport Association
- ICAO International Civil Aviation Organization
- IBC Institutional Biosafety Committee
- IPP Centers for Disease Control and Prevention Import Permit Program
- LAI Laboratory Associated Infection
- LFH Laminar Flow Hood
- MDH Maryland Department of Health
- NIH National Institutes of Health

NIH Guidelines - The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

- NRC U.S. Nuclear Regulatory Commission
- **OPIM Other Potentially Infectious Materials**
- **ORPC Office of Research Protections and Compliance**
- OSHA U.S. Occupational Safety and Health Administration
- PAPR Powered Air Purifying Respirators
- PHS U. S. Public Health Service
- PI Principal Investigator
- PPE Personal Protective Equipment
- rDNA-Recombinant DNA
- UMB EHS University of Maryland, Baltimore Environmental Health and Safety
- UMBC University of Maryland, Baltimore County
- UMBC BSM University of Maryland, Baltimore County Biosafety Manual

USDA APHIS - U.S. Department of Agriculture Animal and Plant Health Inspection Service

USPS - U.S Postal Service

Log of Revisions to the UMBC Biosafety Manual

Revision	Date	Revisions Made	By Whom
Number		(Location and Description)	
Example	9/19/2020	Section 3.6: added figure 3.6, Section 3.9: added scissors and lancets to definition of sharps.	UMBC ESH
1	6/6/2022	Updated Select agent list	UMBC IBC
2	1/2023	Directory: updated contact information, Section 7.6: updated validation requirements, Section 8.2 & 9.1: clarified training requirements, Section 9.6: updated document reviewal list, Section 11.1: clarified biological waste procedures, Added/Updated Appendix F, I, K, R Corrected grammatical errors, links, and formatting throughout.	UMBC IBC
3	1/2024	Addition of Plant Biosafety Level Criteria, Corrected grammatical errors, links, and formatting throughout.	UMBC ESH

1.1 Purpose

This biosafety manual was developed by the University of Maryland, Baltimore County Office of Environmental Safety & Health (UMBC ESH) in order to fulfill the commitment to maintaining a safe environment in all areas where biological materials are utilized. The University of Maryland, Baltimore County Biosafety Manual (UMBC BSM) is intended to provide assistance in the assessment, containment, and control of all biohazardous materials. Furthermore, the primary objectives of the UMBC BSM are to:

- Facilitate research advancement
- Comply with federal, state, and local regulations
- Protect any person on the UMBC campus, the surrounding community, and the environment.

The UMBC BSM outlines university-wide practices, policies, and applicable regulatory requirements all of which contribute to the safe containment of biohazardous materials. Proper implementation of the guidelines set forth in this manual is ultimately the responsibility of the Principal Investigator (PI), Class Instructor, and Laboratory Manager or Supervisor. Success and proper containment depends on every individual in the laboratory strictly adhering to local, state and federal regulations and the guidance outlined in this manual and by the laboratory Standard Operating Procedures.

The UMBC BSM may be adopted directly by anyone intending to work in close proximity to biohazardous materials. Furthermore, sections of this manual may be referenced when creating a laboratory specific biosafety manual, a requirement that is mandatory for all biological laboratories. All laboratory specific biosafety manuals must, at a minimum, abide by the practices, policies, and regulatory guidelines summarized in this manual. UMBC ESH reviewal of laboratory specific biosafety manuals is <u>strongly recommended</u>.

It is essential that all personnel working with biological materials have access to and be familiar with the UMBC BSM as well as seek additional advice and training when needed. For additional information or clarification of contents in this manual you may contact UMBC ESH using contact info found under the Directory of Service and Emergency Providers located after the cover page of this manual.

1.2 University Policy

In accordance with the UMBC policy on Environmental Safety and Health Management and Enforcement (#VI-13.00.01) UMBC ESH intends to provide guidance regarding compliance with federal, state, and local regulations for environmental protection (air, water, soil), occupational safety, public health, biological safety, fire safety, hazardous materials management, and UMBC risk management requirements. UMBC expects all faculty, staff, students, and those who use UMBC property and/or resources to be vigilant in complying with all applicable environmental, safety, and health laws. The success of UMBC's environmental safety and health management activities directly depend upon the active involvement of individuals through participation in training, adherence to established safety and environmental procedures, reporting hazards, and potential violations of regulations, and recommending and implementing improvements. The UMBC BSM aims to work in conjunction with UMBC Policy #VI-13.00.01 in order to fulfill UMBCs commitment to providing a safe and healthy environment for all.

1.3 Scope

The requirements, procedures, and recommendations set forth in the UMBC BSM apply to all university facilities in which exposure to known or potentially biohazardous agents may occur. All UMBC staff, faculty, students, contractors, and visitors who are in laboratory space maintained by UMBC must comply with this manual.

1.4 Roles and Responsibilities

UMBC's Biological Safety Program was developed based upon the university's commitment to maintain a safe environment in all areas where biological materials are used. The UMBC BSM has been developed to protect the interests and resources of UMBC, staff, faculty, students, contractors, visitors, the general public, and the environment from unnecessary exposure to biohazardous materials. For the requirements, procedures, and recommendations presented in the UMBC BSM to be effective, all individuals must be vigilant and work cooperatively with the UMBC Office of Environmental Safety and Health and other associated departments.

1.4.1 Biosafety Officer

The Biosafety Officer (BSO) develops and participates in programs to promote safe microbiological practices, procedures, and the proper use of containment

equipment and facilities. The primary responsibilities of a biosafety officer (BSO) include but are not limited to:

- Assist with establishing and maintaining a safe working environment in all laboratories
- Serve as a member on the Institutional Biosafety Committee
- Investigate safety violations, policy violations, and research related accidents or illnesses and reports findings to IBC
- Conduct periodic laboratory inspections to ensure compliance
- Assist Principal Investigators with risk assessments
- Provide required and relevant training to personnel
- Provide technical advice to Principal Investigators on laboratory containment, safety procedures, best practices, personal protective equipment, and engineering controls.
- Coordinate and provide oversight for annual certification of engineering controls such as biosafety cabinets, chemical fume hoods, and emergency showers/eyewashes.
- Create a biosafety program and ensure all documents are updated as needed

1.4.2 Contractors and Tenants

Contractors and tenants on UMBC campus are expected to abide by the terms and conditions set forth in their contracts as well as the established environmental, safety, and health procedures prescribed by their organization's health and safety plan, or as otherwise instructed by university officials. Any entity working with biohazardous or potentially biohazardous materials must provide a biosafety manual and/or health and safety plan to university officials when requested. The entity's manual(s) must be furnished no later than three business days following the request.

1.4.3 Deans, Directors, Chairpersons, and Organizational Supervisors

These organizational lead roles are responsible for all individuals present in their area(s) of control. They have the overall responsibility for the implementation and maintenance of safe practices/procedures within their department.

1.4.4 Employees and Students

Employees and students are ultimately responsible for following the instructions of the PI, laboratory Supervisor/Manager, or instructor when working in the laboratory. All individuals working with biohazardous or potentially biohazardous materials must be familiar with current university training requirements, approved research protocols, proper use of PPE, NIH recombinant DNA guidelines, OSHA Bloodborne Pathogens guidelines (29 CFR 1910.1030) as applicable in addition to local, state, and federal guidelines, and the UMBC BSM. Every individual working in the laboratory has a duty to report any unsafe work practices, change in health status as related to the research being done, and biological or chemical spills/incidents to their supervisor as well as to the Office of Environmental Safety and Health.

1.4.5 Environmental Safety and Health Department (ESH)

The UMBC ESH office is responsible for developing and maintaining the Biological Safety Program as well as other safety programs/initiatives which are designed to ensure compliance with local, state, and federal regulations. Other duties and responsibilities of UMBC ESH include:

- Transport and/or disposal of chemical, biological, or infectious materials
- Assist (as necessary) with incident response, spill cleanup, and decontamination of biological spills
- Provide technical assistance and consultation in areas concerning industrial hygiene, chemical & biological materials, occupational health, and laboratory safety
- Conduct safety audits to ensure compliance with local, state, and federal regulations

UMBC ESH can be contacted at (410) 455-2918 or at esh@umbc.edu

1.4.6 Facilities, Departments and Building Managers

Each department should promote compliance with the practices, policies, and regulatory guidelines outlined in this manual. Building Managers are expected to work closely with each PI, Laboratory Manager/Supervisor, and instructor within their

department in order to promote compliance. Every building manager is expected to report any hazards and potential violations of regulations to UMBC ESH as well as assist with remedial action, as necessary.

1.4.7 Institutional Animal Care and Use Committee (IACUC)

The UMBC Institutional Animal Care and Use Committee (UMBC IACUC) is primarily responsible for ensuring the humane treatment of animals during research activities as well as compliance with all local, state, and federal regulations concerning animal research. UMBC requires that an animal research protocol, regardless of funding source, be submitted for review and approval by the IACUC before any investigator purchases, obtains and begins research involving vertebrate and some invertebrate species. The IACUC will review all animal use carried out in university facilities, as well as fieldwork conducted by UMBC personnel. All projects are to be approved prior to the actual use of animals, whether it involves research/teaching or warm/cold blooded vertebrates.

1.4.8 Institutional Biosafety Committee (IBC)

The UMBC Institutional Biosafety Committee (UMBC IBC) is responsible for ensuring that the use of recombinant DNA is conducted in compliance with the *NIH Guidelines* and the most current edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). Areas of IBC purview extend to include any biological research or teaching done at or sponsored by UMBC, regardless of funding source. The IBC shall oversee any research or teaching that incorporates recombinant DNA, infectious agents, select agents, biological toxins, and any other materials that exhibit characteristics similar to those already mentioned. The IBC will ensure compliance with proper concern for the safety of research and teaching personnel, the environment, and the surrounding communities. The UMBC IBC responsibilities include:

• Review of recombinant and synthetic DNA in research and teaching labs as well as research and teaching with transgenic animals and biohazardous materials (such as bacterium, fungi, algae, potential infectious agents and select agents) conducted at, or sponsored by, UMBC for compliance with the *NIH Guidelines*, and the most current edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). **ALL** research and teaching activities related to the above is subject to IBC oversight; the source of the funding does not alter this requirement.

- Independent assessment of the containment levels required by the NIH Guidelines.
- Assessment of the facilities, procedures, practices, and training and expertise of the personnel involved in recombinant or synthetic nucleic acid/infectious agent research.
- Ensure that all relevant aspects of the NIH Guidelines have been appropriately addressed by the Principal Investigator and/or Lab Instructor.
- Ensure that no research participant is enrolled in a human gene transfer experiment until the NIH Recombinant DNA Advisory Committee (RAC) review process has been completed, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained.
- Ensure compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines and the Center for Disease Control (CDC) guidelines.
- Adopt plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid/infectious agent research or teaching.
- Report any significant problems, or any significant research-related accidents or illnesses to the appropriate Institutional Official and NIH/OBA within 30 days.
- Make final determination for any disputed biosafety recommendations.

1.4.9 Internal Review Board (IRB)

The UMBC Institutional Review Board (IRB) is responsible for protecting the rights and ensuring the safety of human subjects participating in research. The IRB requires that all investigators who are affiliated with UMBC and who are engaged in research, regardless of funding, comply with both UMBC procedures and all state and federal regulations regarding the protection of human subjects in protocol activities.

1.4.10 Office of Research Protections and Compliance (ORPC)

The UMBC Office of Research Protections and Compliance (ORPC) is a centralized resource to ensure UMBC conducts its research activities in a manner consistent with federal, state and institutional regulatory requirements. The UMBC ORPC provides guidance and resources for the following activities:

- Animal Care and Use
- Biosafety / Institutional Biosafety Committee
- Campus Closure Business Continuity during Emergency
- Conflicts of Interest and Commitment
- Compliance Committee Meeting Dates

- Data Management
- Education and Training
- Export Control and Management
- Human Subjects
- Research compliance feedback and reporting research concerns
- Responsible Conduct of Research / Research Integrity

1.4.11 Principal Investigators, Laboratory Managers and Supervisors, Instructors

Principal Investigators (PI), laboratory managers and supervisors, and instructors are ultimately responsible for the safe implementation of the policies and procedures within the laboratory. These policies and procedures should be consistent with the requirements outlined in this manual as well as conform to all federal, state and local regulations. Responsibilities include:

- Ensuring no research involving animals, microbes, toxins, potentially infectious material, humans, and recombinant or synthetic nucleic acid molecules is conducted until it has met all of the requirements established in this manual as well as those requirements outlined by the Office of Research Protections and Compliance.
- Conducting ongoing risk assessments and ensuring proper risk group classification for the material worked with.
- Maintaining proper containment for the material worked with.
- Working closely with the UMBC Office of Research Protections and Compliance (ORPC) and the UMBC Office of Environmental Safety and Health (UMBC ESH) to create a safe and compliant research setting.
- Reporting to UMBC ESH any laboratory mishap, near miss, biological spill, significant chemical spill, injury, loss of containment, suspected or confirmed laboratory acquired illness, broken or uninspected engineering controls, unsafe work practices, violations of the NIH Guidelines, and any violations of policies and procedures outlined in this manual.
- Ensuring all individuals in the laboratory have received and have access to all required safety training and necessary immunizations.
- Ensuring all individuals in the laboratory have equal access to the laboratory safety manual, laboratory standard operating procedures, updated Safety Data Sheets (SDS) for chemicals used, and appropriate Personal Protective

Equipment (PPE) for work conducted.

- Acquiring and maintaining permits such as those required by the USDA, CDC, DEA, or CBP for transport, handling, or conducting research on specific materials.
- Verifying the performance of safety equipment used in the laboratory.

1.4.12 Visitors

Visitors to laboratories on UMBC campus are required to abide by the guidelines outlined in this manual and are expected to comply with all federal, state, and local regulations. The Principal Investigators (PI), laboratory managers and supervisors, and instructors are ultimately responsible for visitors in their laboratory space and are expected to advise the visitor on potential hazards as well ensure they are appropriately protected. An appropriate Waiver of Liability and Hold Harmless Agreement shall be submitted to departmental managers prior to the visit. A blank copy of adult and minor Waiver of Liability and Hold Harmless Agreement forms can be found in Appendix P and Appendix Q, respectively.

2.0 Regulations and Guidelines

The following is a brief overview of the regulatory authorities that either regulate or provide guidelines regarding the use and handling of infectious agents, potentially infectious material, biological materials, and recombinant DNA molecules.

Code of Maryland Regulations

The <u>Code of Maryland Regulations</u> (COMAR) is the official compilation of all administrative regulations issued by agencies of the state of Maryland. Within COMAR there are regulations concerning subjects such as select agent registration, bloodborne pathogen standards, and hazardous waste disposal.

National Institutes of Health

The National Institutes of Health (NIH), a subordinate agency to the department of Health and Human Services, establishes guidelines for research involving Recombinant or Synthetic Nucleic Acid molecules (<u>NIH Guidelines</u>). These guidelines establish the roles and responsibilities for all parties involved in recombinant nucleic acid research.

Centers for Disease Control

The Centers for Disease Control (CDC), a subordinate agency to the department of Health and Human Services, establishes guidelines for safe laboratory practices in order to prevent and control disease. In 1984 the CDC and NIH published the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) as an advisory tool for safe handling of infectious or potentially infectious materials. The latest edition provides guidance on laboratory facility design, safety equipment, safe microbiological practices, risk group characterization, and biosafety level recommendations. The CDC is also jointly responsible for regulating the possession and use of select agents which require registration under the <u>Select Agent Program</u>, select agent list can be found in Appendix I.

Occupational Safety and Health Administration

The Occupational Safety and Health Administration (OSHA) ensures safe and healthful working conditions for working men and women by setting and enforcing standards. OSHA establishes many guidelines for the protections of workers that are applicable to work done in the laboratory with the Bloodborne Pathogen standard (<u>29 CFR 1910.1030</u>) being one of them. All laboratories that work with human blood, human tissues, human cells, specific human body fluids, and non-human primate derived material must comply with this standard.

United States Department of Agriculture

The United States Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) establishes guidelines for importation, facility design, and work practices for agents of agricultural significance.

Transport of Biohazardous or Potentially Infectious Material

The transport, packaging, and importation of biohazardous material or potentially infectious material is regulated by the entities listed below

- U. S. Department of Transportation (DOT) 49 CFR Parts 171-180
- U. S. Public Health Service (PHS) 42 CFR Part 73
- U. S. Postal Service (USPS) 39 CFR Part 20 & 111

- U. S. Department of Labor, OSHA 29 CFR 1910.1030
- U. S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) 9 CFR Part 121 & 7 CFR Part 340
- U.S. Department of Commerce (DoC) 15 CFR Parts 730-799
- U. S. Fish & Wildlife Service (50 CFR Part 13)
- International Air Transport Association (IATA)
- International Civil Aviation Organization (ICAO)
- United Nations Recommendations of the Committee of Experts on the Transport of Dangerous Goods

3.0 Intro to Biosafety/Principles of Biosafety

Biological safety is the application of knowledge, techniques, and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards. The primary goal of biological safety is to ensure the safe handling and containment of infectious microorganisms and hazardous biological materials. The proper safe handling of these hazardous materials is accomplished using the principles of containment and risk assessment. The following sections outline basic biosafety principles which will aid in creating an overall safer laboratory when working with biohazardous materials.

3.1 Definition of Biohazardous Materials

A biohazardous material is defined as any biological material capable of causing harm to humans, animals or plants, including both biohazardous agents, non-replicating materials such as toxins, and may also be used to refer to material that harbors a biohazardous agent. Examples of biohazardous material include but are not limited to: bacteria, rickettsia, fungi, viruses, prions, parasites, recombinant nucleic acid, human or animal cells and blood products, toxins, animals inoculated with a potentially infected material, animal bedding and waste material, and other biohazardous agents as defined by state and federal regulations.

3.2 Containment

Containment is a term used to describe the microbiological practices, procedures, safety equipment, and facility safeguards used to safely manage biohazardous materials. When done properly containment successfully protects laboratory workers, the environment, and the public from possible exposure.

<u>Primary Containment</u>: Protects laboratory personnel and the immediate laboratory environment. Consists of following good microbiological techniques, using proper PPE, and utilizing engineering controls appropriately

<u>Secondary Containment</u>: Protects the environment external to the laboratory. Consists of a combination of facility design and operational practices.

Specific combinations of laboratory equipment, practices, and laboratory design can be used to achieve certain levels of physical containment. Containment is defined in levels that increase in complexity as the risk associated with the work increases, these levels are termed Biosafety Levels (BSL). There are currently four biosafety levels (BSL1-BSL4) which define the containment necessary to protect personnel and the environment. Since all biological laboratory work at UMBC is either BSL1 or BSL2, this manual will focus on those levels. More information on biosafety levels can be found in section 4 of this manual.

3.3 Routes of Exposure

Whenever there is a loss of containment there is a possibility of exposure. An exposure occurs when a hazardous material comes into close contact with an individual's body. The most common routes of exposure and their causes are:

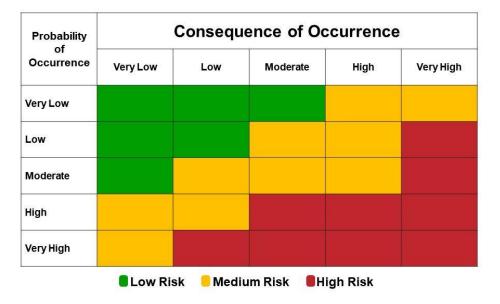
- <u>Ingestion</u>: The entry of hazardous materials through the mouth caused by eating, drinking, smoking, or applying cosmetics in the laboratory as well as not following proper hand washing protocol.
- <u>Injection</u>: The entry of hazardous materials into the blood through the breaking of skin from either sharps or animal bite/scratch.
- Inhalation: The entry of hazardous materials through the lungs caused by

breathing in hazardous aerosols attributed by not wearing the proper PPE for the task at hand or improperly using engineering controls intended to mitigate the formation and dispersion of aerosols

 <u>Absorption</u>: The entry of hazardous materials into the body through mucosal membranes or thin skin caused by not wearing proper PPE or by not following splash prevention protocols

3.4 Risk assessment

Risk assessment is the process by which an individual identifies the potential hazards posed by specific biological agents as well as identifying the hazards associated with the laboratory practices/equipment when working with those agents. The risk assessment process showcases the appropriate selection of microbiological practices, safety equipment, and facility safeguards that can prevent laboratory-associated infections (LAI).



Qualitative Risk Analysis with Probability of Occurrence

Figure 3.4 "Qualitative Risk Analysis With Probability Of Occurrence." *PowerPoint Templates | PowerPoint Slides Templates | PPT Themes Presentation*, www.slideteam.net/qualitative-risk-analysis-with-probability-of-occurrence.html

Risks are commonly categorized according to the likelihood of occurrence and impact of the consequence. A risk that has a high probability of occurrence and a high consequence of occurrence should command more attention than a risk with a low probability of occurrence and low consequence of occurrence. It is impossible to completely eliminate all risk and this type of analysis allows individuals to determine the level of risk that is acceptable while outlining higher risk activities that require more attention.

Risk assessment is ultimately the responsibility of the Principal Investigators (PI), laboratory managers and supervisors, and instructors; although the Biosafety Officer may assist in assessing risk as necessary. When conducting risk assessment, it is imperative to consider all aspects of the laboratory setting which may contribute to an increased possibility to exposure. Considerations should include agent hazards, facility design faults, personnel training, safety programs, and containment features. A simple risk assessment often consists of analyzing the "five Ps" in a laboratory, they are:

- <u>Personnel</u>: Consider the experience and comfort level of the research personnel as well as their susceptibility to disease. Also make note of their training, proficiency, and microbiological habits.
- 2. <u>Pathogen</u>: Consider the capability to infect and cause disease in a susceptible human host, severity of disease, infectious/lethal dose, genetic modifications, origin, and the availability of preventive measures and effective treatments. Make sure to consider the agent's Risk Group and Agent Summary Statement if applicable (more information found in Section 3.5 of this manual).
- 3. <u>Procedures</u>: Consider the agent concentration, suspension volume, equipment and procedures that generate small particle aerosols and larger airborne particles (droplets) and use of sharps. Animals can also present a number of hazards such as bites and scratches, exposure to zoonotic agents, and the handling of experimentally generated infectious aerosols.
- 4. <u>Protective Equipment</u>: Consider the protective equipment used including PPE and engineering controls. Ensure equipment is inspected/certified, as necessary.
- 5. <u>Place</u>: Consider the facility design, laboratory placement, and ease of access if security is required.

It is also important to note that risk assessment is not only required before the

start of research, but that it should be continuously evaluated. This means that risk assessment should occur before, during, and after any type of work in order to monitor the effectiveness of any implemented controls. It may be helpful to complete the CITI risk assessment worksheet which can be found at the end of this manual in Appendix A.

All biological laboratories require some degree of security and depending on the research being conducted a security risk assessment may be necessary. Dual Use Research of Concern (DURC) is research that can be directly misapplied to pose a significant threat to public health and the environment. Individuals conducting DURC are required to conduct a security risk assessment which should consist of:

- 1. Identify and prioritize biologicals/toxins.
- 2. Identify and prioritize the adversary/threat to these biologicals/toxins.
- 3. Analyze the risk of specific security scenarios.
- 4. Implement risk management practices.
- 5. Continuously evaluate risk management practices and objectives.

3.5 Risk Groups

Risk groups are classifications which describe the relative hazard posed by specific biohazardous materials. Determination of risk group for a particular material is based on the hazard characteristics of that material and it can vary from country to country. Hazard characteristics used to determine risk group include an agent's:

- Infectious dose, its viability in an aerosol, aerosol concentration, and particle size
- Capability to infect and cause disease in a susceptible human or animal host, host range
- Virulence as measured by the severity of disease
- Availability of preventive measures and effective treatments for the disease
- Probable routes of transmission of laboratory infection
- Stability in the environment and endemic nature

Certain high hazard agents may have an Agent Summary Statement as found in <u>Section VII of the BMBL</u>. These statements describe the hazards, recommended precautions, and recommended levels of containment for specific agents. It is important to understand that the **absence of an agent summary statement for an agent does not indicate minimal risk** and that probable laboratory route of transmission of the

infectious agent may differ from the route of transmission and severity associated with the naturally acquired disease. Please also remember that **risk group does NOT equate to biosafety level**. The risk group of an agent should be one of the many factors considered when conducting a risk assessment to determine the biosafety level in which the work will be conducted.

Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions <i>may be</i> available (high individual risk but low community risk)
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are <i>not usually</i> available (high individual risk and high community risk)

Basis for the Classification of Biohazardous Agents by Risk Group (RG)

 Table 3.5 "Basis for the Classification of Biohazardous Agents by Risk Group" National Institutes of Health. NIH Guidelines for

 Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2019., p. 28.

3.6 Risk Management

Once a risk assessment is completed it is paramount to prioritize risks according to the likelihood of occurrence and severity of the consequences. Risk management includes the development, implementation, and evaluation of controls to minimize the prioritized risks identified during the risk assessment. Risk management implementation strategies should follow the hierarchy of controls when possible.

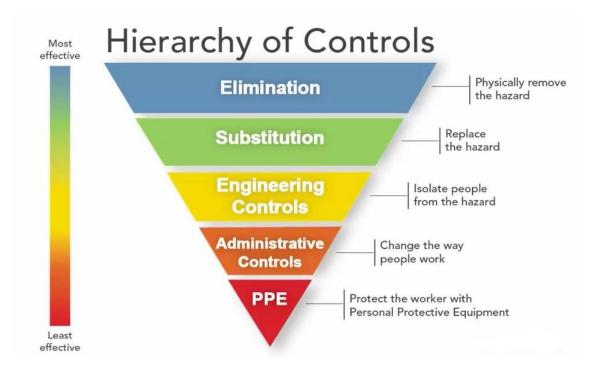


Figure 3.6 "Hierarchy of Controls." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 13 Jan. 2015, www.cdc.gov/niosh/topics/hierarchy/default.html.

Examples of hierarchy of controls:

- A. Elimination and Substitution Eliminate the hazard or substitute something less hazardous such as eliminating the need for sharps for a particular experiment or substituting plastic equipment for glassware.
- B. Engineering Controls Isolate and contain the hazard at or close to its source.
 - <u>Primary Containment</u>: This can be accomplished using biosafety cabinets, sharps containers, splash guards, safety cups, etc.
 - <u>Secondary Containment</u>: This can be accomplished by changing directional airflow, sealing up holes in laboratory, adding sinks for handwashing.
- C. Administrative Controls Write policies that, when followed, mitigate the hazards.
 - Prohibit unsafe laboratory practices such as eating, drinking, or smoking in the lab
 - Require handwashing before and after entering laboratory
 - Limit the use of sharps
 - SOPs for minimizing formation of splashes and aerosols

- Require specific training
- Implement good housekeeping policy
- D. **Personal Protective Equipment** Provide adequate PPE for hazards that cannot be mitigated by the above controls.

3.7 Standard Practices and Procedures

The following is a list that includes basic standard practices and procedures that apply to all individuals in the biological laboratory.

- Wear proper protective clothing and personal protective equipment as determined by risk assessment. Under no circumstance are open toed shoes allowed in the laboratory.
- Never mouth pipet.
- Never eat, drink, apply cosmetics, or handle contact lenses in the laboratory.
- Utilize aseptic technique whenever possible.
- Avoid touching head, face or neck when working with biohazardous materials to reduce chance of transmission.
- Wash hands after the removal of gloves and other personal protective equipment. Wash hands prior to leaving the laboratory.
- Follow OSHAs Bloodborne pathogen standards (29 CFR 1910.1030) when utilizing sharps. Whenever possible find a substitute for sharps or engineer this hazard out of current procedures. If sharps are required please remember to never recap needles, always store sharps in a puncture resistant container, and always dispose of sharps in a properly labeled university approved sharps container. More information on sharps can be found in the following section.
- Always handle biohazardous materials as determined by risk assessment
- Avoid the use of aerosol generating procedures. Any hazard that produces aerosols or has the possibility to become aerosolized should be handled in a certified biological safety cabinet
- All engineering controls such as biosafety cabinets, emergency shower and eyewashes, shielding, ect should be properly functioning, maintained, and inspected.
- Never let biohazardous materials or contaminated glassware outside of containment. All hazardous materials should be stored securely in sealed, leak proof, labeled containers when outside of the biosafety cabinet.

- Any equipment which store biohazardous material such as freezers, incubators, refrigerators, or storage units should be labeled with the universal biohazard symbol (examples of which are found in Appendix B). These pieces of equipment may only be used for biohazardous material, no other type of storage is permitted.
- When infectious materials are present, the doors of the laboratory must have a door sign clearly posted. This door sign must include the universal biohazard symbol, name of biohazardous agent(s), emergency contact name and phone number, as well as entry and exit requirements (e.g., PPE, handwashing, sign out). More information can be found in Section 3.12 of this manual.
- Read, understand, and follow the laboratory biosafety plan for the biohazardous material you are working with. Understand and be able to implement the laboratory biosafety plan for an accidental spill of biohazardous materials.
- Always handle broken glass with a mechanical device (e.g., tongs, forceps, plastic scoop), never handle broken glass directly with hands or absorbent towel.
- Always keep an appropriate, well stocked spill kit available in the lab.
- Clean laboratory work surfaces and equipment with facility approved disinfectant after working with biohazardous materials
- Laboratories should be clean and free of clutter to allow for proper disinfection of areas.
- Never allow biohazardous material to leave laboratory containment unless it has been properly sterilized or packaged for transport as determined by the risk assessment. Proper training is required for the shipping party and receiving party prior to the transport of biohazardous material. When transporting biohazardous materials to another facility always follow USPS, DOT, and/or IATA regulations.
- Report all accidents, spills, near misses, and possible laboratory acquired infections to your Principal Investigator (PI), laboratory manager and supervisor, or instructor as well as the Office of Environmental Safety and Health.
- Remember to think safety at all times when in the laboratory. If you do not understand the proper safety procedures or how to use safety equipment properly then seek advice from a knowledgeable individual or contact the Office of Environmental Safety and Health.

Safety is ultimately the responsibility of every individual in the laboratory. Actively choosing to participate in safe practices as well as continual risk assessment and management will contribute to a safe and healthy workplace.

3.8 Sharps Safety

Sharps are mechanical devices that are used for or have the potential to cut or puncture membranes such as skin. Sharps include but are not limited to needles, scalpels, razor blades, broken glass, scissors, and lancets. Whenever possible find a substitute for all sharps used in the laboratory or engineer this hazard out of current procedures. When sharps must be utilized in the laboratory, it is imperative that individuals are trained on their proper use and disposal.

Sharps Handling Procedures

- Needles must not be bent, broken, sheared, or otherwise removed prior to disposal
- Disposable needles may not be reused or recapped. If a specific laboratory
 procedure requires multiple uses of the same needle then specific SOPs
 must be adopted in conjunction with the use of an approved re-sheathing
 needle with a retractable guard.
- Broken glass should be handled with a mechanical device (e.g., tongs, forceps, plastic scoop), never handle broken glass directly with hands or absorbent towel.
- Never cut, inject, or otherwise inoculate towards your body or hand.

Sharps Disposal

- All sharps disinfection and disposal shall be in accordance with section 11 of this manual
- Promptly dispose of all sharps immediately after use in an appropriate sharps container.
- Sharps must be disposed of in a puncture resistant, facility approved sharps container located in the immediate vicinity of the work being performed.
 Sharps containers may not be used for any other waste disposal and must be properly labeled.
- Replace sharps containers before it reaches 3/4 full
- Sharps containers that are set for disposal should have the lid securely

closed by either tape or other mechanical means.

 Contact UMBC ESH at 5-2918 or <u>esh@umbc.edu</u> to schedule a pick up 3/4 full of partially full sharps containers

Reusable Sharps Disinfection

- Handle sharps with a mechanical device such as tongs.
- Place sharps in a labeled, unbreakable, leak proof container filled with a facility approved disinfectant. Ensure appropriate contact time.
- If possible, place instruments such that all of the sharps ends are facing in the same direction.
- Use a brush to clean any visible blood or debris on the reusable sharp, place back in container to complete disinfection making note of contact time.
- After disinfection place reusable sharps in a clean, labeled, unbreakable, leak proof container.

3.9 Hand Washing

Proper hand washing is an essential skill in the biological laboratory and is conducive to proper personal hygiene. By utilizing proper hand washing technique an individual can greatly reduce the possibility of transmission of biohazardous materials. Hands should be washed after the removal of gloves and other personal protective equipment as well as prior to leaving the laboratory. In order to promote proper personal hygiene and good laboratory practice, hand washing materials such as soap, running water, and absorbent towels <u>are required</u> in every laboratory.

Proper Hand Washing Technique:

- 1. Wet your hands with clean, running water (water can be warm or cold).
- 2. Lather your hands by rubbing them together with soap. Ensure to get full coverage of both hands including the back of your hands, in between the fingers, around your wrists, and under your nails.
- 3. Scrub your hands for at least 20 seconds.
- 4. Rinse your hands with clean, running water.
- 5. Dry your hands with a clean absorbent towel.
- 6. Repeat as necessary.

Remember to take your time and ensure coverage of your entire hand. Note that

depending on the risk assessment it may be required to wash hands twice or if soap and water are not available the use of an alcohol-based hand sanitizer may be permitted.

Hand Sanitizer Considerations

- Sanitizers do **not** neutralize all biohazardous materials.
- Sanitizers may not be effective when hands are dirty or greasy.
- Sanitizers may not remove harmful chemicals, toxins, or heavy metals.
- Sanitizers with a concentration of 60%-95% ethanol or isopropanol is recommended.

Proper Use of Hand Sanitizer

- 1. Apply sufficient product to the palm of one hand.
- 2. Rub hands together. Ensure to get full coverage of both hands including the back of your hands, in between the fingers, around your wrists, and under your nails.
- 3. Continue rubbing hands together until your hands are dry.
- 4. Repeat as necessary.

Note: It is strongly recommended to wash your hands with soap and water as soon as possible after using hand sanitizer.

3.10 Engineering Controls

Engineering controls are intended to protect individuals by removing hazardous conditions or by creating space or placing a barrier between the individual and the hazard. Engineering controls are only effective when utilized properly, therefore it is paramount that individuals receive training on the proper use and maintenance of this equipment. Many engineering controls can be found in the biological laboratory, a few of the most common ones are listed below. More information on this equipment can be found in Section 7 of this manual

- <u>Biosafety Cabinet</u>: A biosafety cabinet is an enclosed, ventilated workspace that allows users to manipulate biohazardous materials safely. Biosafety cabinets may **not** be used for chemical vapors or hazardous toxic fumes.
- <u>Chemical Fume Hoods</u>: A Chemical Fume Hood (CFH), much like a biosafety cabinet, is an enclosed, ventilated workspace. Fume hoods protect users from chemical vapors or hazardous toxic fumes. Chemical Fume Hoods may **not** be

used for biohazardous materials.

- <u>Centrifuge Safety Cups</u>: Are used as a form of secondary containment for biohazardous materials that are being centrifuged.
- <u>Downdraft tables:</u> Are workbenches with built in ventilation which pulls air down and away from the operator. This equipment provides protection to the operator and the environment but not to the specimen.
- <u>Emergency Shower and Eyewash Stations</u>: Are used in the event of chemical exposure and are intended to reduce workplace injury. Any laboratory working with hazardous chemicals and any BSL2 laboratory requires this equipment.
- <u>Glove Box</u>: A type of biosafety cabinet that consists of a closed chamber in which a pair of gloves project from an opening on the side. Glove boxes are entirely enclosed and are often used for containing highly hazardous materials.
- <u>Inline Filters for vacuums</u>: Are HEPA filters that are used to protect centralized vacuum systems as well as localized vacuum pumps.
- <u>Ventilation and Exhaust systems</u>: A building's ventilation and exhaust system can allow for specific areas to be positively or negatively pressured. This acts as a form of secondary containment in the event that primary containment is lost.
- <u>Laminar Flow Clean Bench</u>: A laminar flow bench pushes clean air through the workspace and out into the open lab environment. This protects the specimen but does NOT protect the operator or the environment. It is important to note that laminar flow benches may not under any circumstance be used with hazardous or potentially hazardous materials.

The use of engineering controls must be considered when conducting a risk assessment and subsequent implementation of risk management practices. It is also important to note that oftentimes certain engineering controls are required for specific types of laboratories regardless of what the risk assessment dictates. Engineering controls should be inspected, maintained, and be in proper working order. The office of Environmental Safety and Health will be responsible for scheduling biological safety cabinet, chemical fume hood, and emergency shower recertification/inspection as required. It will be the responsibility of the laboratory staff to ensure all other equipment in the laboratory is inspected and/or tested weekly in accordance with applicable safety standards.

3.11 Personal Protective Equipment

Personal Protective Equipment (PPE) is equipment designed to protect the wearer's body from a variety of hazards. PPE can come in a variety of different configurations based on the hazard it is designed to mitigate. Some of the more common PPE that can be found in the biological laboratory is listed below.

- <u>Face and Eye Protection</u>: Intended to protect mucosal membranes from exposure to splashes or aerosols. Includes safety glasses, goggles, UV protective glasses/laser safety glasses and goggles, face shields, and surgical masks.
- <u>Clothing Protection</u>: Intended to protect the wearer's street clothing and body from contamination/exposure. Includes lab coat, gown, booties, and Tyvek suit.
- <u>Bite/Scratch Protection</u>: Intended to prevent injection/inoculation when handling laboratory animals or using sharps. Includes Kevlar sleeves, chain gloves, and thick gloves
- <u>Respiratory Protection</u>: Intended to protect wearer from inhaling harmful aerosols or vapors. Includes N95 masks, Powered Air Purifying Respirators (PAPR), full face respirators, supplied air respirators (SAR), and Elastomeric Half Face Respirators (EHFR). Note an individual who intends to wear a respirator must be enrolled in the university's Respiratory Protection Program prior to using a respirator.
- <u>Hand Protection</u>: Intended to protect the wearer's hands from minor abrasions, absorption, and/or thermal hazards. Includes gloves of various material. Note that nitrile gloves do not provide heat protection and must not be used as such. Heat resistant gloves will primarily be made out of flame-retardant material and be labeled as to the heat rating.

PPE is the last level on the Hierarchy of Controls and therefore should be the last strategy used when mitigating risk. Some PPE requires the user to enroll in specific programs to ensure compliance (e.g. respiratory protection program for respirator use). All PPE requires proper training in order to be used effectively, it is the responsibility of the principal investigators (PI), laboratory managers and supervisors, and instructors to ensure laboratory staff are properly trained on proper PPE usage.

3.12 Signage

All UMBC laboratories, regardless of the discipline of study, should have a facility approved door sign to denote specific hazards that may be present within that laboratory. The use of specific agents or dual use research of concern may require different signage requirements as determined by a security assessment. Facility approved door signs can be generated using the <u>Apply for a door sign</u> form found on <u>https://safety.umbc.edu/</u>, directions for applying can be found in Appendix H. Biological laboratories may generate a facility approved door sign using the directions found in Appendix H or create a custom door sign given that sign includes the following elements:

- Universal biohazard symbol that conforms to OSHA 1910.145 (Specifications for accident prevention signs and tags). An example can be found in Appendix B of this manual.
- Laboratory biosafety level (BSL) or animal biosafety level (ABSL)
- Full name of agent(s) in use (as determined by risk and security assessment).
- Name and phone number of laboratory supervisor or other responsible personnel.
- Entry and exit requirements, Required PPE, Required Vaccinations or medical clearance
- Emergency contact phone numbers
 - Please use a current and monitored phone number such as a cell phone number, avoid using an office phone number
- Any special instructions/information required for safe operations

Note: A biological door sign is only required when biohazardous agents are present in the laboratory, if no biohazardous agents are present then the sign or biohazard symbol must be removed or otherwise obscured. Laboratories may generate their own door sign that contains all of the above elements much like the generic biological laboratory door sign example below. Door signs must be posted on all doors leading into the laboratory.

AUTHORIZED PERSONNEL ONLY!



Principle Investigator: _____

Agent(s):_____

Entry/Exit Requirements (PPE, vaccinations, special information):____

Emergency ContactContact NamePhone NumberAlternate Phone
NumberPrimarySecondaryBuilding ManagerUMBC ESH(410) 455-2918(410) 455-2918UMBC Police(410) 455-5555(410) 455-5555

Figure 3.12 "Generic Biological Laboratory Door Sign". For use on all doors leading into the laboratory.

A universal biohazard symbol that conforms to OSHA 1910.145 (Specifications for accident prevention signs and tags) is also required to be placed on containers and storage units such as freezers, refrigerators, incubators, waste containers, contaminated equipment, and anything that may contain biohazardous or potentially biohazardous materials.

3.13 Cage Cards

All research related animals in the biological laboratory shall be easily identified by a sign, label, or card securely affixed to the outside of the animal housing. The elements of such, at a minimum, should include:

- PI/Responsible person name
- PI/Responsible person email and a reachable phone number (please refrain from using office numbers)
- Full biological agent name
- Infection/inoculation date
- Room # where organism shall be housed
- Universal biohazard symbol that conforms to OSHA 1910.145 (Specifications for accident prevention signs and tags). An example can be found in Appendix B of this manual.
- Date of latest cage change
- Any specific notes concerning organism, agent, or special treatment or precautions.

ABSL-1 and ABSL-2 cage cards should be easily distinguished from one another; this could be accomplished by generating two different color cards for each respective containment level or otherwise denoting on cage card. It is important to note that certain biological agents, when introduced to living organisms, may present a higher risk as opposed to being separate from the organism. A thorough risk assessment is required to determine the appropriate precautions and level of containment for inoculated organisms. See example below of a generic ABSL cage card.

Agent Name:	
Date of Infection://	
Containment Level	
ABSL-1 ABSL-2	X
	BIOHAZARD
Building & Room #:	
PI Name :	Date of Last Cage Change
Responsible Person	
Phone Number:	
Email:	
Notes:	
	Initials

Figure 3.13: "Generic Cage Card". For use on exterior of animal cages housed in ABSL-1 or ABSL-2 containment.

4.0 Biosafety Level Criteria

Biosafety levels (BSL) denote specific combinations of laboratory equipment, practices, and laboratory design that are used to achieve certain levels of physical containment. These levels of containment increase (BSL1 – BSL4) as the level of risk associated with the work increases. Each biosafety level builds upon the requirements/controls of the preceding levels. All biological laboratory work at UMBC is either BSL1 or BSL2, therefore this manual will focus primarily on those levels.

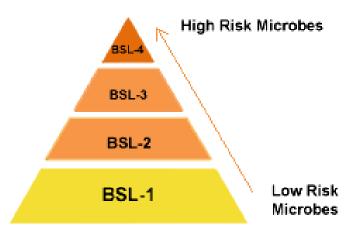


Figure 4.0 "CDC LC Quick Learn: Recognize the Four Biosafety Levels." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, <u>www.cdc.gov/training/QuickLearns/biosafety/</u>.

It is important to understand that low risk microbes may require a higher level of containment as dependent on the risk assessment. Production of aerosols, splashes, or other high potential of exposures may dictate increased containment.

4.1 Biosafety level 1 Laboratory

Biosafety level 1 (BSL-1) containment is primarily used for agents that are not known to cause disease in healthy (immunocompetent) adult humans and presents a minimal hazard to the environment and society. Agents are typically well characterized and do not require specialized equipment for handling (as determined by risk assessment). Biosafety level 1 laboratories are expected to comply with all recommendations outlined in the *Biosafety in Microbiological and Biomedical Laboratories* (most current edition) as well as all regulations outlined in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.*

4.2 Biosafety level 2 Laboratory

Biosafety level 2 (BSL-2) containment is typically used for agents that pose a moderate hazard to laboratory personnel. Lower risk agents in high concentrations or that have a high potential for aerosol production may also require this level of containment. Individuals working in the BSL-2 laboratory are required to have adequate training under the supervision of a competent supervisor. Special engineering controls such as certified biosafety cabinets, emergency shower/eyewash stations, and centrifuge safety cups combined with PPE such as gowns, gloves, and face/eye protection are required as determined by the risk assessment. Biosafety level 2 laboratories are expected to comply with all recommendations outlined in the *Biosafety in Microbiological and Biomedical Laboratories* (most current edition) as well as all regulations outlined in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

4.3 Biosafety level 3 and 4 Laboratory

Biosafety level 3 (BSL-3) and biosafety level 4 (BSL-4) work is typically conducted with agents that pose a significant or high hazard to laboratory personnel, the environment, and society. These agents can be uncharacterized, pose inhalation risks, have no known treatment, and be exotic to the surrounding areas. Biosafety level 3 and biosafety level 4 work is conducted in extremely high containment. This work requires extensive resources and personnel for safe handling, of which is not available at UMBC. Biosafety level 3 and biosafety level 4 work is not permitted at UMBC or its associated properties.

BSL	Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in healthy adults	Standard microbiological practices	 No primary barriers required. PPE: laboratory coats and gloves; eye, face protection, as needed 	Laboratory bench and sink required
2	 Agents associated with human disease Routes of transmission include per- cutaneous injury, ingestion, mucous membrane exposure 	 BSL-1 practice plus: Limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies 	 Primary barriers: BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials PPE: Laboratory coats, gloves, face and eye protection, as needed 	BSL-1 plus: ■ Autoclave available
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	 BSL-2 practice plus: Controlled access Decontamination of all waste Decontamination of laboratory clothing before laundering 	 Primary barriers: BSCs or other physical containment devices used for all open manipulations of agents PPE: Protective laboratory clothing, gloves, face, eye and respiratory protection, as needed 	 BSL-2 plus: Physical separation from access corridors Self-closing, double-door access Exhausted air not recirculated Negative airflow into laboratory Entry through airlock or anteroom Hand washing sink near laboratory exit
4	 Dangerous/exotic agents which post high individual risk of aerosol-trans- mitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments Agents with a close or identical anti- genic relationship to an agent requir- ing BSL-4 until data are available to redesignate the level Related agents with unknown risk of transmission 	 BSL-3 practices plus: Clothing change before entering Shower on exit All material decontaminated on exit from facility 	 Primary barriers: All procedures conducted in Class III BSCs or Class I or II BSCs in com- bination with full-body, air-supplied, positive pressure suit 	 BSL-3 plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum, and decontamination systems Other requirements outlined in the text

Summary of Recommended Biosafety Levels for Infectious Agents

Table 4.3 "Summary of Recommended Biosafety Level for Infectious Agents" Centers for Disease Control, and National

Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories, 5th ed., U.S. G.P.O., 2010, p. 59.

5.0 Animal Biosafety Level Criteria

Animal biosafety level criteria establishes levels of containment for animals that are are experimentally infected or otherwise known to harbor infectious agents. These animals are housed in indoor research facilities (vivaria) which are designed in accordance with IACUC and NIH standards. Although work with animals can present unique and specific problems, biosafety levels are typically comparable when working with agents in *vivo* and in *vitro*. All research must be approved by IACUC and abide by all local, state, and federal guidelines.

5.1 Animal Biosafety Level 1 Laboratory

Animal biosafety level 1 (ABSL-1) containment is primarily used for agents that are not known to cause disease in healthy (immunocompetent) adult humans and presents a minimal hazard to the environment and society. Agents are typically well characterized and do not require specialized equipment for handling (as determined by risk assessment). Animal biosafety level 1 laboratories are expected to comply with all recommendations outlined in the *Biosafety in Microbiological and Biomedical Laboratories* (most current edition) as well as all regulations outlined in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Guide for the Care and Use of Laboratory Animals,* and Laboratory Animal Welfare *Regulations.*

5.2 Animal Biosafety Level 2 Laboratory

Animal biosafety level 2 (ABSL-2) containment is typically used for animals infected with agents that that are associated with human disease which pose a moderate hazard to laboratory personnel. ABSL-2 containment requires specific personnel training for the proper handling of animals infected with the agent as well as adequate supervision by an experienced individual knowledgeable of hazards associated with the work being done. Access to the ABSL-2 laboratory should be restricted and special engineering controls such as certified biosafety cabinets, emergency shower/eyewash stations, and centrifuge safety cups combined with PPE such as gowns, gloves, and face/eye protection are required as determined by the risk assessment. Animal biosafety level 2 laboratories are expected to comply with all recommendations outlined in the *Biosafety in Microbiological and Biomedical Laboratories* (most current edition) as well

as all regulations outlined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Guide for the Care and Use of Laboratory Animals, and Laboratory Animal Welfare Regulations.

5.3 Animal Biosafety Level 3 and 4 Laboratory

Animal Biosafety level 3 (ABSL-3), animal biosafety level 4 (ABSL-4), and animal biosafety level 3 agriculture (ABSL-3-Ag) work is typically conducted with agents that pose a significant or high hazard to laboratory personnel, the environment, and society. These agents can be uncharacterized, pose inhalation risks, have no known treatment, and be exotic to the surrounding areas. ABSL-3 and ABSL-4 work is always conducted in extremely high containment. This work requires extensive resources and personnel for safe handling, of which is not available at UMBC. Animal Biosafety level 3 (ABSL-3), animal biosafety level 4 (ABSL-4), and animal biosafety level 3 agriculture (ABSL-3-Ag) work is not permitted at UMBC or its associated properties.

Summary of Recommended Animal Biosafety Levels for Activities in which Experimentally or Naturally Infected Vertebrate Animals are Used

BSL	Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in healthy adults	Standard animal care and management practices, including appropriate medical surveillance programs	As required for normal care of each species PPE: laboratory coats and gloves; eye, face protection, as needed	Standard animal facility: No recirculation of exhaust air Directional air flow recommended Hand washing sink is available
2	 Agents associated with human disease Hazard: percutaneous injury, ingestion, mucous membrane exposure 	ABSL-1 practice plus: Limited access Biohazard warning signs "Sharps" precautions Biosafety manual Decontamination of all infectious wastes and animal cages prior to washing	 ABSL-1 equipment plus primary barriers: Containment equipment appropriate for animal special PPE: Laboratory coats, gloves, face, eye and respiratory protection, as needed 	 ABSL-1 plus: Autoclave available Hand washing sink available Mechanical cage washer recommended Negative airflow into animal and procedure rooms recommended
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	 ABSL-2 practice plus: Controlled access Decontamination of clothing before laundering Cages decontaminated before bedding is removed Disinfectant foot bath as needed 	 ABSL-2 equipment plus: Containment equipment for housing animals and cage dumping activities Class I, II or III BSCs available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols PPE: Appropriate respiratory protection 	 ABSL-2 facility plus: Physical separation from access corridors Self-closing, double-door access Sealed penetrations Sealed windows Autoclave available in facility Entry through ante-room or airlock Negative airflow into animal and procedure rooms Hand washing sink near exit of animal or procedure room
4	 Dangerous/exotic agents which post high risk of aerosol transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to redesignate the level Related agents with unknown risk of transmission 	 ABSL-3 practices plus: Entrance through change room where personal clothing is removed and laboratory clothing is put on; shower on exiting All wastes are decontaminated before removal from the facility 	ABSL-3 equipment plus: Maximum containment equipment (i.e., Class III BSC or partial contain- ment equipment in combination with full body, air-supplied positive- pressure suit) used for all procedures and activities	 ABSL-3 facility plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum, and decontamination systems Other requirements outlined in the text

Table 5.3 "Summary of Recommended Animal Biosafety Levels for Activities in which Experimentally or Naturally Infected

Vertebrate Animals Are Used" Centers for Disease Control, and National Institutes of Health. Biosafety in Microbiological and

Biomedical Laboratories, 5th ed., U.S. G.P.O., 2010, p. 103.

6.0 Plant Biosafety Level Criteria

The principal purpose of plant containment is to avoid the unintentional transmission of a recombinant or synthetic acid molecule-containing plant genome, including nuclear or organelle hereditary material or release of recombinant or synthetic nucleic acid molecule-derived organisms associated with plants.

The containment principles are based on the recognition that the organisms that are used pose no health threat to humans or higher animals (unless deliberately modified for that purpose), and that the containment conditions minimize the possibility of an unanticipated deleterious effect on organisms and ecosystems outside of the experimental facility, e.g., the inadvertent spread of a serious pathogen from a greenhouse to a local agricultural crop or the unintentional introduction and establishment of an organism in a new ecosystem.

BL1-P through BL4-P are designed to provide differential levels of biosafety for plants in the absence or presence of other experimental organisms that contain recombinant or synthetic nucleic acid molecules. These biosafety levels, in conjunction with biological containment conditions, provide flexible approaches to ensure the safe conduct of research.

When determining the appropriate BL-P there are several issues to consider:

- What is the source and nature of the introduced genetic material?
 - o Is it from an exotic infectious agent or pathogenic organism?
 - o Is it a fragment of DNA or a complete genome?
- What is the nature of the host organism?
 - Can the Host readily disseminate the genetic material?
 - o Is the recipient likely to be invasive to local ecosystems?
 - Is the recipient a USDA APHIS-listed noxious weed or capable of interbreeding with noxious weeds?
 - What is the potential for outcrossing between the recipient organism and related species?
 - What is the potential for detrimental impact on natural or managed ecosystems?
- Are bioactive proteins expressed?
 - o What is the nature of the expressed proteins?
 - o Are the proteins vertebrate toxins or potential/known allergens?
 - Are the proteins toxic to other organisms in the local environment?

- What is the profile of the local environment?
 - Are potentially affected important crops located nearby?
 - Are sexually compatible wild plant or weed species capable of sustaining and/or spreading the genetic modifications?
- What experimental procedures may impact containment?
 - Will it be necessary to transport sensitive materials to/from the greenhouse facilities?
 - Will arthropods or other potential vectors be used during the course of the project? How will these be contained to prevent or minimize the release of genetically modified materials?

It is important to note that certain plants, organisms, or plant material may require a to permit be filed with the Animal and Plant Health Inspection Service (APHIS). Researchers are responsible for filing and maintaining all required permits. Due to the complexity of the permitting process, researchers should contact <u>USDA – APHIS Permits and Certifications</u> for questions concerning the permitting process. Additional information on plant biosafety level criteria and permitting can be found in the UMBC Greenhouse Practices Manual.

6.1 Biosafety Level 1 – Plants (BL1-P)

Biosafety Level 1 – Plants (BL1-P) is used for experiments that are deemed low risk to the environment and have limited or no threat potential. This containment level applies to plant associated microorganisms that are considered to have minimal impact on the environment as well as transgenic plants that are not noxious weeds and are not easily disseminated or detrimental to the environment. BL1-P laboratories are expected to comply with all recommendations outlined in the *Biosafety in Microbiological and Biomedical Laboratories* (most current edition) as well as all regulations outlined in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.*

6.2 Biosafety Level 2 – Plants (BL2-P)

Biosafety Level 2 – Plants (BL2-P) is used for experiments with transgenic plants and plant associated organisms that have the potential for rapid and widespread dissemination, and the capability of interbreeding with weeds or related species. This containment level applies to transgenic plants that are noxious weeds or can interbreed with noxious weeds, transgenic plants that contain the genome of a non-exotic infectious agent, and transgenic plants or plant pathogens that may have a detrimental impact to the environment. BL2-P laboratories are expected to comply with all recommendations outlined in the *Biosafety in Microbiological and Biomedical Laboratories* (most current edition) as well as all regulations outlined in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.*

6.3 Biosafety Level 3 & 4 – Plants (BL3-P & BL4-P)

Biosafety level 3 – Plant (BL3-P) and biosafety level 4 - Plant (BL4-P) work is typically conducted with agents that pose a significant or high hazard to laboratory personnel, the environment, and society. These agents can be uncharacterized, exotic, and be readily transmissible. BL3-P and BL4-P work is conducted in extremely high containment. This work requires extensive resources and personnel for safe handling, of which is not available at UMBC. Biosafety level 3 – Plant (BL3-P) and biosafety level 4 - Plant (BL4-P) work is not permitted at UMBC or its associated properties.

7.0 Laboratory Equipment

Choosing the proper laboratory equipment for the task at hand plays a crucial part in maintaining a safe atmosphere in the research laboratory or classroom. The improper or deliberate misuse of laboratory equipment outside the scope of its intended purpose can produce severe consequences. When selecting equipment to use in the laboratory please consider the following:

- The manufacturer's recommended operating procedures, maintenance, and cleaning processes
- The training required to safely operate and service the equipment
- Inherent hazards associated with the equipment and how to mitigate them
- The ease at which the equipment is disinfected as well as suitable disinfectants. All equipment should be disinfected before and after use.
- The level of containment or how well the equipment limits contact between the operator and the agent.

It is important to note the significant risk caused by the generation of aerosols in the

biological laboratory. The generation of aerosols is a major concern in the biological laboratory as it can occur during the course of many routine laboratory procedures. The containment of all aerosols is paramount in minimizing risk and creating a safer laboratory. Aerosols are generally produced while manipulating liquid suspensions, examples of aerosol generating procedures include but are not limited to:

- Centrifuging
- Sonicating
- Handling or changing animal bedding
- Inoculation
- Pipetting
- Transferring liquid
- Stirring liquid
- Dissection and vivisection
- Tissue manipulation

Many aerosol generating procedures should be performed using an engineering control as determined by the risk assessment. When selecting laboratory equipment that generates aerosols consider utilizing one that provides containment of the aerosol closest to its source as this will be the most effective

7.1 Biological Safety Cabinet (BSC)

A Biological Safety Cabinet (BSC) is a specific engineering control used in the biological laboratory to prevent exposure to or the contamination of biohazardous agents. BSCs should be used whenever there is a risk of splash or aerosol formation. BSCs work by manipulating air flow surrounding the area where work is being done such that the majority of aerosols generated remain in containment. BSCs utilize HEPA filters and require certification every year, whenever major repairs are made, or whenever the unit is moved. BSCs are divided into three classes (I, II, III) with class II being subdivided into five types (A1, A2, B1, B2, C1). Below are descriptions of each BSC class as well as a table denoting the differences between the major BSCs.

<u>Class I</u>

Class I BSCs provide protection to the operator and the environment but do not

provide protection to the sample. This class of cabinet is typically used to provide containment during the use of specific equipment such as centrifuges or sonicators.

Class II

Class II BSCs provide protection to the operator, the environment, and the sample. Subtypes differ in percent recirculated air, velocity of inflow air, pressure status of plenum, and method of exhaust discharge.

Class III

Class III BSCs provide the highest degree of protection for the operator, the environment, and the sample. These BSCs, commonly known as glove boxes, are comprised of a completely enclosed workspace that has openings for thick gloves to allow for sample manipulation. Class III BSCs are gas tight and have no recirculation or exhaust. Materials typically enter or exit the cabinet through a sanitizing dunk tank or pass through autoclave.

BSC Class	Airflow Pattern	Notes
I	Airflow comes in the front and is exhausted through a HEPA filter	 Provides protection to the operator and environment only, does not provide protection to the sample Non-volatile chemicals may be used May not be used with volatile chemicals
II A1	70% of air is re-circulated inside the cabinet, 30% is exhausted through the HEPA filter into the room or to the outside.	 Provides protection to the operator, environment, and specimen. May not be used with volatile chemicals Only small amounts of non-volatile chemicals may be used
II A2	70% of air is re-circulated inside the cabinet, 30% is exhausted through the HEPA filter into the room or to the outside. Plenums are under negative pressure relative to the room	 Provides protection to the operator, environment, and specimen. Non-volatile chemicals may be used May not be used with volatile chemicals or radionuclides
II B1	40% of air is re-circulated inside the cabinet and 60% is exhausted through the HEPA filter. Exhaust is pulled through a dedicated duct to the outside.	 Provides protection to the operator, environment, and specimen. Non-volatile chemicals may be used Can be used with very small amounts of volatile chemicals and radionuclides as determined by chemical risk assessment
II B2	No re-circulation, cabinet is hard ducted. Exhaust air is pulled through HEPA filter into dedicated duct to the outside.	 Provides protection to the operator, environment, and specimen. Non-volatile chemicals may be used Can be used with small amounts of volatile chemicals and radionuclides as determined by chemical risk assessment
II C1	40% of air is re-circulated and 60% is exhausted. Similar to type B1 except exhaust air is pushed through the HEPA filter by an internal motor	 Provides protection to the operator, environment, and specimen. Non-volatile chemicals may be used May not be used with volatile chemicals
111	None, completely enclosed, gas tight work area	Provides the highest level of protection to the operator, the environment, and the sample

Table 7.1 Biological Safety Cabinet Class and Appropriate Use

In order to maintain a safe biological laboratory, the following guidelines should be followed when operating a BSC:

Biosafety Cabinet General Guidelines

- All individuals working with a BSC must be trained in the proper operation, disinfection, and safe practices before starting work.
- Ensure BSC is within certification date, this can be found on the certification sticker located on the front of the BSC. If BSC is not within certification date please notify the Office of Environmental Safety and Health. Never use a BSC that is not certified.
- Never store items on top of the biological safety cabinet
- Never store items inside the BSC that impede or otherwise disrupt the airflow. BSCs may not be used for storage of materials when not in use.
- Always wear a gown, face/eye protection, a surgical mask, and a double set of gloves when working in a BSC.
- Never put you head inside the BSC, utilize mechanical devices to reach far areas.
- The BSC should be turned on at all times when working inside or when biohazardous agents are inside.
- The UV light should be turned off when working in the BSC as it can cause skin or eye damage.
- Always disinfect items (including gloved hands) before placing into or removing from the BSC. This applies even when items are within proper containment such as a leak proof container or other facility approved containment.
- Place all disinfected items required for the experiment, including biological waste containers within the biological safety cabinet before starting the experiment in order to minimize the movement of hands.
- Utilize aseptic technique at all times.
- Move arms using straight in and straight out movements, as opposed to sweeping arms in a sideways motion which displaces more airflow, creating turbulence.
- Flames in cabinet can damage the HEPA filter, use flame with pilot light for momentary activation if absolutely necessary or use a micro-incinerator.
- Collect waste/sharps within cabinet, use facility approved containers.
- If a spill occurs within the BSC, keep the unit running and immediately implement spill clean up procedures.

Biosafety Cabinet Placement

- Position BSC away from overhead supply diffusers, sprinkler/fire alarm systems, door openings, benchtops, and heavy traffic patterns within the room, minimize air and people movement near the work face. Please maintain the following minimum distances when placing BSCs:
 - 40" of undisturbed space around the face of the BSC as well as at least 80" away from the opposing wall and at least 60" from opposing bench top or areas with intermittent traffic
 - 12" of distance from adjacent walls relative to the face of the BSC as well as 40" away from any adjacent bench top
 - 12" from any columns
 - 120" between opposing BSCs and at least 40" between BSCs along the same wall
 - o 68" between BSCs along perpendicular walls
 - 60" from any doorway behind the workspace and at least 40" away from adjacent doorways. Note that it is not recommended to place BSCs near any doorway.

Biosafety Cabinet Disinfection

- Always clean the BSC as well as other equipment before and after use.
 - Note that a UV light, if present, does not provide adequate disinfection. All BSC disinfection procedures require the use of a facility approved disinfectant as determined by risk assessment.
 - Never put you head inside the BSC, utilize mechanical devices to reach far areas.
 - Before work in the BSC is initiated and before initial disinfection, let the unit run for five minutes to let the air inside purge.
 - After work in the BSC is completed and before final disinfection, let the unit run for five minutes to let the air inside purge.

Biosafety Cabinet Certification

- All BSCs at UMBC require an in date certification before use.
- BSCs require certification every year, when major repairs are made, or whenever the unit is moved
- It is the responsibility of supervisors, building managers, or PIs to notify ESH when they have repaired, relocated, or purchased a BSC.
- The Office of Environmental Safety and Health (ESH) is responsible for scheduling

annual certifications of all BSCs on campus.

 The maintenance or replacement of a BSC is the financial responsibility of the department/person responsible for the respective BSC. Any additional inspections outside of ESHs annual scheduled inspections shall be the responsibility of the person/department requesting the inspection.

It is important to note that BSCs **do not** provide the same level of protection (if any) as Chemical Fume Hoods (CHF) when working with volatile chemicals. Although very small amounts of volatile chemicals may be used in hard ducted Class II Type B cabinets, it is strongly recommended to handle all volatile chemicals within a chemical fume hood.

7.2 Laminar Flow Hoods & Clean Benches

Laminar Flow Hoods (LFH) and clean benches work by discharging HEPA filtered air across the work area in the direction of the operator. This provides protection to the sample but not to the operator or the environment. Typical uses for LFHs include microfabrication or dust free assembly of electronics or other sterile equipment. The Office of Environmental Safety and Health does not schedule annual inspections of LFHs, certification is the responsibility of individual/department who owns the unit.

It is important to note that laminar flow hoods are not equivalent to biosafety cabinets and shall never be used as a substitute for such. **Under no circumstances may biohazardous material be used in a laminar flow hood.** Individuals using laminar flow hoods must be trained in the proper operation, maintenance, and safe practices before starting work. All laminar flow hoods should have a notification sign (Appendix O) that advises against the use of hazardous chemicals or biohazardous material when working with this equipment.

7.3 Centrifuges, Sonicators, and Agitators

Centrifuges

Centrifuges are a very powerful tool used for many routine procedures in the biological laboratory. Centrifuges can spin at extremely high rpms and impart great energy onto samples, thus increasing risk of aerosol generation. This equipment can also present a physical hazard due to mechanical stress or fatigue. When utilizing centrifuges in the laboratory, the following guidelines should be followed:

- Individuals must be trained in the proper operation, disinfection, and safe practices before starting work.
- Wear appropriate PPE such as face/eye protection, gloves, gown, or other PPE as determined by risk assessment
- Inspect all tubes for deficiencies, affix lids if present
- Disinfect equipment before and after use
- Balance all loads, use simulated samples if necessary to counterbalance. Ensure tubes are properly seated in rotor.
 - Do not overload the rotor, consult manufacturer for maximum weight rating
 - Avoid overfilling tubes or other containers. Angled rotors may drive liquid up the side.
- Risk group 2 Biohazardous material may be centrifuged on an open bench top **only** when utilizing centrifuge safety cups, buckets, or a sealed rotor. All other centrifuging of risk group 2 material shall occur within a BSC as determined by risk assessment.
 - o Inspect gaskets before each use, replace gaskets if cracked or broken.
 - Biohazardous material should be loaded and unloaded within a certified biosafety cabinet. The BSC should be turned on when in use.
 - Decontaminate tubes as they are removed from the centrifuge safety cup/rotor.
- Ensure rotor, rotor lid, and unit lid is fully secured/latched before starting cycle
- Choose an appropriate speed for the material and tubes being used. Consult manufacturer for maximum rate speeds for tubes and materials
- When centrifuging biohazardous materials, wait 15 minutes **after the rotor comes to a complete stop** before opening the lid.
- Clean and maintain rotors with appropriate facility approved, non-corrosive disinfectant.
- If a spill occurs within the centrifuge inside a BSC: shut the unit down immediately, keep the BSC running and **keep the centrifuge lid closed**, implement spill clean up procedures.
- If a spill occurs within the centrifuge outside of a BSC: shut the unit down
 immediately and keep the centrifuge lid closed, wait for aerosols to settle and
 move unit to BSC or other form of containment if possible and implement spill clean
 up procedures.
- Establish a schedule for preventative maintenance. Be sure to include regular cleaning and equipment/accessory inspection.

- Never use a rotor that has been dropped
- Retire rotors and other accessories after the manufacturer's recommended lifespan.

Sonicators

Sonicators use sound energy to disrupt or agitate particles in a sample. This process can create many aerosols and has been linked to multiple laboratory acquired infections. When utilizing sonicators in the laboratory, the following guidelines should be followed:

- Individuals must be trained in the proper operation, disinfection, and safe practices before starting work.
- Wear appropriate PPE such as face/eye protection, gloves, gown, or other PPE as determined by risk assessment
- Inspect all tubes/equipment before using in the unit. Do not use broken or otherwise malformed equipment
- Disinfect equipment before and after use
- Ensure proper fluid level in sonicator, routinely replace.
 - Dispose of old sonicator fluid the same as you would the biohazardous material being sonicated.
- Always use secondary containment when sonicating biohazardous material.
 - Biohazardous material should be loaded, unloaded, and sonicated within a certified biosafety cabinet. The BSC should be turned on when in use.
- Wear adequate ear protection when sonicating. Consult manufacturer for recommended net reduction rating of ear protection.
- Allow aerosols to settle for at least 15 minutes before opening tubes/containers.

Agitators

Agitation, homogenization, and vortexing of biohazardous agents are frequently used techniques in the biological laboratory. As with many other techniques the generation of aerosols is a major concern and should be mitigated using a combination of engineering controls and operating procedure. When utilizing agitators in the laboratory, the following guidelines should be followed:

- Individuals must be trained in the proper operation, disinfection, and safe practices before starting work.
- Wear appropriate PPE such as face/eye protection, gloves, gown, or other PPE as determined by risk assessment

- Inspect all tubes/equipment before using in the unit. Do not use broken or otherwise malformed equipment
- Disinfect equipment before and after use
- Do not overfill container, liquid may be forced to the sides.
- Ensure tubes/containers are securely capped
- The agitation of higher risk biohazardous agents (risk group 2 and above) shall be performed within a certified biosafety cabinet.

7.4 Chemical Fume Hoods

A Chemical Fume Hood (CFH) is a piece of equipment used to control the ventilation of the work area contained within. CFHs are designed for working with volatile toxic chemicals as the ventilation pulls air away from the user. The two major designs of CFHs are ducted and ductless, the later recirculates filtered air back into the laboratory space while the former dispenses filtered air to the outside. The vast majority of CFHs at UMBC are ducted and require an annual inspection to ensure compliance. Annual inspections include average face value readings, sash operation, and qualitative smoke testing. Annual inspections are the responsibility of the Office of Environmental Safety and Health, maintenance or replacement of a CFH is the financial responsibility of the department/person responsible for the respective CFH. Any additional inspections outside of ESHs annual scheduled inspections shall be the responsibility of the person/department requesting the inspection. It is important to understand that chemical fume hoods do not provide any protection when working with biohazardous materials. Chemical fume hoods are not equivalent to biosafety cabinets and shall never be used as a substitute for such. **Under no circumstances may biohazardous material be used in a chemical fume hood.**

Listed below are some general guidelines for safe chemical fume hood operation:

- Individuals must be trained in the proper operation, cleaning, and safe practices before starting work.
- Wear appropriate PPE such as gloves, aprons, etc. If a respirator is needed then the hood should be inspected as it may require service
- Only use a fume hood that has been inspected within one (1) year of the date listed on the orange inspection sticker. Contact ESH at 5-2918 or esh@umbc.edu if fume hood requires inspection.
- Operate the hood using the proper sash height. During operation keep the sash at or below the height listed on the orange inspection sticker. The sash may set above the listed height only for experimental set up as required.

- Minimize pedestal traffic or other sources of air turbulence such as air conditioners or fans.
- Keep the hood clean and organized. Do not block airflow by placing large items in the hood or by blocking the vents. If large items are required, raise them up ~2 inches to allow for better airflow.
- Do not remove any panels located on the inside or outside of the hood. Older fume hoods are documented to have fireproofing on panels, also the removal of panels can interfere with proper airflow.
- Conduct experiments in the middle of the hood at least 6 inches from the sash opening to decrease the likelihood of material escaping.
- Do not use perchloric acid unless the hood and ducting is specifically designed for such use. Perchloric acid can severely damage regular fume hoods and associated ducting.
- Close sash when done with the experiment/leaving the hood. This prudent practice conserves energy as well as provides additional containment.
- If a fume hood is not functioning properly or is believed to require maintenance, contact UMBC ESH at 5-2918 or <u>esh@umbc.edu</u> to schedule a test of the unit. If a fume hood requires repair, contact Facilities Management Work Control 5-2550 to schedule an appointment.

7.5 Pipettes

There are many different types of pipettes and virtually all of them can be found in the biological laboratory. Since pipettes are used to transfer liquids, they have the potential to generate aerosols. In order to create a safe laboratory atmosphere, minimize splashing, and inhibit aerosol production, the following guidelines should be followed.

- Individuals must be trained in the proper operation, disinfection, and safe practices before starting work.
- Wear appropriate PPE such as face/eye protection, gloves, gown, or other PPE as determined by risk assessment.
- Check pipettes and pipette tips before use. Inspect for cracks, chips, or otherwise malformed areas.
- Manipulation of high risk biohazardous agents shall be performed within a certified biosafety cabinet.
- Gently collect and release liquid. Be careful not to forcefully expel or otherwise agitate sample liquid.
- Properly decontaminate pipettes that have overdrawn biohazardous material into the operating mechanism, follow manufacturer recommendations.

7.6 Autoclaves and Sterilizers

An effective way to decontaminate waste is required for all biological laboratories regardless of containment level. For the vast majority of laboratories this is accomplished using an autoclave which utilizes steam to sterilize. Other methods of sterilization may include but are not limited to dry heat sterilization, chemical sterilization, ionizing radiation, incineration and microwaves. A proper sterilization method should be dictated by a thorough risk assessment. Regardless of the sterilization method chosen for a particular laboratory, the following guidelines should be followed:

- Individuals must be trained in the proper operation and safe practices before starting work.
- Always follow manufacturer's recommendations for operation and maintenance
- Wear appropriate PPE such as face/eye protection, gloves, gown, or other PPE as determined by risk assessment.
- Maintain a logbook (Appendix R) for the autoclave/sterilizing unit that includes the following:

General information

- Unit information such as manufacturer, model number, serial number, and location
- Any maintenance or repair done

Use information

- Equipment user
- Date used
- Material decontaminated
- Quantity of material decontaminated
- Process type
- Run time/cycle time
- Chemical/biological indicator used as well as changes (if any) observed
- Validate/spore test all sterilizers every 30 days using an adequate challenge strain for the method chosen.
 - A simulated load that mimics the material expected to be decontaminated (sans any biohazardous material) should be made up (e.g microisolator cages and bedding).

- Validation should be conducted for each cycle that differs in temperature, time, or any other parameter.
- o Do not use a sterilizer if it has not been validated
- Dispose of sterilized material according to facility SOPs that are in accordance with section 11.5 of this manual.

8.0 Protocol Submission and Review

In order to maintain a safe environment and ensure compliance with all local, state, and federal guidelines, the UMBC Institutional Biosafety Committee (IBC) regularly reviews protocols pertaining to any research or teaching on UMBC campus that involves recombinant DNA, synthetic DNA, transgenic animals, and biohazardous material. For more information on protocol submission and review process visit <u>https://research.umbc.edu/umbc-institutional-biosafety-committee-overview-2/</u>

8.1 Do I Need IBC Approval?

IBC approval or registration is **required** for any research, regardless of funding, and teaching labs that involve any of the following:

- Biohazardous material
 - Includes but is not limited to: bacterium, fungi, algae, potentially infectious agents and <u>select agents</u>.
- Non-exempt experiments as defined in the NIH Guidelines Section III-A to Section III-E
- Human tissues, fluids, cell lines, and exempt recombinant DNA
 - IRB approval may be required as well
- Animals, animal fluids and animal cell lines (including transgenic animals)
 - IACUC approval may be required as well

Note: IBC registration is required even if your recombinant DNA research is considered exempt. Contact the Office of Research Protections (ORPC) at 5-2737 or <u>compliance@umbc.edu</u> for questions or assistance with form submission.

8.2 Obtaining IBC Approval

In order to obtain IBC approval, the investigator or lab instructor must complete the following steps:

- Completion and submission of an IBC <u>Research Application Form</u> or an <u>IBC</u> <u>Teaching Lab Application Form</u>. The application form should be submitted electronically to <u>compliance@umbc.edu</u>. Forms can be found at <u>https://research.umbc.edu/umbc-institutional-biosafety-committee-overview/</u>
- 2. Complete appropriate training as outlined in https://research.umbc.edu/2041-2/
 - Please note that certain trainings should be repeated on a recurring basis. Training such as Blood Borne Pathogens (BBP) training must be repeated annually.
- **3.** Wait for the reviewal of submitted protocol conducted at the next scheduled IBC meeting.
 - a. Any recommendations or notes ensuing the IBC review must be adequately addressed
- **4.** Post approval, submit an <u>Annual Update Form</u> or a <u>Modification to Research Form</u> if applicable.
 - a. Annual Update Forms must be submitted on an annual basis to continue research.

Note: If an ESH hazardous material reviewal is required for the IBC application, please complete an ESH Hazardous Materials Reviewal Form and submit to <u>esh@umbc.edu</u>. A copy of the reviewal form can be found in Appendix J of this manual.

8.3 IACUC

Institutional Animal Care and Use Committee (IACUC) approval is required for all animal research carried out in university facilities as well in the field. All projects require approval prior to the start of the actual use of animals and approvals are granted for a three-year period with research activities reviewed annually. For more information on the protocol creation and submission process visit <u>https://research.umbc.edu/umbc-iacuc-forms-and-procedures/</u> or call the Office of Research Protections (ORPC) at 5-2737

8.4 IRB

Institutional Review Board (IRB) approval is required for all research involving human participants. All projects require approval prior to the start of research and are continuously monitored for compliance. For more information on the protocol creation and submission process visit <u>https://research.umbc.edu/post-approval-protocol-monitoring-papm/</u> or call the Office of Research Protections (ORPC) at 5-2737

9.0 Laboratory Procedure Guidelines and Other Requirements

The sections below denote specific requirements and procedures that pertain to safe research in the biological laboratory.

9.1 Training

Training is an integral part of maintaining a safe environment in any setting, proper training being especially important in the biological laboratory. Training is required for all persons working with biohazardous or potentially biohazardous materials. UMBC utilizes Webnet online safety training as well as CITI Program (Collaborative Institutional Training Initiative) online training in order to fulfill training requirements. Required trainings for individuals working in the biological laboratory are as follows:

- UMBC Laboratory Safety (Provided by CITI or Webnet)
- Biosafety Complete Training Series (Provided by CITI)
- Hazard Communication Part 1 & 2 (Provided by CITI or Webnet)
- OSHA Personal Protective Equipment Training (Provided by CITI)
- NIH Recombinant DNA Guidelines (As needed, provided by CITI)
- Bloodborne Pathogens (Provided by CITI or Webnet, required if working with blood or other potentially infectious materials, must be repeated annually)

Information on how to access required trainings can be found on the UMBC ORPC website at <u>https://research.umbc.edu/2041-2/</u>. Upon completion of required training, individuals are encouraged to review any or all of the other non-required training provided. Following the successful completion of online training, evidence of completion such as certificates should be maintained. An individual may request additional online or in person training by contacting the Office of Environmental Safety and Health at 5-2918 or <u>esh@umbc.edu</u>

Note: <u>All required trainings must be completed **on a recurring basis**. If trainings are not completed an individual may not work in the laboratory. The above trainings are considered the minimum for all individuals in the laboratory, these trainings do not replace any area specific training which is the responsibility of the Principal Investigators (PI), laboratory managers, supervisors, and instructors.</u>

9.2 Standard Operating Procedures

All principal Investigators (PI), laboratory managers and supervisors, and instructors are required to create or adopt a specific set of Standard Operating Procedures (SOPs) that outline common processes conducted in the biological laboratory. At a minimum there should be SOPs that address the following:

- Spill/Incident response
- Waste disposal
- Material transfer and transport
- Disinfection of equipment
- Personal Protective Equipment
- Operation and maintenance of specific equipment used
- Post exposure response

All individuals in the laboratory should have access, have read, and be trained annually on laboratory specific SOPs. A generic standard operating procedure template can be found in Appendix C of this manual. Contact the Office of Environmental Safety and Health at 5-2918 or <u>esh@umbc.edu</u> for questions or SOP reviewal.

9.3 Containment

All biohazardous materials must be in sufficient laboratory containment (as determined by risk assessment) at all times even during transport where the material should be packaged such that all DOT and/or IATA standards are met. If for any reason there is a loss of containment, individuals should follow the proper course of action outlined in their specific SOPs and correct the issue as soon as possible. Any loss of containment should be reported to the Office of Environmental Safety and Health.

Containment not only applies to biohazardous materials but to any toxic or potentially harmful chemicals. It is prudent practice to have all chemicals stored in proper containers and placed in secondary containment such as totes or spill pallets. Flammable chemicals should always be stored in a flammable storage cabinet and corrosives should never be stored above eye level. It is imperative that all chemical and biological containers remain closed when not in use as to mitigate the chance of a spill.

9.4 Transporting and Shipping

All biohazardous material must be properly packaged in appropriate containment prior to leaving the laboratory. Biohazardous material must be packaged for transport whenever it leaves the containment of a laboratory, even if the destination is within the confines of the same facility. Only individuals who have been annually trained on packaging and transporting biohazardous material may do so, contact the Office of Environmental safety and Health by calling 5-2918 or by email at <u>esh@umbc.edu</u> for questions regarding training or transport.

General Steps for Transporting Hazardous Materials.

- 1. **Complete required training**. Complete all required online or in person training as required by the Office of Environmental Safety and Health.
- 2. **Obtain hazard information on material to be transported**. This information includes things such as reactivity, toxicological data, physical data, etc.. A Safety Data Sheet (SDS) should be included if available.
- 3. Ensure recipient of material has all required training, permits, and facilities for the incoming material.
- 4. Obtain proper packing materials and package according to package instructions and ESH guidance. Ensure package is properly packaged and labeled and in accordance with all local, state, federal, and international guidelines as applicable.
- 5. **Retain copies of any paperwork.** Transportation paperwork should be retained and made available upon request to ESH or any local, state, or federal agencies.

The transport of biohazardous materials can be characterized in two sections, on campus transport and off campus transport.

On Campus Transport of Biohazardous Materials

On campus biohazardous transportation is defined as transporting any type or amount of biohazardous or potentially biohazardous material from one laboratory or building to a different laboratory or building <u>within the confines</u> of the main UMBC campus (1000 Hilltop Circle, Baltimore, MD 21250). On campus biohazardous transportation must abide by the following guidelines:

- Biohazardous material must be placed in a sealed, leak proof primary container that is suitable for the material (e.g.non-porous material for liquid)
 - Animal carcasses and associated material should be double bagged for the primary container prior to placement in the secondary container.
- Primary containers must be placed in a sealed, leak proof, puncture resistant, unbreakable secondary container.
 - Adequate absorbent material must be placed between the primary container(s) and the secondary container as to catch any spills
 - Secondary container must be packed such that any extraneous movement such as dropping will contain packaged material within
- Secondary container is labeled with the quantity and amount of biohazardous material contained therein. (e.g *HEK293 Cells, 9 3mL vials*)
- Secondary container is labeled with the universal biohazard symbol that conforms to OSHA 1910.145 (Specifications for accident prevention signs and tags) An example can be found in Appendix B of this manual.
- Transport properly packaged material using a dedicated cart whenever possible.
- Properly packaged material shall never be transported in passenger elevators or along areas of heavy traffic. Utilize freight elevators and areas of low traffic.
- Be familiar with and have the ability to implement loss of containment SOPs
- Select agent transportation requires quantity and location logs to be maintained
- Before transporting large quantities of biohazardous material or materials of significant risk as determined by risk assessment, notify the Office of Environmental Safety and Health by calling 5-2918 or by email at <u>esh@umbc.edu</u>

Off Campus Transport of Biohazardous Materials

Off campus biohazardous transportation is defined as transporting any type or amount of biohazardous or potentially biohazardous material from one laboratory or building to a different laboratory or building **outside** the confines of the main UMBC campus. The transport of biohazardous materials outside of the contiguous property of UMBCs main campus (1000 Hilltop Circle, Baltimore, MD 21250) is subject to federal and/or international regulations.

U.S. Federal Regulatory Organizations

- U. S. Department of Transportation (DOT) 49 CFR Parts 171-180
- U. S. Public Health Service (PHS) 42 CFR Part 73
- U. S. Postal Service (USPS) 39 CFR Part 20 & 111
- U. S. Department of Labor, OSHA 29 CFR 1910.1030
- U. S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) 9 CFR Part 121 & 7 CFR Part 340
- U.S. Department of Commerce (DoC) 15 CFR Parts 730-799
- U. S. Fish & Wildlife Service (50 CFR Part 13)

International Regulatory Organizations

- International Air Transport Association (IATA)
- International Civil Aviation Organization (ICAO)
- United Nations Recommendations of the Committee of Experts on the Transport of Dangerous Goods

It is important to understand that these different regulatory organizations may have different shipping or permit requirements for a given material or quantity of material. Also note that specific carriers may also have more stringent requirements in order to utilize their services (e.g. FedEx and UPS will not ship select agents). If one does not abide by the applicable regulations, dangerous situations and costly fines will ensue. It is the responsibility of the shipping party to ensure all relevant regulations are followed. Questions may be directed to the Office of Environmental Safety and Health by calling 5-2918 or by email at <u>esh@umbc.edu</u>

Below are useful links regarding permits for transport of animals or etiologic agents:

- <u>Code of Maryland Regulations (COMAR) Animal Health Regulations and Executive</u> Orders (COMAR 15.11.01- 15.11.19)
- Maryland Department of Natural Resources Scientific Collection Permit/License
- U. S. Fish & Wildlife Service (50 CFR Part 13)
- USDA APHIS Veterinary Services
- USDA APHIS Biotechnology Regulatory Services (BRS)
- USDA APHIS Plant Protection and Quarantine Program (PPQ)
- <u>CDC Import Permit Program (IPP)</u>
- U. S. Department of Commerce Export of Biological Agents (15 CFR, Parts 730-774)

Keep in mind that Select Agent transfer, use, and possession will require further compliance under CDC and USDA federal regulations as outlined in 42 CFR Part 73, 9 CFR Part 121 and 7 CFR Part 331. Select Agents are defined as a set of biological agents or toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal health and safety, or to animal or plant products. The Select Agent list can be found in Appendix I of this manual. Below are useful links for working with Select Agents:

- CDC/APHIC Federal Select Agent Program
- Select Agent and Toxin List
- <u>CDC/APHIS Select Agent Forms</u>

When in doubt, always ask for help. The Office of Environmental Safety and Health is more than happy to assist in the process.

9.5 Medical Surveillance

All individuals working with biohazardous agents shall know the dangers associated with that agent as well as be aware of any signs or symptoms associated with diseases caused by that agent. In some instances, an advanced medical surveillance program may be implemented as determined by the risk assessment. This medical surveillance program shall apply to all individuals working in the laboratory and may consist of immunizations, surveillance testing, medical evaluations, treatment, and baseline serum sample storage. A thorough risk assessment will determine if medical surveillance is required prior to the start of working with biohazardous materials. If an individual feels that a medical surveillance program is needed or requires review please contact the Office of Environmental Safety and Health by calling 5-2918 or by email at <u>esh@umbc.edu</u>

9.6 Recordkeeping

It is prudent practice to maintain records in the biological laboratory. The ability to review properly kept records can greatly assist in after action reporting as well as regulatory compliance inspections. Listed below are some examples of records that all biological laboratories should maintain:

- Safety Data Sheets (SDS)
 - All laboratories must maintain a collection of Safety Data Sheets for every harmful or potentially harmful agent used. SDSs can be physical or electronic and must be made available to all individuals working in the laboratory.
- Training Records
 - A record of all required training as well as any area specific training shall be maintained.
- Document Reviewal
 - All individuals working in the laboratory shall review the following laboratory specific documents on an annual basis as applicable. This reviewal should be documented in an Annual Review Log that is maintained by the laboratory managers, supervisors, and PIs:
 - Laboratory biosafety manual
 - Laboratory specific standard operating procedures (SOPs)
 - Exposure Control Plan (as required by 29 CFR 1910.1030)
 - Emergency Response Plan
 - Chemical Hygiene Plan
 - Laboratory Safety Guide
 - Occupational Health & Safety Plan
 - Laboratory Animal Facility Occupational Health & Safety Plan
 - Medical surveillance program
- Medical Records
 - Any medical records required for a medical surveillance program such as vaccinations records or vaccination declination forms shall be

maintained by the employee or their medical practitioner.

- Engineering controls and safety equipment testing/certification
 - Records of testing, certification, repair, or maintenance for the following equipment shall be maintained:
 - Autoclaves, cage washers, and sterilization equipment
 - Biological Safety Cabinets (BSC), testing organized by UMBC ESH
 - Chemical Fume Hoods (CFH), testing provided by UMBC ESH
 - Emergency shower testing provided by UMBC ESH
 - Emergency eyewash testing. Should be conducted weekly by laboratory personnel.
- Logs
 - The following logs shall be maintained as applicable:
 - Select agent use and transfer logs (required for select agent research)
 - Sterilization logs (as needed)
 - Room duty logs (as needed)
- Shipping Papers
 - Any papers, manifests, dangerous goods declarations, or documents relating to the shipping of hazardous materials shall be maintained.

Any questions concerning recordkeeping can be referred to the Office of Environmental Safety and Health by calling 5-2918 or by email at <u>esh@umbc.edu</u>

10.0 Incident Response

Many different kinds of incidents/accidents can occur in the biological laboratory, even the safest practices and procedures have some degree of inherent risk associated with them. It is important to understand that incidents will occur regardless of the experience of individuals, equipment used, or controls utilized within the laboratory. Understanding the proper response or SOP for a given incident will greatly decrease the associated impacts. Questions concerning incident response, or assistance with responding to an incident can be referred to the Office of Environmental Safety and Health by calling 5-2918.

Note: All laboratory related incidents must have a <u>Laboratory Incident Report Form</u> completed as soon as possible **after** the incident is stabilized. Form may be submitted online at <u>esh@umbc.edu</u> or in person, a copy of the form can be found in Appendix E of this manual.

10.1 Biological Spills

Biological spills can occur anytime when biohazardous or potentially biohazardous material is released from containment, regardless of the mechanism of release. All biological laboratories should have within their SOPs a section denoting the laboratory specific procedures for responding to a spill. Below are some general guidelines which all biological laboratories should follow.

- Have the following spill materials readily available:
 - Absorbent material such as paper towels.
 - A facility approved disinfectant solution that is appropriate for the agent being worked with.
 - Proper PPE as determined by risk assessment such as gloves, gown, surgical mask, eye protection, coveralls, or footwear coverings.
 - $\circ \quad \text{Autoclave bags}$
 - o Sharps containers
 - Mechanical device for picking up broken glass or sharps
- Minimize personal exposure
 - Notify others of spill and cordon off area as necessary
 - o Wait for aerosols to settle
 - Always wear proper PPE as determined by risk assessment
 - Seek medical attention if any injury or exposure occurred, notify ESH at 5-2918
 - Ask for help if the spill is large or complex, contact ESH at 5-2918
- General spill guidelines
 - Wear proper PPE as determined by risk assessment
 - Utilize disinfectant solution that is appropriate for agent being worked with
 - o Wait for aerosols to settle if spill occurs outside BSC
 - Place absorbent materials on spill, then start to pour disinfectant around the outside circumference of the spill slowly working towards the middle.
 - Allow for proper contact time of disinfectant
 - Handle all glass and absorbent material with a mechanical device
 - Dispose of all sharps in a sharps container

- Discard all used spill materials in a biohazard container and properly sterilize.
- o Wash hands after cleanup procedures

A detailed example of a spill SOP can be found in Appendix D of this manual.

10.2 Injury or Exposure Involving Biological Materials

In the event of injury and/or exposure to biohazardous material seek medical assistance immediately. Any injury or exposure should be reported to the Office of Environmental Safety and Health at 5-2918 following medical treatment. Below are some guidelines to assist in responding to an injury and/or exposure to biohazardous materials.

For Severe Injuries

- Call 911 or seek appropriate medical assistance. Individual may seek medical care at a provider of their choice.
- Attempt to contain any contaminated clothing, equipment, or other materials that can pose a hazard to medical personnel, notify medical personnel prior to arrival.
- Provide relevant SDSs and information about agent to responding personnel
- Notify ESH at 5-2918

Splashes to Eye

- Immediately flush effected area with a gentle stream of clean tepid water for at least 15 minutes, be sure to hold eyelid open.
- Seek appropriate medical assistance as required. Individual may seek medical care at a provider of their choice.
- Notify ESH at 5-2918

Splashes on Skin

- Immediately wash effected area thoroughly with soap and clean tepid water for at least 15 minutes.
- Seek appropriate medical assistance as required. Individual may seek medical care at a provider of their choice.
- Notify ESH at 5-2918

Needle Sticks/Punctures and Lacerations to Skin

- Immediately wash effected area thoroughly with soap and clean tepid water for at least 15 minutes.
- **Do not** squeeze or "milk" the puncture site in an attempt to prevent additional infection.
- **Do not** put surface disinfectant solution that is used for disinfecting equipment on effected area.
- Control any severe bleeding as appropriate.
- Seek appropriate medical assistance as required. Individual may seek medical care at a provider of their choice.
- Notify ESH at 5-2918

If an individual believes they have been exposed to biohazardous agents or have a laboratory acquired infection (LAI) they should immediately seek medical attention, notify their supervisor, and notify the Office of Environmental Safety and Health. It is imperative that any injury/exposure or possible injury/exposure to biohazardous agents be reported. Timely reporting will allow for the initiation of an incident investigation which includes a thorough risk assessment as well as the implementation of risk mitigation controls in order to better protect effected individuals.

10.3 Building Emergencies or Loss of Power

During the event of a building emergency or loss of power it is important to follow all established laboratory/facility specific SOPs. It is important to remember that all actions should conducted with the intent to preserve human life in the safest way possible. Listed below are guidelines to assist in dealing with building emergencies or a loss of power

Building Emergencies

- Ensure emergency contact information is up to date and that all individuals in the laboratory have this information, notify emergency contact if situation occurs.
- If required, leave the building immediately. Do not save samples or finish an experiment. Place any hazardous material in adequate containment and perform all required exit procedures quickly and safely.
- Notify others of the emergency and contact UMBC Police (5-5555) or

emergency services (911) if necessary.

 Do not re-enter building unless directed to do so by emergency personnel.

Power Outage

- Ensure emergency contact information is up to date and that all individuals in the laboratory have this information, notify emergency contact if situation occurs.
- Prior to outage put all essential equipment on emergency power circuits (red outlets) or uninterrupted power sources (UPS) and always use proper surge protectors for sensitive equipment.
- Make a list of all equipment that must be reset, recalibrated, or reprogrammed after power returns.
- During a power outage ensure all hazardous materials are in proper containment. If working in a BSC, close all hazardous material containers and place in proper containment. Close the BSC sash and leave note on BSC as it needs to be disinfected upon reentry.
- Do not re-enter building until if: the fire alarm horn/strobes are active, power is still off/lights are unable to be turned on, or if exit signs are not illuminated.

10.4 Security Breach

As defined in the BMBL, Biosecurity is intended to prevent loss, theft or misuse of microorganisms, biological materials, and research-related information. This is achieved by adhering to specific parameters concerning facility, material, and information access. Embedded within all biosafety levels is a certain degree of biosecurity, despite this, a thorough risk assessment will be required to determine the need for enhanced biosecurity practices. Given that UMBC does not conduct dual use research of concern (DURC) and strictly operates within BSL-1 and BSL-2 parameters, the relative consequence of a biosecurity breach may not be as severe and is unlikely given all laboratory specific standard operating procedures are followed.

Biosecurity is a shared responsibility for every individual working in the biological laboratory. It is essential that every individual be vigilant in their efforts to seek out possible instances of a security breach and notify the appropriate entities of such findings. Examples of a possible security breach include but are not limited to:

- Unlocked doors that are normally locked
- Broken or vandalized security equipment (doors, locks, windows, etc.)
- Missing lab equipment, files, or biohazardous material
- Unauthorized persons attempting to gain access to restricted areas
- Suspicious persons loitering

If an unauthorized person is present in or attempting to gain access to a restricted area such as a laboratory, immediately contact Campus Police at (410) 455-5555. If an individual suspects a security breach has occurred, they should immediately notify Campus Police, their supervisor, and the Office of Environmental Safety and Health at (410) 455-2918

10.5 Reportable Events

Accidents, violations, exposures, and spills of a certain degree are required to be reported to the National Institutes of Health Office of Science Policy (NIH OSP) in accordance with the NIH guidelines which identify reportable events as:

- "any significant research-related accidents or illnesses to the appropriate institutional official and NIH OSP within 30 days" Section IV-B-2b-(7).
- "Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Institutional Biosafety Committee and NIH OSP" Appendix G-II-B-2-k.

Any spill, accident, exposure, near miss, or any other reportable action otherwise denoted in the *NIH Guidelines* should be reported as soon as possible to the Pl/supervisor, the Office of Environmental Safety and Health (5-2918), and the Office of Research Protections and Compliance (5-2737). In the event of injury or exposure it is imperative to seek medical attention first, incidents shall be reported within 24 hours of occurrence. Once an incident is reported, the Office of Environmental Safety and Health together with the Institutional Biosafety Committee will assess the situation to determine if the incident falls within the *NIH Guidelines* and a report will be filed, as necessary. If an individual wishes to submit a report anonymously they may fill out and submit a Laboratory Incident Report Form found on safety.umbc.edu , a copy can also be found in Appendix E of this manual.

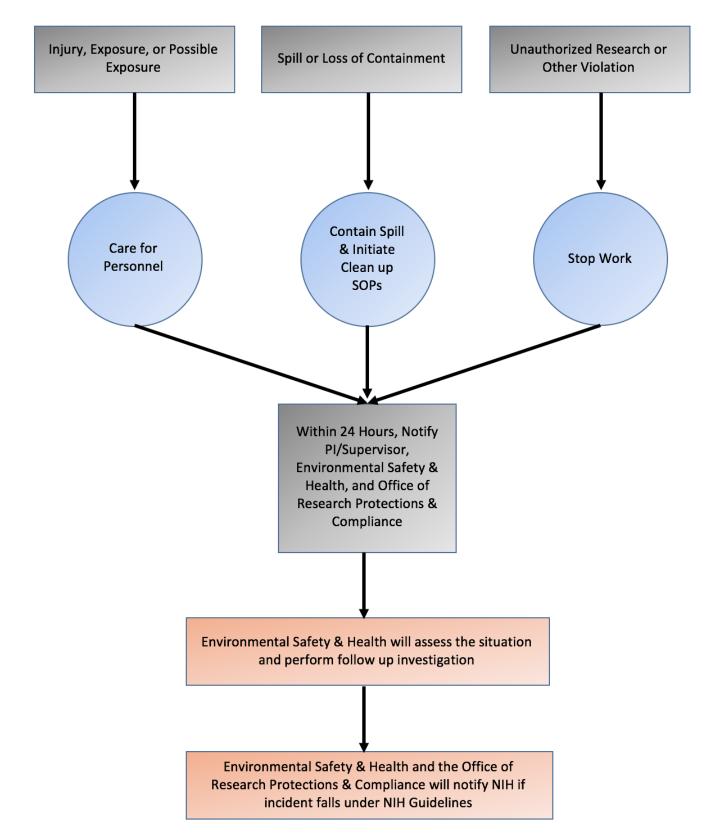


Figure 10.5 "Reportable Events Sequence of Operations". Identifies the actions proceeding a possible reportable event as defined by the NIH Guidelines.

11.0 Biological Waste and Equipment Disposal

The proper disposal of any hazardous material is paramount to protecting the surrounding environment as well as maintaining a safe laboratory. Biohazardous waste is defined as any waste or material that contains or may have come in contact with biohazardous materials. The improper disposal of biohazardous material can create a significant safety issue as well as violate local, state, and federal laws and regulations. The following guidelines are intended to assist in the safe and proper disposal of biohazardous materials. The UMBC Waste Disposal Guide found in Appendix F may be helpful in the classification, handling, and disposal of most laboratory waste. Contact UMBC ESH 5-2918 or email esh@umbc.edu for questions or assistance with waste determinations.

11.1 Responsibilities

Principal Investigators, laboratory managers, supervisors

Principal Investigators, laboratory managers, supervisors, and Instructors are responsible for ensuring the safe and proper sterilization and disposal of biohazardous materials. Laboratories should develop standard operating procedures that are specific to the agent being worked on. SOPs should denote the proper containment, handling, sterilization, and disposal for the waste generated.

The Office of Environmental Safety and Health

The Office of Environmental Safety and Health is responsible for advising on the proper disposal of biohazardous materials, assisting with clean up (as necessary), and the picking up of sharps containers and biological waste boxes. EHS is also responsible for collecting all chemical waste as well as any unused chemicals/reagents. Call 5-2918 or email <u>esh@umbc.edu</u> for questions or to schedule a waste pick up.

11.2 Classification and Handling

Biohazardous waste, as defined above, can take on many different forms. Below is a list of different forms of biological wastes, examples of those wastes, and proper handling procedures.

Solid Waste

Solid wastes are wastes that are firm or stable in shape and not liquid or fluid. Solid biological wastes can include agents themselves or equipment/PPE that have come in contact with biological agents. Some examples of solid biological waste include:

- Culture plates or medium
- Biological samples (does not include animal carcasses)
- Contaminated glass/plastic ware
- Microscope slides and cover slips
- Contaminated Gloves, gowns, face shields, and any other PPE
- Contaminated spill clean up equipment

Solid biological wastes should be collected in a puncture resistant facility approved outer container lined with a leak proof primary container that is suitable for the material (e.g. autoclavable biohazard bag inside a Biohazard waste container). Wet waste such as saturated absorbent pads require two leak proof primary containers (e.g. double bagging, each bag separately closed). This container should be located as close as possible to the point of origin of the waste. The container should be replaced before it reaches 3/4 full and packaged in accordance with the guidelines outlined in section 9.4 of this manual prior to transport if sterilization is conducted outside laboratory containment.

Liquid Waste

Liquid wastes are wastes that flow freely but have constant volume. Some examples of liquid biological wastes include:

- Liquid culture medium
- Blood, serums, or any other animal bodily fluids
- Blood, serums, or any other human bodily fluids
- Used or unused stocks of biological material

Liquid biological wastes should be collected in a rigid, leak proof primary container that is suitable for the material (e.g. labeled plastic container with tight fitting lid). This

container should be located as close as possible to the point of origin of the waste. The primary container should be replaced before it reaches 3/4 full and packaged in accordance with the guidelines outlined in section 9.4 of this manual prior to transport if sterilization is conducted outside laboratory containment.

Animal Carcasses

Animal carcasses include the deceased animal body and associated material. Animals should only be handled according to protocols approved by IACUC. All carcasses and associated material should be double bagged in leak proof primary containers and frozen. The primary containers should be replaced before it reaches 3/4 full and packaged in accordance with the guidelines outlined in section 9.4 of this manual.

<u>Sharps</u>

Sharps include any device or object that can be used to lacerate, puncture, or otherwise damage a barrier such as skin or tissue. Some examples of sharps include:

- Needles
- Scalpels
- Lancets
- Scissors
- Razor blades
- Auto injectors
- Syringes of various sizes
- Connection needles
- Contaminated broken glass

Sharps should be collected in a rigid, leak proof, puncture resistant, dedicated container specifically designed to safely house sharps. This container should be located as close as possible to the point of origin of the waste, within arms reach is best. The sharps container should be replaced before it reaches 3/4 full and packaged in accordance with the guidelines outlined in section 9.4 of this manual prior to transport if sterilization is conducted outside laboratory containment.

Do not bend, cut, shear, or otherwise separate a needle or sharps from its housing. Also do not attempt to recap or resheath any sharps. If a sharps must be handled (e.g. in the event of a sharps breakage), do so with a mechanical device.

Mixed Waste

Contact the Office of Environmental Safety and Health at 5-2918 for waste that includes a mixture of any of the following:

- Radioactive material
- Hazardous chemicals
- Toxic materials
- Biohazardous materials

The Office of Environmental Safety and Health will gladly assist in providing specific instructions for the proper classification and handling of any material, call 5-2918 or email <u>esh@umbc.edu</u> for questions.

11.3 Storage and Labeling

All biohazardous agents or potentially biohazardous agents shall be stored in adequate containment as determined by the risk assessment. Below are additional general guidelines which all biological laboratories should follow.

- All containers, equipment, or other items which contain biohazardous material require a universal biohazard symbol that conforms to OSHA 1910.145 (Specifications for accident prevention signs and tags). An example can be found in Appendix B of this manual.
- Labels should include an itemized list of contents and starting accumulation date
- Do not store waste for more than 30 days
- Do not store waste in open containers. A cover must be affixed such that no material can escape.
- When storing liquid waste use secondary containment such as totes or spill pallets.
- Storage areas located outside of the laboratory should have restricted access equal to or greater than that of the generating laboratory.

- Storage areas located outside of the laboratory should have signage that conforms to section 3.12 of this manual
- All animal cages should be labeled with an appropriate cage card that conforms to section 3.13 of this manual.
- For select agents, continuously maintain logs for all agents on hand.

The Office of Environmental Safety and Health will assist in providing specific instructions for the proper storage and labeling of any material, call 5-2918 or email <u>esh@umbc.edu</u> for questions.

11.4 Sterilization and Disinfection

The proper treatment of wastes is an important part of maintaining a safe laboratory and environment. When choosing a treatment method it is important to ldentify the contaminants, perform a risk assessment, identify potential disinfectants and processes for treatment, and compare/choose the product/procedure that yields adequate results with maximum safety. This section will denote the different treatment methods used for biological laboratory waste.

Autoclaves and Sterilizers

Autoclaves and other sterilizers are commonly used for solid materials that can withstand higher temperatures for long durations. When utilizing any autoclave or other sterilizing equipment it is imperative to follow the manufacturer's recommended operating procedures in order to ensure safe and effective function. All individuals utilizing autoclaves and sterilizers must be trained on the proper operation and safety procedures by an experienced laboratory manager, supervisor, principal investigator, or instructor. Refer to section 7.6 of this manual for more information on sterilizing equipment including requirements and considerations for operation.

Chemical Disinfection

When utilizing chemicals to sterilize biological waste it is important to understand the three C's of disinfection:

- 1. **Chemical** Select a chemical that can effectively inactivate the agent of concern
 - a. Identify the contaminants
 - b. Perform a risk assessment
 - c. Identify potential disinfectants and processes for disinfection
 - d. Compare choices and choose the product that yields adequate results with minimal risk.
- Concentration Follow the manufacturer's preparation instructions for dilution and use. Remember that a disinfectant may become more dilute when added to the material being disinfected.
- 3. **Contact Time** Utilize an appropriate contact time for the chosen chemical and concentration.

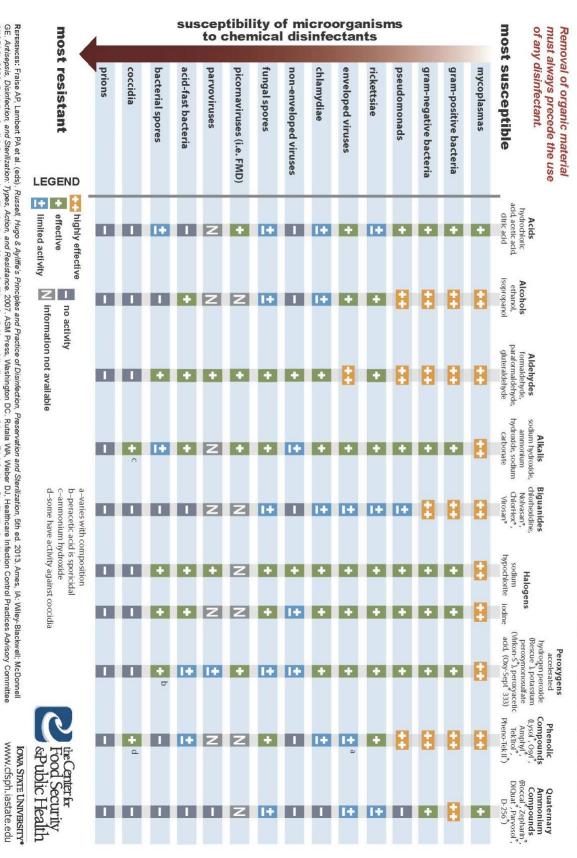
Note: Certain chemical disinfectants such as bleach should be prepared fresh each day since sunlight and air exposure can degrade effectiveness.

Disinfectant	Notes
Chlorine	Corrosive
	Inactivated by organic material
	Does not have a long shelf life. Loses concentration with exposure to light and air.
lodine	Relatively long shelf life
	Inactivated by organic material
	Concentrated solutions are less effective as iodine can bind to itself or carrier molecules
Alcohol	Highly volatile, may require multiple applications for contact time
	Highly flammable
	Lower percentage concentrations such as 70% are usually more effective than 90-100% concentrations.
Quaternary Ammonium	Long shelf life
Compounds	Lower level disinfectant.
	Inactivated by organic material
Phenol	Long shelf life
	Corrosive
	Can leave residue
	Hard water can impact effectiveness
Hydrogen Peroxide	Strong oxidizer, higher concentrations can burn skin
	Higher concentrations can be sporicidal

Table 11.4 Characteristics of Common Disinfectants

Figure 11.4 - The Antimicrobial Spectrum of Disinfectants- Center for Food Security and Public Health 2160 Veterinary Medicine Ames, IA 50011 515-294-7189 http://www.ctsph.iastate.edu/pdf/antimicrobial-spectrum-of-disinfectants

(HICPAC). 2008. Guideline for disinfection and sterilization in healthcare facilities. Available at: http://www.cdc.gov/hicpac/Disinfection_Sterilizationfoc.html; Ouinn PJ, Markey FC et al. (eds). Veterinary Microbiology and Microbial Disease. 2nd ed. 2011. West Sussex, UK: Wiley-Blackwell, pp 851-889. © CFSPH 2010-2018



This table provides general information for selected disinfectant chemical classes. Antimicrobial activity may vary with formulation and concentration. The use of trade names does not in any way signify endorsement of a particular product. They are provided as examples.

The Antimicrobial Spectrum of Disinfectants

11.5 Disposal

Following the proper sterilization of biohazardous waste, material should be disposed of according to facility approved SOPs. Questions can be directed to the Office of Environmental Safety and health at 5-2918 or esh@umbc.edu. Listed below are proper disposal methods for the different classifications of sterilized biological waste.

<u>Solid</u>

Solids that have been properly sterilized should remain in their leak proof container(s) and be placed in a standard black trash bag. Ensure contents are stable and securely tie off black trash bag such that the primary leak proof container is not visible. Dispose of in the facility designated dumpster.

<u>Liquid</u>

Liquids that have been properly sterilized and have no other hazardous properties may be disposed of in the sanitary sewer system using copious amounts of water. If you are unsure if a drain leads to the sanitary sewer system please contact the Office of Environmental Safety and Health at 5-2918 or <u>esh@umbc.edu</u>. Empty containers may then be disposed of as solid waste following proper disinfection.

Animal Carcasses

Animal carcasses, once properly packaged, should be transported according to section 9.4 of this manual to a facility designated freezer. For questions contact University of Maryland, Baltimore (UMB) Office of Environmental Health and Safety at (410) 706-7055 or the UMBC Office of Environmental Safety and Health at 5-2918 or <u>esh@umbc.edu</u>

Sharps

³⁄₄ full sharps containers that have been properly closed will be collected by the UMBC Office of Environmental Safety and Health, Call 5-2918 or email <u>esh@umbc.edu</u> to schedule a pick up. Sharps containers <u>shall not</u> be disposed of in the regular waste stream.

Mixed Waste

Mixed waste will be regulated at the discretion of the UMBC Office of Environmental Safety and Health. For questions call 5-2918 or email <u>esh@umbc.edu</u>.

Note: Ethidium Bromide contaminated material, equipment, pipette tips, and gels are considered hazardous waste and should be picked up by ESH. Call 5-2918 or email esh@umbc.edu to schedule a pickup.

See Appendix G for the UMBC Biohazardous Waste Disposal Flow Chart and Appendix F for the general UMBC Waste Disposal Guide

12.0 Laboratory Inspections and Safety Violations

The UMBC Office of Environmental Safety and Health is responsible for ensuring UMBCs compliance with all environmental safety and health regulations as well as assisting the UMBC community in maintaining a safe atmosphere for all. In order to confirm compliance and promote safety at UMBC, all research activities will be subject to periodic laboratory safety inspections.

12.1 Reporting Suspected Safety Violations

Safety is a shared responsibility for every individual on UMBC campus. It is essential that every individual be vigilant in their efforts to maintain a safe environment. Any individual, regardless of affiliation, can and should report any activities that are unsafe or not in accordance with UMBC policies as soon as possible. Notify the Office of Environmental Safety and Health at 5-2918 or at esh@umbc.edu to report suspected safety violations. If an individual wishes to submit a report anonymously they may fill a Laboratory Incident Report Form found on safety.umbc.edu and submit it to UMBC ESH, a copy can also be found in Appendix E of this manual.

13.0 Special Laboratory Considerations

Biological research can span multiple disciplines and as a result may require more specialized risk assessments and preventative measures. In such situations UMBC ESH will assist Principle Investigators, Laboratory Managers, Supervisors, and Instructors with determining the proper course of action to ensure safety and compliance.

13.1 Radiological Research in the Laboratory

Radiation or radiological research is characterized by the production or emission of ionizing radiation or particles. Radiological research, regardless of nature, is primarily regulated by the following authorities:

- U.S. Nuclear Regulatory Commission (NRC)
- U.S. Environmental Protection Agency (EPA)
- U.S. Food and Drug Administration (FDA)
- State Government (Maryland department of The Environment)

The aforementioned authorities enact regulations that concern the handling, monitoring, proper disposal, exposure limits, and material control of radiological materials. All individuals on UMBC campus conducting research with radiological materials must do so in compliance with Federal, State, and local regulations. UMBC is subject to the broad scope radiological license held by the University of Maryland, Baltimore (UMB). The following aspects of radiation safety are handled by the UMB department of Environmental Health and Safety (UMB EHS) in agreement with UMBC:

- Radiological risk assessments
- Dosimetry testing and surveillance
- Permit submission and auditing
- Site and equipment inspections
- Radiological waste determination and disposal

If an individual is planning to conduct radiological research they should contact UMB EHS as soon as possible using the following contact information:

University of Maryland, Baltimore Environmental Health and Safety Radiation Safety Officer 714 W. Lombard St. Baltimore, MD 21201 P:(410) 706-7055 F:(410) 706-8212 https://www.umaryland.edu/ehs/

It is important to note that researchers must first contact UMB EHS, be in compliance with all regulations, and have gone through the proper protocol submission and permitting procedures **PRIOR TO** acquiring, handling, purchasing, or transferring radiological material.

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Appendix A

Risk Assessment Checklist

Agent Characteristics

Agent Name (Biohazard): Strain: Size of Microorganism/Molecule: Source: **Risk Group: Prior Laboratory-Associated Infections: Route(s) of Exposure: Zoonosis: Pathogenicity:** Morbidity: **Gene Product Effects: Toxicity:** Allergenicity: **Infectious Dose: Incubation Period:**



Environmental Stability:
Disease(s) Caused:
Signs/Symptoms of Disease:
Communicability:
Host Range:
Reservoir:
Endemicity:
Vector:
Virulence:
Mortality:
Oncogenic Potential:
Physiological Effects:
Prophylaxis:
Immunization:
Booster:
Treatment:
Effective Disinfectants:



Procedural Elements

Quantity of Agent (ml/mg):

Storage:

Cell Culture Experiments:

Cell Lines Utilized:

Type/Size Flasks Utilized:

Media:

Liquid Transfer Equipment:

Pipettes:

Tips:

Scrapers:

Tissues:

Homogenization:

Mortar/pestle:

Grinder:

Blender:



Procedural Elements Continued

Incubation:
Shaker:
Rollers:
Cell Sorting:
Microscopy:
Sonication:
Other:
Concentration:
Transport (Location):
Animal Research Experiments:
Animal Species:
Other Diseases Associated with the Animal:
Caging/Housing:



 Inoculation (route):

 Needle/syringe:

 Pipettes:

 Aerosolized System:

 Restraint/Anesthesia:

 Euthanization/Necropsy:

 Tools:

 Scalpel, Scissors, Fine-tipped forceps:

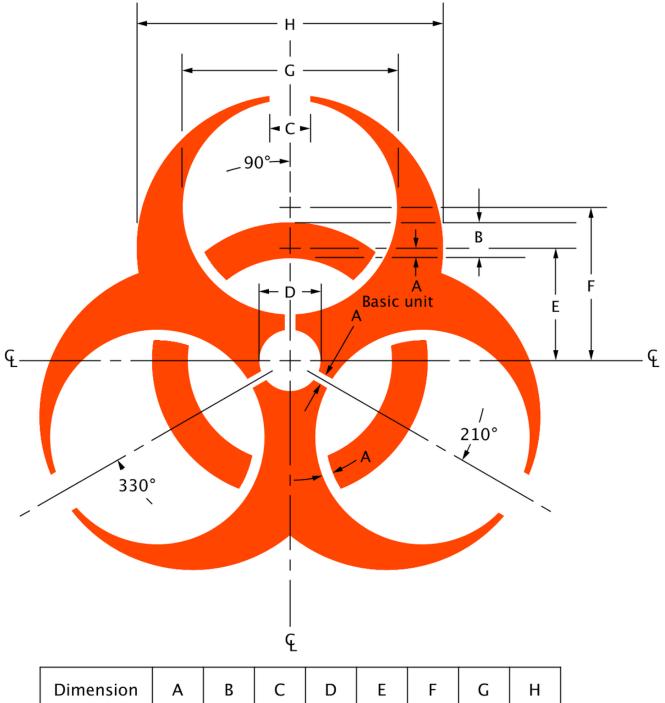
 Board, Pins, Tape:

 Transport of Samples to Cell Culture Lab:

 Other:

Appendix B

Universal Biohazard Symbol



Dimension	A	В	C	D	E	F	G	Н
Units	1	3.5	4	6	11	15	21	30

Appendix C

Generic Standard Operating Procedure Template



TITLE: Template SOP	SOP NO.: T001
EFFECTIVE DATE: 10/27/2020	REVISION NO.: 00

1. PURPOSE

1.1. Describe purpose of SOP

2. RESPONSIBILITY

2.1. Describe the responsibilities of all parties involved.

3. MATERIALS AND EQUIPMENT

3.1. Describe all materials and equipment required for proper SOP execution.

4. **DEFINITIONS**

4.1. Define any acronyms or technical language such that writing is clearly and easily understood.

5. PROCEDURE

5.1. Describe in clear detail the proper execution of standard operating procedures. Divide this section into multiple sections as required.

6. ADDITIONAL RESOURCES

6.1. Add any additional resources such as charts, pictures, forms, etc that may be helpful.

Appendix C-1

Directions for Equipment SOP Development



Directions for Equipment SOP Development

The purpose of this document is to provide guidance for PIs, Instructors, Laboratory Managers & Supervisors, and anyone working in a laboratory on UMBC property assistance in developing their own laboratory specific equipment safety plan or SOPs. This document is not intended to be a complete resource and will not cover the specifics of individual pieces of equipment. This document may contain errors or omissions; therefore, it is prudent to consult the manufacturers recommendations when developing laboratory specific safety plans or SOPs.

Key Responsibilities

- It is the responsibility of the PIs, Instructors, Laboratory Managers & Supervisors to:
 - Train all individuals on the proper use, maintenance, and administrative functions prior to the utilization of equipment
 - o Maintain a training log for all individuals working in the laboratory.
 - Ensure all laboratory specific SOPs, trainings, safety procedures, user manuals, use logs, and other administrative articles are in accordance with UMBC, local, state, and federal guidelines and policies.
 - Ensure copies of laboratory specific SOPs, safety procedures, user manuals, use logs, and other administrative articles are readily available to all individuals working in the laboratory.
 - Ensure adequate personal protective equipment is readily available to all individuals working with specific equipment.
 - o Confirm all users fill out the equipment logs appropriately.
 - Ensure all regular and periodic preventative maintenance is completed by an appropriate party and recorded in the maintenance log.
 - Remove and/or cease use of any malfunctioning equipment or equipment requiring inspection.
 - Ensure equipment is calibrated and/or certified following manufacturer recommendations.

- Refer to manufacturer or user manual when unsure of the proper safe operation, maintenance, or repair procedures for a specific piece of equipment.
- It is the responsibility of the user of the equipment to:
 - Attend all trainings on the proper use, maintenance, and administrative functions prior to the utilization of equipment.
 - o Maintain personal log of trainings.
 - Read and periodically review laboratory specific SOPs, trainings, safety procedures, user manuals, use logs, and other administrative articles related to the specific equipment utilized
 - Operate and maintain equipment as described in laboratory specific SOPs, safety procedures, user manuals, use logs, and other administrative articles.
 - Properly fill out the appropriate logs every time equipment is used.
 - Report any stoppages or malfunctions of equipment to PI, Instructor, or Laboratory Manager/Supervisor. Make note on appropriate log.
- It is the responsibility of Office of Environmental Safety and Health to:
 - As necessary, provide interpretation of manufacturer publications concerning specific pieces of equipment to assist laboratory personnel in the development of laboratory specific SOPs, trainings, safety procedures, user manuals, use logs, and other administrative articles.

1. Positively identify the equipment being used.

- Locate and record information such as the manufacturer, model, sub-model, serial number, date of manufacture, batch or group number, date of certification, and any other identifiable information.
 - Most specialized equipment will have an information plaque or label affixed at an inconspicuous location on the outside of the housing.
 - If information plaque or labels are absent, consult the manufacturer (if known) or the vendor from which the equipment was purchased.

2. Obtain proper manufacturer manuals/resources for equipment.

• Ensure resource is current and applicable to the specific make, model, group, etc as determined by the manufacturer.

3. Develop Standard Operating Procedures

- Using the resource(s) identified in step 2, outline all important information. Be sure to include the following:
 - All manufacturer information (make, model, etc) for the specific piece of equipment the SOP was developed for.
 - o All safety warnings and notes.
 - All required PPE as determined by a risk assessment that accounts for manufacturer recommendations.
 - All major operating steps, safety procedures, and maintenance instructions.
 - Emergency shut off procedures, preparation for times of inactive use, emergency power supply set up.
 - Where to find additional information.
- Compile all important information in an easy to comprehend format.
 - o Laboratory specific SOP format may include the following Elements:
 - Title that includes: SOP Name, Effective Date, Revision Number.
 - Pictures, diagrams, or figures
 - Clearly denoted sections such as:
 - Purpose
 - Responsibility
 - Materials and Equipment
 - Definitions
 - Procedure
 - Additional Resources

- Be sure to segregate out any extraneous information that is not necessary for the safe and proper use of the equipment.
- Laboratories may choose to design their own specific SOPs in whatever way they deem fit. Laboratories may adopt a format similar to the template found on <u>https://safety.umbc.edu</u>.

4. Develop training for specific equipment.

- Using the information compiled in step 3, the PI, Instructor, or Laboratory Manager/Supervisors should develop training that is suitable for all individuals utilizing the equipment. Training can include but is not limited to: PowerPoint presentations, online courses, publication reviewal, video presentations, and hands on exercises.
- Trainings should denote all hazards associated with the equipment and showcase techniques for their mitigation.
- It is helpful to highlight all major safety and operational points in trainings as well as provide reasoning behind their significance.
- Training is determined to be effective if, at the conclusion of training, the individual receiving the training can safely conduct operations, maintenance, etc for that specific piece of equipment.
 - Tests or practical exercises may be used to determine an individual's competency.
- Training should be recorded and conducted at least annually for each piece of equipment.

5. Develop logs for specific equipment

- The following logs should be created and maintained concerning each piece of equipment:
 - Run, cycle, or use log that includes equipment pedigree information (make, model, serial number, etc), date/time of use, description of use (process type, run time, etc), equipment certification or calibration date, and name of individual using equipment.

- Maintenance log that includes equipment pedigree information (make, model, serial number, etc), regular and periodic maintenance intervals, dates of completed maintenance, description of maintenance, equipment certification date, name of individual filling out log.
- Training log that includes trainer's name, trainees name, date of training, description of training, pedigree information (make, model, serial number, etc) of specific equipment trained on.
- Below is an example of an equipment use log. Note that different pieces of equipment will require different parameters be recorded (e.g. autoclaves require recording of cycle type, material type, and indicator used)

Equipment Use Log

SN: A.011059	Equipment Name: <u>Anemometer</u>
Lab: Tec 2, ESH	Make: <u>Extech</u>
Date Last Certified: 1/2021	Model: <u>SDL350</u>





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Date				
Condition Prior to use				
Start Time				
Stop Time				0
Condition After Use			5	
Description of Use/Notes				
Operator initials				

6. Review all SOPs, trainings, and logs.

- Review and inspect the following items at least annually.
 - o Equipment
 - Training, maintenance, use, and any other log related to specific equipment.
 - All SOPs related to equipment. Ensure compliance with all UMBC, local, State, and Federal policies and regulations.

Appendix D

Spill SOP Example



TITLE: Generic Biological Spill SOP	SOP NO.: BS001
EFFECTIVE DATE: 1/8/2021	REVISION NO.: 00

Generic Biosafety Level 2 Spill Response

1. PURPOSE

- 1.1 To provide guidelines and outline the proper response for biological spills in the BSL2 laboratory
- 1.2 To reduce the risk of exposure of research staff to biohazardous or potentially biohazardous agents within the research facility

2. RESPONSIBILITY

- 2.1 UMBC research faculty and staff are responsible for the implementation of this SOP. This SOP will be overseen and monitored by the respective UMBC building Facility Manager
 - 2.1.1 The Principle Investigator is responsible for ensuring:
 - 2.1.1.1 That staff working in the laboratory are adequately trained to perform the spill response procedure described.
 - 2.1.1.2 Implementation of the procedure described
 - 2.1.1.3 Appropriate personal protective equipment (PPE) is available
 - 2.1.1.4 Appropriate spill response supplies are available
 - 2.1.1.5 Biohazard Safety Data Sheets (SDS) are accessible, when available.
 - 2.1.1.6 Notification of any biological spills or loss of containment to the UMBC Office of Environmental safety and Health (5-2918)
 - 2.1.1.7 Safety procedures have been communicated to the relevant personnel
 - 2.1.2 It is the responsibility of the research staff to:
 - 2.1.2.1 Read, understand, and follow the procedures described
 - 2.1.2.2 Wear appropriate PPE and review room signage and SDS prior to implementing the procedures described.

3. MATERIALS AND EQUIPMENT

3.1 Proper PPE which may include gloves, masks, gowns, face shields, overboots, or lab coat

3.2 Facility Approved Disinfectant

- 3.3 Mechanical device for handling broken glass (tongs, forceps, autoclavable broom and dustpan, plastics scoops)
- 3.4 Sharps container
- 3.5 Absorbent towels
- 3.6 Facility approved biohazard container
- 3.7 Hand washing supplies
- 3.8 Door signs (optional)
- 3.9 Biosafety Cabinet

4. **DEFINITIONS**

- 4.1 (BSC) Biosafety Cabinet
- 4.2 (PPE) Personal Protective Equipment
- 4.3 (PI) Principle Investigator

5. PROCEDURE

- 5.1 General Spill
 - 5.1.1 Leave area and allow aerosols to disperse for at least 30 minutes before initiating spill cleanup. Close area and post warning signs if necessary
 - 5.1.2 Carefully remove contaminated clothing and PPE, place in facility approved biohazard container
 - 5.1.3 Wash any exposed skin with soap and water
 - 5.1.4 Report spill to the Principle Investigator (PI), Facility Manager, and the UMBC Office of Environmental safety and Health (5-2918)
 - 5.1.5 Assemble clean-up materials
 - 5.1.6 Don appropriate personal protective equipment (PPE)
 - 5.1.7 Handle sharp objects with mechanical device and discard in sharps container
 - 5.1.8 Cover the spill area with disinfectant soaked towels, and then carefully pour disinfectant AROUND the spill, slowly working in towards the center of the spill. Avoid enlarging the contaminated area. It may be necessary to use more concentrated disinfectant as it will be diluted by the spill
 - 5.1.9 Soak up the disinfectant and spill, and place material into a facility approved biohazard container or a sharps container.
 - 5.1.9.1 Small pieces of glass may not be visible so do not wipe surface directly with hands. Use a thick wad of absorbent towels in conjunction with a mechanical device to wipe surface.
 - 5.1.10 Spray area with facility approved disinfectant and allow it to air dry
 - 5.1.11 Wipe down area with facility approved disinfectant soaked towels and allow proper contact time

- 5.1.12 Place any contaminated towels, equipment, and PPE in a facility approved biohazard container and properly dispose of it. Any used sharps containers should also be properly disposed of at this time.
- 5.1.13 Wash hands and exposed skin with soap and water upon leaving area
- 5.1.14 Remove signs if necessary and reopen area for use
- 5.2 Spill in Biosafety Cabinet (BSC)
 - 5.2.1 If extra PPE is not required, leave cabinet turned on and begin cleanup immediately
 - 5.2.1.1 Gloves, gown, and eye/face protection are required for cleaning BSCs
 - 5.2.2 DO NOT PLACE HEAD INSIDE THE BSC TO CLEAN SPILL
 - 5.2.3 Handle sharp objects with mechanical device and discard in sharps container
 - 5.2.4 Cover spill area with facility approved disinfectant soaked towels and then carefully pour disinfectant AROUND the spill, slowly working in towards the center of the spill. Avoid enlarging the contaminated area. It may be necessary to use more concentrated disinfectant as it will be diluted by the spill
 - 5.2.4.1 If necessary, flood work surface, catch basins, and drain pans with facility approved disinfectant
 - 5.2.5 Spray or wipe cabinet walls, work surfaces, and inside front view screen with facility approved disinfectant and allow it to air dry
 - 5.2.5.1 Small pieces of glass may not be visible so do not wipe surface directly with hands. Use a thick wad of absorbent towels in conjunction with a mechanical device to wipe surface.
 - 5.2.6 Soak up disinfectant and spill and drain catch basins into facility approved biohazard container recommended for liquids
 - 5.2.7 Lift the front exhaust grill and tray, and wipe all surfaces with facility approved disinfectant and allow it to air dry. Ensure no foreign materials are in the area below the grill.
 - 5.2.8 Place any contaminated towels, equipment, and PPE in a facility approved biohazard container and properly dispose of it. Any used sharps containers should also be properly disposed of at this time.
 - 5.2.9 Wash hands and exposed skin with soap and water upon leaving area
 - 5.2.10 Report spill to the Principle Investigator (PI), Facility Manager, and the UMBC Office of Environmental safety and Health
 - 5.2.11 If the spill overflows into the interior of the cabinet, a more extensive denomination may be required, contact the UMBC Office of Environmental safety and Health for guidance.
- 5.3 Spill in Centrifuge

- 5.3.1 If a spill is identified inside the centrifuge following the end of a run, immediately close lid and leave area for at least 30 minutes to allow for aerosols to settle before initiating spill cleanup. Close area and post warning signs if necessary
- 5.3.2 If a spill is identified inside the centrifuge during the middle of a run, immediately turn off centrifuge and keep lid closed. leave area for at least 30 minutes to allow for aerosols to settle before initiating spill cleanup. Close area and post warning signs if necessary
- 5.3.3 Carefully remove contaminated clothing and PPE, place in facility approved biohazard container
- 5.3.4 Wash any exposed skin with soap and water
- 5.3.5 Report spill to the Principle Investigator (PI), Facility Manager, and the UMBC Office of Environmental safety and Health (5-2918)
- 5.3.6 Assemble clean-up materials
- 5.3.7 Don personal protective equipment (PPE)
 - 5.3.7.1 Full face protection, gown/lab coat, and gloves are required for cleaning centrifuge spills.
- 5.3.8 Transfer rotors and buckets to biological safety cabinet using facility approved secondary containment. Immerse in facility approved non-corrosive disinfectant and allow proper contact time.
- 5.3.9 Handle sharp objects with mechanical device and discard in sharps container.
- 5.3.10 Uncapped or unbroken tubes may be wiped down with disinfectant after contact time has surpassed.
- 5.3.11 Carefully wipe the inside of centrifuge with facility approved disinfectant and allow to air dry
 - 5.3.11.1 Small pieces of glass may not be visible so do not wipe surface directly with hands. Use a thick wad of absorbent towels in conjunction with a mechanical device to wipe surface.
- 5.3.12 Place any contaminated towels, equipment, and PPE in a facility approved biohazard container and properly dispose of it. Any used sharps containers should also be properly disposed of at this time.
- 5.3.13 Wash hands and exposed skin with soap and water upon leaving area
- 5.3.14 Remove signs if necessary and reopen area for use

Appendix E

Laboratory Incident Report Form

Laboratory Incident Report Form

The purpose of this form is to allow <u>any individual</u> the ability to report a safety incident or concern that is related to lab work conducted at UMBC. Information contained within this form will be kept confidential and the individual filling out this form may do so anonymously. At a bare minimum please fill out **Section 1** and the **incident description** found in Section 4 as this greatly assists the follow up investigation.

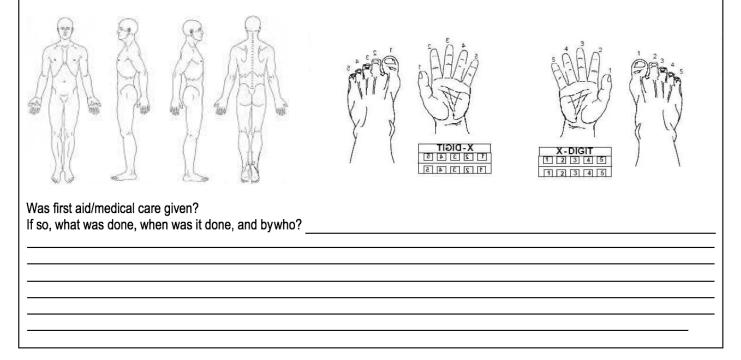
If there was an injury to a worker associated with this event please have effected individual submit an <u>Employee's First Report of Injury</u> form and have their supervisor submit a <u>Supervisor's First Report of Injury form</u> to the UMBC Office of Environmental Safety and Health **Before** competing this form. Forms can be found on <u>safety.umbc.edu</u>. First Report of Injury forms must be submitted within 24hrs of incident, visit <u>https://hr.umbc.edu/policies/work-related-injury-procedures/</u> or call (410) 455-2918 for more information.

Section 1: General Information				
Date of Report_		Date of Incident	Time of Incident	AM/PM
Incident Locatior Building	1			
Floor	Room#	Specific location		
Nature of incider	nt (select all that	apply)		
	Biological S	Spill	Unethical F	Research Practices
	🗆 Biological A	Agentexposure	□ Loss ofCo	ntainment
	Chemical S	Spill	□ Loss of Lal	boratory Animal
Chemical Exposure		Exposure	🗆 Mistreatme	ent of Laboratory Animal
	Failure to Obtain IBC Approval		🗆 Needle Sti	ck/Laceration
□ Hazardous work practices/Failure to follow SOPs		Immediate	ly seek medical attention	
Possible Laboratory Acquired Infection		following a	ny possible exposure to	
Security Breach		hazardous	• • • • • • • • • • • • • • • • • • • •	
Animal Bite/Scratch				
Other (please describe)				
		- /		

Section 2: Reporting Party Information (Optional)		
Position (Student, TA, PI, ect):		
First Name:	Last Name:	
Email:	UMBC Campus ID:	
Cell Phone Number:	Alt. Phone Number:	
PI/Supervisor:	Department:	

Section 3: Affected Party Information (Complete this section for each individual involved)		
Position (Student, TA, PI, ect) :		
First Name: Last Name:		
Email:	UMBC Campus ID:	
Cell Phone Number:	Alt. Phone Number:	
PI/Supervisor:	Department:	
If no injury or exposure was sustained skip to section 4		
Location of injury or route of exposure:		

Please draw or otherwise denote location of injury/route of exposure on pictures below



Section 4: Incident Information

List any chemical or biological material that was involved in the incident Please Note:

- List full chemical name and percent of each constituent, do not use abbreviations or formulas
- · List full name of organism using proper binomial nomenclature and ensure any subspecies are identified
- · Identify origin of any toxin, recombinant nucleic acid, or otherwise infectious agents

Personal Protective Equipment (PPE) and Engineering Controls Please list the PPE worn during incident:_____

Please list the engineering controls used during incident, make note of any engineering controls not properly working:

Standard Operating Procedures (SOP)

Is there a standard operating procedure for the work being conducted at the time of the incident?______ If yes, please attach a copy to this form.

Was the individual trained on this SOP?

Was the SOP being followed at the time this incident occurred?

Incident Description

Please Note:

- Provide as much detail as possible and list external events that may have contributed to the incident
- Maintain confidentiality if desired for respective parties
- Describe follow up action taken (if any)

Retraining
Retraining
Retraining Was there any retraining as a result of this incident?
Was there any retraining as a result of this incident? If ves, please include name of training and date taken.
Was there any retraining as a result of this incident? If ves, please include name of training and date taken.
Was there any retraining as a result of this incident?If yes, please include name of training and date taken. Name of training
Was there any retraining as a result of this incident?If yes, please include name of training and date taken. Name of training
Was there any retraining as a result of this incident? If ves, please include name of training and date taken.
Was there any retraining as a result of this incident?If yes, please include name of training and date taken. Name of training

By submitting this form the reporter hereby certifies that all of the above information is correct to the best of their knowledge, that all information provided will remain confidential, and that they understand they may be contacted to provide more information during the course of any follow up investigation.

Appendix F

UMBC Waste Disposal Guide



chemicals or radioactive materials. contaminated with infectious agents, hazardous **Definition:** Any non hazardous waste that is not

-xamples:

properly decontaminated Laboratory materials and media which have been Uncontaminated animal bedding Disposable cloth, paper, plastic and glass items Office waste



Recyclable Items:

Ensure that they are clean and place in the appropriate receptacle

Von-Hazardous Liquid Media:

Place empty container in sturdy, closable cardboard box Flush with large amounts of water Pour down sink drain

Glass and broken plasticware

Close box and secure with filament tape and label Utilize proper glassware disposal container container

Gallon container with lic

Definition: Any waste with properties that make it on human health or the environment. dangerous or capable of having a harmful effect

Examples: Solvents

Motor oil & Coolant Heavy metals

Laboratory chemicals

Chemical Waste Labeling Requirements: Containers should be labeled with the following

information:

The words "Hazardous Waste"

- Building and room where the waste was generated
- Full names of all constituents within the container
- Point of contact name and phone number Relative percentages of each constituent

Date of waste production





iohazard Waste Labeling Requirements:

Containers should be labeled with the following

- information: The universal biohazard symbol
- The type and origin of waste is recommended

Services:

ESH will pick up properly labeled chemical waste quantities of chemical waste generated. above) as well as 5 gallon carboys and buckets for larger include the location of the waste, type of waste, number of containers as well as sharps containers. Please email ESH provides yellow chemical waste labels (pictured) sh@umbc.edu to schedule a pickup. Please ensure to

Visit safety umbc.edu for additional resources and containers, and any additional pertinent information. printouts concerning hazardous waste

potentially contaminated with infectious Definition: Waste contaminated or sharps (devices that can or have the potential agents, potentially biohazardous agents, or

Examples: to puncture membranes).

- Microbiological cultures
- Clinical specimens (urine, feces, blood, etc.)
- Animal carcasses (note: those containing)
- radioactive materials require additional management)
- Contaminated animal bedding
- Contaminated glass and plastic labware
- Sharps not contaminated with radioactive materials Disposable clothing, towels, absorbent liners, etc.

Sharps

Place needles and syringes intact in a facility approved sharps container.

- Do NOT recap, bend, or clip needles
- Fill ¾ full, snap lid closed and secure with filament tape (overfilling or force filling may result in puncture
- Contact ESH to schedule a pickup wounds)
- Contaminated Disposable Glassware Decontaminate the glass via autoclave or chemical methods
- Place in sturdy closable cardboard box, secure with filament tape and label broken glass

Animal Carcasses/ Tissues

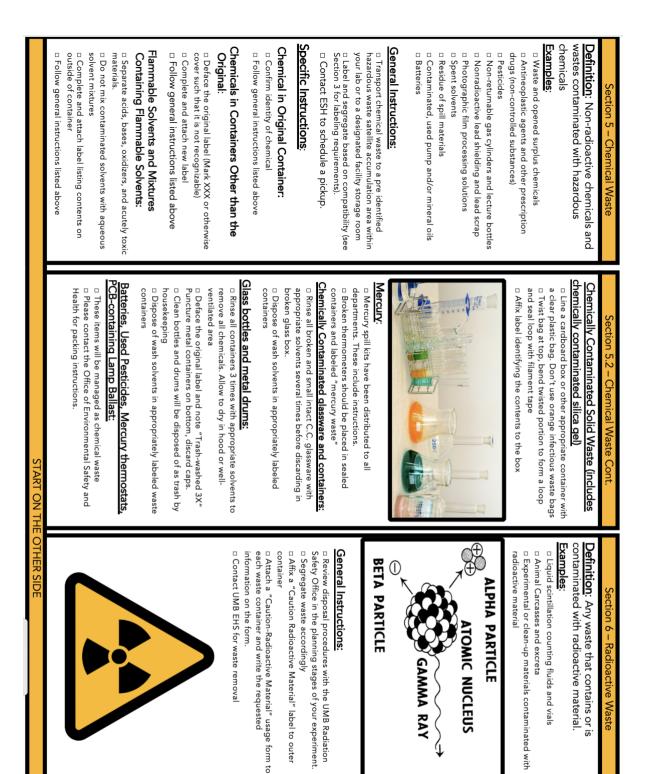
Call UMB (410) 706-7055 for assistance/ instructions Place bag in designated freezer not exceed 35lbs per bag. Add additional bag or Place animal carcass/tissues into a leakproot container around the primary container (Double bag) container or bag. Do not add paper or plastics. Do

General instructions:

waste disposal bag, double bag wet waste Place contaminated materials in a biohazardous

Place contaminated materials in autoclave pan, process according to facility SOP utilizing appropriate autoclave validation indicators





Section 7 – Multihazard Wa

Definition: Waste with multiple types of hazardous constituents including contamination with radioactive waste and either infectious agents or hazardous chemicals or both.

Examples:

 Aqueous radioactive wastes with trace levels of chloroform or toxic heavy metals
 Radioactive methanol/acetic acid solutions from

HPLC or gel rinse procedures
Spent cocktail from continuous liquid scintillation

counting adioactive trichloroacetic acid solutions from protein precipitations

Phone Precipitations
Phonol/chloroform mixtures used to extract DNA

from radiolabeled cells
Spent chromic acid from critical cleaning of

contaminated glassware contaminated with

adioactive materials □ Vacuum pump oil contaminated with radioactive

Chemical or radioactive wastes containing blood

products



General Instructions:

 Avoid generating mixed waste or combining chemicals, radioactive and infectious waste.
 Receive permission from UMB EHS prior to the creation of multihazard radioactive waste

creation of multihazard radioactive waste.

If generation of mixed wastes can't be avoided

Keep volume to a minimum

Keep aqueous and organic wastes separate

Don't combine reactive chemicals such as strong oxidizers with organic compounds

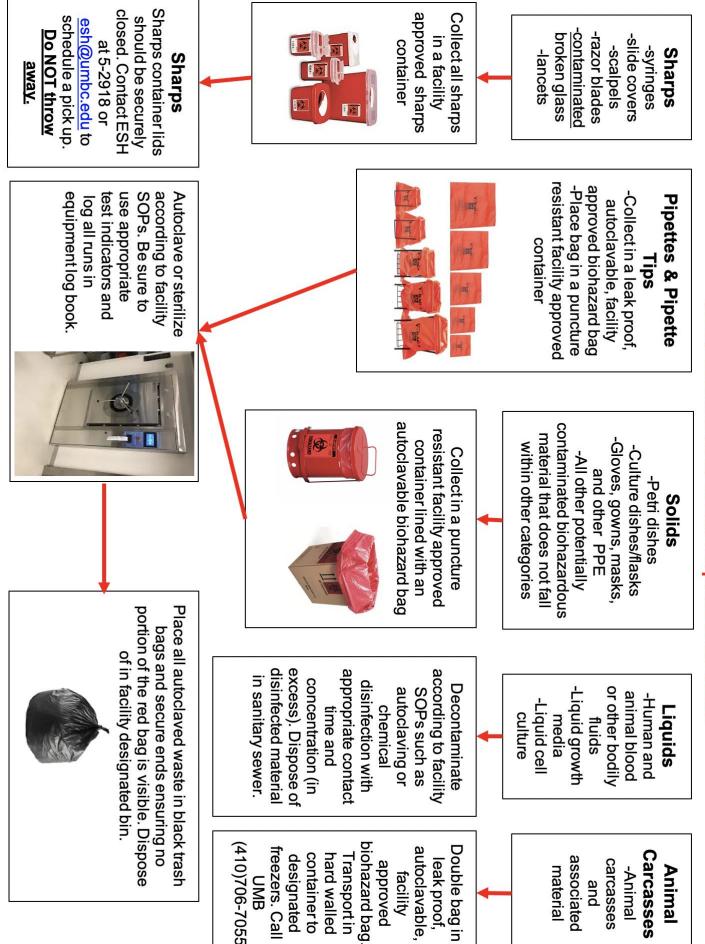
strong oxidizers with organic compounds
Keep liquid and solid wastes separate
Keep short half life (730 dave) is trong separate

 Keep short half-life (<30 days) isotopes separate from longer half-life isotopes

om longer nait-life isotopes
Identify all constituents

Appendix G

UMBC Biohazardous Waste Disposal Flow Chart

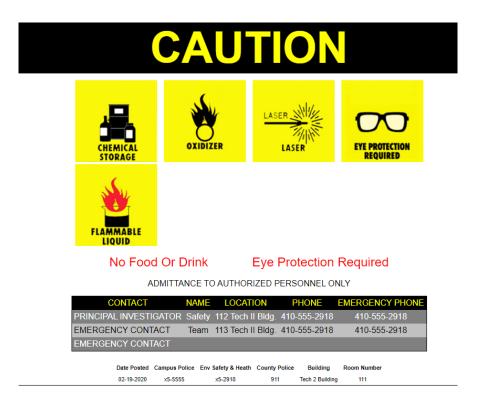


UMBC Biohazardous Waste Disposal Flow Chart

Appendix H

Laboratory Door Sign Request Directions

Laboratory Door Sign Request



To help first responders and campus staff in the event of an emergency in campus laboratories, door signs should be posted on all campus laboratory doors. The door signs can give responders quick information about emergency contacts for the lab space as well as any hazards that may be inside of the lab.

Through the UMBC Environmental Health and Safety website, safety.umbc.edu, you can provide the necessary information for the door sign and request copies for as many doors as the laboratory space has. We do ask that you fill out a door sign for each lab that you occupy separately as contacts and hazards identified in the lab space may change from lab to lab. Once you enter the information, we will be notified of the door sign request and will print, laminate and post the sign on your lab door(s). Please review the lab information periodically and make updates as needed. To assist with this, we will send reminders out with the annual laboratory audits to remind laboratory managers and Principal Investigators to review the information. Thank you for assisting us with this process and creating a safer campus community.

How to Request a Door Sign:

- 1. Go to the Environmental Safety and Health web page at: safety.umbc.edu
- 2. On the right side of the page under "Popular Forms", click on "Apply for Door Sign"
- 3. Fill out all the required fields. Note: Please try to include someone who is knowledgeable about the laboratory operations other than the Principal Investigator in the Emergency Contact Section
- 4. Select the Hazard symbol(s) that best represent the hazard conditions in the laboratory space.
- 5. Submit the Request using the Blue button at the bottom of the screen.
- 6. ESH will then review the request, print, laminate and provide the door sign to the lab staff.

Appendix I

Select Agent List

HHS and USDA Select Agents and Toxins 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS Select Agents and Toxins

- 1. Abrin [6]
- 2. Bacillus cereus Biovar anthracis [1]
- 3. Botulinum neurotoxins [1][6]
- 4. Botulinum neurotoxin producing species of *Clostridium* [1]
- Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7) [6]
- 6. *Coxiella burnetii*
- 7. Crimean-Congo haemorrhagic fever virus
- 8. Diacetoxyscirpenol [6]
- 9. Eastern Equine Encephalitis virus [4][5]
- 10. Ebola virus [1]
- 11. Francisella tularensis [1]
- 12. Lassa fever virus
- 13. Lujo virus
- 14. Marburg virus [1]
- 15. Monkeypox virus [4][9]
- Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
- 17. Ricin [6]
- 18. Rickettsia prowazekii
- 19. SARS-associated coronavirus (SARS-CoV) [5]
- 20. SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors
- 21. Saxitoxin [6]

South American Haemorrhagic Fever viruses:

- 22. Chapare
- 23. Guanarito
- 24. Junin
- 25. Machupo
- 26. Sabia
 - 27. Staphylococcal enterotoxins (subtypes A,B,C,D,E) [6]
 - 28. T-2 toxin [6]
 - 29. Tetrodotoxin [6]

Tick-borne encephalitis complex (flavi) viruses:

- 30. Far Eastern subtype [5]
- 31. Siberian subtype [5]
 - 32. Kyasanur Forest disease virus [5]
 - 33. Omsk hemorrhagic fever virus [5]
 - 34 Variola maior virus (Smallnov virus) [1]

Overlap Select Agents and Toxins

- 37. Bacillus anthracis [1]
- 38. Bacillus anthracis Pasteur strain
- 39. Brucella abortus
- 40. Brucella melitensis
- 41. Brucella suis
- 42. Burkholderia mallei [1]
- 43. Burkholderia pseudomallei [1]
- 44. Hendra virus
- 45. Nipah virus
- 46. Rift Valley fever virus
- 47. Venezuelan equine encephalitis virus [4][5][8]

USDA Veterinary Services (VS) Select Agents and Toxins

- 48. African horse sickness virus
- 49. African swine fever virus
- 50. Avian influenza virus [4]
- 51. Classical swine fever virus [5]
- 52. Foot-and-mouth disease virus [1][5]
- 53. Goat pox virus
- 54. Lumpy skin disease virus
- 55. Mycoplasma capricolum [4]
- 56. Mycoplasma mycoides [4]
- 57. Newcastle disease virus [3][4]
- 58. Peste des petits ruminants virus
- 59. Rinderpest virus [1]
- 60. Sheep pox virus
- 61. Swine vesicular disease virus [5]

USDA Plant Protection And Quarantine (PPQ) Select Agents and Toxins

- 62. Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines)
- 63. Peronosclerospora philippinensis (Peronosclerospora sacchari)
- 64. Ralstonia solanacearum [7]
- 65. Rathayibacter toxicus
- 66. Sclerophthora rayssiae [7]
- 67. Synchytrium endobioticum
- 68. Xanthomonas oryzae

[1] Denotes Tier 1 Agent

[2] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins a-MI and a-GI (shown above) as well as a-GIA, Ac1.1a, a-CnIA, a-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

[3] A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

[4] Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category.

[5] For determining the regulatory status of nucleic acids that are capable of producing infectious forms of select agent viruses, please reference guidance <u>here</u>.

[6] For determining the regulatory status of Recombinant and/or Synthetic nucleic acids that encode for the toxic form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro, or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in vitro; please reference guidance <u>here</u>.

[7] Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: Any subspecies of *Ralstonia solanacearum* except race 3, biovar 2 and all subspecies of *Sclerophthora rayssiae* except var. *zeae*, provided that the individual or entity can identify that the agent is within the exclusion category.

[8] Modified Venezuelan Equine Encephalitis Virus TC-83(A3G) strain is a select agent.

[9] Note that this is a change in nomenclature, which is aligned with the <u>World Health Organization decision</u>, and does not represent a change in the listed agent.

Appendix J

ESH Hazardous Materials Reviewal Form

UMBC ESH Hazardous Materials Reviewal Form

Please list all hazardous chemical, biological, radioactive, or otherwise harmful materials in the space provided below. Provide a detailed purpose or use for every item listed, please be explicit and do not list "Refer to IBC/IACUC application". Once all materials have been listed please provide contact information, sign the bottom of this document, and submit to UMBC ESH at <u>esh@umbc.edu</u>. You will be notified by ESH upon completion of reviewal. Questions can be directed to UMBC ESH (5-2918) or <u>esh@umbc.edu</u>.

Hazardous Material	Purpose or Use
Bleach, sodium	Used for disinfecting bench tops and surfaces. Used in excess to disinfect liquid
hypochlorite 10%	cultures.

Are all individuals in the laboratory trained to work with the above materials?	□Yes □No
Are the Safety Data Sheets(SDS) available to all individuals working in the laboratory?	□Yes □No
Are there laboratory specific standard operating procedures (SOPs) in place for working with the above materials?	□Yes □No

By signing and submitting this form you agree to the best of your knowledge that the provided information is correct and is not misrepresented in any way.

Name:	Phone:	Email:	
Signature:	Date:	//	

Hazardous Material	Purpose or Use

Appendix K

Laboratory Animal Risk Assessment Form

UMBC Laboratory Animal Risk Assessment Form



Please download and complete this brief assessment to determine your potential risks when working in UMBC's animal facilities. Email completed forms to <u>esh@umbc.edu</u>. You will be contacted by Environmental Safety and Health if follow up medical services are required. Services include physical evaluations, immunizations, and laboratory testing. Information collected in this form will be stored with Environmental Safety and Health in accordance with all current regulatory and confidentiality requirements.

Risk assessment is an integral part of UMBC's Laboratory Animal Facilities Occupational Health & Safety Plan (OHSP). The OHSP serves to educate and promote safe practices, ensure personnel safety, as well as prevent occupational injury and illness for the animal care personnel who work with laboratory animals at UMBC. Animal care personnel include individuals who handle live laboratory animals, animal cages, cage accessories or have contact with animal tissues, body fluids or wastes in which a potential exposure may exist. A tetanus immunization within the past ten (10) years is required for any personnel to work with animals at UMBC. Animal care personnel that are pregnant, planning to become pregnant, are ill, or have impaired immunocompetence should consult a physician regarding such conditions and how they might pertain to their working with laboratory animals.

The OHSP is written in accordance with the University of Maryland, Baltimore County's Animal Welfare Assurance of Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (# A3784-01) and is consistent with the principles outlined in the Office of Laboratory Animal Welfare Guide for the Care and Use of Laboratory Animals. If you have any questions, please contact Environmental Safety and Health at 410-455-2918 / esh@umbc.edu or the Office of Research Protections and Compliance at 410-455-2737 / compliance@umbc.edu

Enter your name	
Enter vour departme	ent

What is your position? (check all that apply)

Faculty
Research Assistant – Name of PI/Lab Supervisor:
Staff
Student – Name of PI/Lab Supervisor:
Animal Care Technician
Lab Technician
Other:

Identify the animal species you will be working with (check all that apply). Skip this question if you do not work directly with animals

	Mice
	Rats
	Amphibians - tanked
	Amphibians - field studies
	Birds – caged
	Birds - field studies
	Fish – tanked
\square	Fish - field studies

Do you have any allergies to animals?



Do you have any potential workplace allergies? e.g., latex

Yes

If yes, please explain:

When were you last vaccinated for Tetanus? Enter the four digit year (e.g. 1987). A tetanus vaccination within the past 10 years is required for any personnel to work with animals at UMBC.

Are you aware of any reason why you should not work with laboratory animals?

Yes	
No	
lf yes, please explain:	

By submitting this form for review:

I acknowledge the information I provided is accurate to the best of my knowledge and I have been provided the opportunity to download and read:

The Basic Guide for Working Safely with Animals
The UMBC Occupational Health and Safety Plan
The UMBC Laboratory Animal Facility Occupational Health & Safety Plan

Appendix L

Weekly Equipment Inspection/Test Log

Weekly Equipment Inspection/Test Log



Building:_____

Room#:

	UMBC					
Date	Ву	Pass/Fail] [Date	Ву	Pass/Fail
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Appendix M

Biohazard Spill Sign



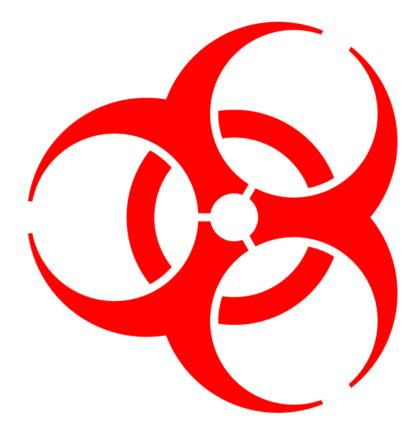
DO NOT ENTER! Biohazard spill

Time:

Contact:

Appendix N

Biohazard Equipment Spill Sign



DO NOT USE THIS EQUIPMENT! **Biohazard spill**

Time:

Contact:

Appendix O

Laminar Flow Hood & Clean Bench Sign

DOES NOT PROVIDE PROTECTION TO OPERATOR

FOR STERILE EQUIPMENT AND SAMPLES ONLY

<u>DO NOT</u> USE WITH THE FOLLOWING MATERIALS:

- Biohazardous (cell culture, blood, etc.)
- Radioactive
- Sensitizing
- Toxic
- Any hazardous or potentially hazardous material

For questions please contact UMBC ESH (5-2918) esh@umbc.edu



DOES NOT PROVIDE PROTECTION TO OPERATOR

FOR STERILE EQUIPMENT AND SAMPLES ONLY

DO NOT USE WITH THE FOLLOWING MATERIALS:

- Biohazardous (cell culture, blood, etc.)
- Radioactive
- Sensitizing
- Toxic
- Any hazardous or potentially hazardous material

For questions please contact UMBC ESH (5-2918) esh@umbc.edu

DOES NOT PROVIDE PROTECTION TO OPERATOR

FOR STERILE EQUIPMENT AND SAMPLES ONLY

DO NOT USE WITH THE FOLLOWING MATERIALS:

- Biohazardous (cell culture, blood, etc.)
- Radioactive
- Sensitizing
- Toxic
- Any hazardous or potentially hazardous material

For questions please contact UMBC ESH (5-2918) esh@umbc.edu

DOES NOT PROVIDE PROTECTION TO OPERATOR

FOR STERILE EQUIPMENT AND SAMPLES ONLY

DO NOT USE WITH THE FOLLOWING MATERIALS:

- Biohazardous (cell culture, blood, etc.)
- Radioactive
- Sensitizing
- Toxic
- Any hazardous or potentially hazardous material

For questions please contact UMBC ESH (5-2918) esh@umbc.edu **Appendix P**

Adult Waiver of Liability and Hold Harmless Agreement



WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT

- 1.0 In consideration of being permitted to participate in [name of activity] ("the Activity") to be held during the period of [specific period] I, the undersigned Participant, hereby in advance RELEASE, WAIVE, DISCHARGE, AND COVENANT NOT TO SUE the University of Maryland, Baltimore County, the University System of Maryland, the State of Maryland, their officers, agents, servants, faculty, administrators, employees, and students acting as such (collectively, "Releasees") from and against any and all liability for any harms, injuries, damages, claims, actions, causes of action, costs, demands, and expenses of any nature whatsoever which I may have or which may hereafter accrue to me, arising out of or related to any loss, damage, or injury, including but not limited to suffering and death, that may be sustained by me, or to any property belonging to me, WHETHER CAUSED BY THE NEGLIGENCE OR CARELESSNESS OF THE RELEASEES, or otherwise, while participating in the Activity, or while in, on, upon, or in transit to or from the premises where the Activity is being conducted.
- 2.0 I attest that I have actual and complete knowledge of all the risks, dangers, and hazards ("Risks") of the Activity, including other activities taken as an adjunct thereto (e.g., travel to, from, or during the Activity). I UNDERSTAND THAT WHEN THE RISKS OF THE ACTIVITY MANIFEST THEY WILL RESULT IN INJURY (MINOR, SERIOUS, OR MORTAL) TO ME AND/OR DAMAGE TO MY PROPERTY. Possessing subjective knowledge of the Risks of the Activity and appreciating those Risks, I, nevertheless, voluntarily assume those Risks. I hereby release and hold harmless the Releasees who through negligence or carelessness or otherwise might be liable to me (or my heirs or assigns) for damages.
- 3.0 I understand and agree that Releasees do not have medical personnel available at the location(s) of the Activity. I grant permission to Releasees to authorize emergency medical treatment, if determined necessary by Releasees. I further understand and agree that such action or inaction on the part of the Releasees and any resulting injuries or damages shall be subject to the terms of this WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT.
- 4.0 I expressly intend that this WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT shall bind the members of my family and spouse, if I am alive, and my estate, heirs, administrators, personal representatives, or assigns, if I am deceased, and shall be deemed as a RELEASE, WAIVER, DISCHARGE, AND COVENANT NOT TO SUE the above-named Releasees. I further agree TO SAVE AND HOLD HARMLESS, INDEMNIFY, AND DEFEND Releasees from any claim by me, or my family, arising out of my participation in the Activity.
- 5.0 I agree that this WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT shall be governed in all respects by the laws of the State of Maryland without reference to its conflicts of laws principles. I expressly consent and submit to the exclusive jurisdiction of any court of competent jurisdiction in the State of Maryland.

Revised 08/2020

- 6.0 I agree that each provision of this **WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT** shall be deemed to be a separate, severable, and independently enforceable provision. The invalidity or breach of any provision shall not cause the invalidity or breach of the remaining provisions, which shall remain in full force and effect.
- 7.0 I ACKNOWLEDGE AND REPRESENT THAT I have read the foregoing WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT, understand it, and sign it voluntarily as my own free act and deed; no oral representations, statements, or inducements, apart from the foregoing written WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT, have been made; I am at least eighteen (18) years of age and fully competent; and I execute this WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT for full, adequate, and complete consideration fully intending to be bound by the same.

THIS IS A RELEASE OF LEGAL RIGHTS - READ BEFORE SIGNING

IN WITNESS WHEREOF, we have signed this WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT under seal on date of signature below.

Participant's Printed Name:	

Participant's Campus ID (If One Exists):

Participant's Signature:	Date:
--------------------------	-------

Appendix Q

Minor Waiver of Liability and Hold Harmless Agreement



WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT

- 1.0 In consideration of my minor child or minor ward ("Minor") being permitted to participate in [name of activity] ("the Activity") to be held during the period of [specific period] I, the undersigned, on behalf of my Minor, hereby in advance RELEASE, WAIVE, DISCHARGE, AND COVENANT NOT TO SUE the University of Maryland, Baltimore County, the University System of Maryland, the State of Maryland, their officers, agents, servants, faculty, administrators, employees, and students acting as such (collectively, "Releasees") from and against any and all liability for any harms, injuries, damages, claims, actions, causes of action, costs, demands, and expenses of any nature whatsoever which my Minor may have or which may hereafter accrue to my Minor, arising out of or related to any loss, damage, or injury, including but not limited to suffering and death, that may be sustained by my Minor, or to any property belonging to my Minor, WHETHER CAUSED BY THE NEGLIGENCE OR CARELESSNESS OF THE RELEASEES, or otherwise, while participating in the Activity, or while in, on, upon, or in transit to or from the premises where the Activity is being conducted.
- 2.0 I, on behalf of my Minor, attest that I have actual and complete knowledge of all the risks, dangers, and hazards ("Risks") of the Activity, including other activities taken as an adjunct thereto (e.g., travel to, from, or during the Activity). I, ON BEHALF OF MY MINOR, UNDERSTAND THAT WHEN THE RISKS OF THE ACTIVITY MANIFEST THEY WILL RESULT IN INJURY (MINOR, SERIOUS, OR MORTAL) TO MY MINOR AND/OR DAMAGE TO HIS OR HER PROPERTY. Possessing subjective knowledge of the Risks of the Activity and appreciating those Risks, I, on behalf of my Minor, nevertheless, voluntarily assume those Risks. I, on behalf of my Minor, hereby release and hold harmless the Releasees who through negligence or carelessness or otherwise might be liable to my Minor (or his or her heirs or assigns) for damages.
- 3.0 I, on behalf of my Minor, understand and agree that Releasees do not have medical personnel available at the location(s) of the Activity. I, on behalf of my Minor, grant permission to Releasees to authorize emergency medical treatment, if determined necessary by Releasees. I, on behalf of my Minor, further understand and agree that such action or inaction on the part of the Releasees and any resulting injuries or damages shall be subject to the terms of this **WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT**.
- 4.0 I, on behalf of my Minor, expressly intend that this WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT shall bind my Minor, the members of his or her family and spouse, if he or she is alive, and his or her estate, heirs, administrators, personal representatives, or assigns, if he or she is deceased, and shall be deemed as a RELEASE, WAIVER, DISCHARGE, AND COVENANT NOT TO SUE the above-named Releasees. I, on behalf of my Minor, further agree TO SAVE AND HOLD HARMLESS, INDEMNIFY, AND DEFEND Releasees from any claim by me, my Minor, or my family, arising out of my Minor's participation in the Activity.

Revised 08/2020

- 5.0 I, on behalf of my Minor, agree that this WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT shall be governed in all respects by the laws of the State of Maryland without reference to its conflicts of laws principles. I, on behalf of my Minor, expressly consent and submit to the exclusive jurisdiction of any court of competent jurisdiction in the State of Maryland.
- 6.0 I, on behalf of my Minor, agree that each provision of this **WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT** shall be deemed to be a separate, severable, and independently enforceable provision. The invalidity or breach of any provision shall not cause the invalidity or breach of the remaining provisions, which shall remain in full force and effect.
- 7.0 I, ON BEHALF OF MY MINOR, ACKNOWLEDGE AND REPRESENT THAT I have read the foregoing WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT, understand it, and sign it voluntarily as my own free act and deed; no oral representations, statements, or inducements, apart from the foregoing written WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT, have been made; I am at least eighteen (18) years of age and fully competent; I am the parent or legal guardian of the Minor; and I execute this WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT for full, adequate, and complete consideration fully intending to be bound and for my Minor to be bound by the same.

THIS IS A RELEASE OF LEGAL RIGHTS - READ BEFORE SIGNING

IN WITNESS WHEREOF, we have signed this WAIVER OF LIABILITY AND HOLD HARMLESS AGREEMENT under seal as of the date of signatures below.

Minor's Printed Name:										
Minor's Campus ID (If One Exists):										
Minor's Signature:	Date:									
Parent/Guardian's Printed Name:										
Parent/Guardian's Signature:	_Date:									

Appendix R

Generic Autoclave Log

							Contents Date (Type & Weight)	Person responsible for autoclave:	Lab/Facility name:	Autoclave make/model:	W UMBC
							Cycle Number or Type				
							Sterilization Time (min)				
							Pressure (psi)				AUTO
							Max Temp Reached	Phon	Princi Supei	Location (building	AUTOCLAVE LOG SHEET
							Tape Result (pass/fail)	Phone number:	Principal Investigator/ Supervisor name:	Location (building/room number):	G SHEET
							Chemical Integrator Result (pass/fail)		r/	ber):	Mate manu minin been
							Last spore test date (every 30 days)				ial should be facturer reco num of 60 min proven effect
							Operator				processed mmendation nutes unles ive with bi
							Comments				Material should be processed according to the autoclave manufacturer recommendations or at 121°C for a minimum of 60 minutes unless shorter intervals have been proven effective with biological indicators. 12/2022