University of Massachusetts Lowell

ENVIRONMENTAL AND EMERGENCY MANAGEMENT

ENVIRONMENTAL HEALTH AND SAFETY

IV. BIOSAFETY MANUAL

Contents

1.0 INTRODUCTION

Biosafety is the application of preventive methods to reduce the risk of exposure to biological agents or biohazards that can affect the health of laboratory personnel, the community, and the environment. Preventing exposure can be achieved by containment, risk assessment, work practices, personal protective equipment (PPE), and training.

The following paragraph comes from *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) published by the Center for Disease Control (CDC) and the National Institutes of Health (NIH) in 2009-5thed.[1]

"A fundamental objective of any biosafety program is the containment of potentially harmful biological agents. The term "containment" is used to describe safe methods, facilities and equipment for managing infectious materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents. The use of vaccines may provide an increased level of personal protection. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of these elements".

At UMass Lowell (UML), the Department of Environmental and Emergency Management / Office of Environmental Health and Safety (EEM/EHS), Office of Institutional Compliance, and Institutional Biosafety Committee (IBC) closely follow the CDC/NIH practices and recommendations for working safely with biological and infectious agents.

[1] http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_sect_III.pdf

2.0 UMASS LOWELL BIOSAFETY SUMMARY PROGRAM

The UMass Lowell EEM/EHS and IBC are committed to providing a safe and healthy work environment for students, faculty, staff, and visitors by developing programs and providing training to all members of the UMass Lowell community.

The Biosafety Program comprises of several components including:

- The Bloodborne Pathogens (BBP) and Hepatitis B (HepB) Vaccination Programs;
- Personal protective equipment (PPE);
- Certification and testing of biological equipment offered free of charge to the teaching and research community, such as the annual certification and testing of biosafety cabinets (BSC) and monthly bio-test validation of autoclaves;
- Biological waste and sharp disposal;
- Emergency response to spills and response to incidents/accidents involving biological material;
- Medical surveillance for person(s) working with animals;
- Support to assist faculty when arriving and/or leaving UMass Lowell, during commissioning and decommissioning of biological labs;
- Technical support to faculty during the application process to register his/her research work with the Institutional Biosafety Committee (IBC);
- Customized training in biosafety and BBP for faculty, students, lab workers, trades, visiting research fellows, and others;
- Review and approval of requisition and purchasing of biological materials and oversight of inventory;
- Provide Occupational Health resources through 3rd party facilities for post exposure evaluation/care.

All research using biological agents requires registration with the IBC[2]. The current use of biological agents at UMass Lowell is done at containment Biosafety Level 1 (BL-1) and Biosafety Level 2 (BL-2)

In addition, EEM-EHS offers complementary programs such as respiratory protection, hazardous waste management, chemical hygiene, laboratory safety, and a lab coat program with the purpose of maintaining safety and compliance at UMass Lowell.

[2] http://www.uml.edu/Research/OIC/biological-safety/default.aspx

3.0 SCOPE

The Biosafety Program and the Biosafety Manual apply to all students, faculty, staff and visitors working with or having the potential for exposure to biological agents on the premises of UMass Lowell. This manual is intended to be a resource for information, policies, guidelines, and procedures enabling those working in labs or support personnel to perform their work safely and reduce or eliminate potential exposure to biological and other hazards.

This Biosafety Manual describes all UMass Lowell policies, procedures and best practices to comply with federal, state and local regulations for working with biological agents at UMass Lowell. It is the principal investigator's (PI) responsibility to register his or her work with the IBC, as well as to follow all guidelines to ensure that all personnel in his/her laboratory are trained to work in a safe manner. It is the supervisor's role to ensure that police, trades, and emergency response personal abide by these policies and procedures.

4.0 DEFINITIONS

Terms, acronyms, and definitions used in this Biosafety Manual are listed or defined in this section.

Animal and Plant Health Inspection Service (APHIS) is an agency of the U.S. Department of Agriculture (USDA) that is responsible for protecting and promoting U.S. agricultural health while administering the Animal Welfare Act, in addition to carrying out wildlife damage management activities.

Antisepsis is the application of a liquid antimicrobial chemical to skin or living tissue to inhibit or destroy microorganisms. It includes swabbing an injection site on a person or animal and hand washing with germicidal solutions. Although some chemicals may be utilized as either a disinfectant or an antiseptic, adequacy for one application does not guarantee adequacy for the other. Manufacturers' recommendations for appropriate use of germicides should always be followed.

Biohazardous is an adjective used to describe biological materials that present potential risk to the health of humans or other organisms, either directly through infection or indirectly through damage to the environment.

Biohazardous Agents are materials of biological origin that could present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. All biohazardous or pathogenic agents have the capability to infect and cause disease in a susceptible human or animal host. Their virulence can be measured by the severity of the disease that they produce. Treatment of the disease may or may not be effective.

Biohazardous Waste is waste that requires inactivation (i.e. decontamination) in an approved manner prior to disposal.

Biological Etiologic Agents are agents of biological origin (e.g. bacterium, fungus, parasite, virus, etc.) that cause disease in humans (i.e. pathogenic to humans).

Biological Materials are a broad range of organisms, cells, viruses, and other materials of biological origin that pose differing levels of risks to plants, animals, or humans.

Biosafety Cabinets (BSCs) are hoods with high-efficiency particulate air (HEPA) filters that provide personnel, environmental, or product protection when appropriate practices and procedures are followed.

Biosafety in Microbiological and Biomedical Laboratories (BMBL)[3] is the title of a national code of practices and standards for biosafety that outlines and defines biosafety risk assessment and control, published by the National Institutes of Health (NIH) and the Center for Disease Control (CDC)

Biosafety Level (BL or BSL) is a combination of practices and techniques, safety equipment, and facilities that are specified in the BMBL or NIH Guidelines[4] as being appropriate to safely contain the biohazardous materials or agents to be used in the work.

Biosafety Officer (BSO) is a safety professional with expertise in microbiology that is part of the EEM-EHS department. The BSO develops and maintains the Biosafety Program in accordance with institutional, state, and federal standards and regulations.

Bloodborne Pathogen Material is a term used to describe biological agents or materials that are covered by the OSHA Bloodborne Pathogens Standard[5] including, for example, bloodborne pathogens, human blood, human blood components, products made from human blood, and other potentially infectious materials (OPIM).

Bloodborne Pathogens (BBP) are infectious agents such as HIV, the Hepatitis B Virus (HBV) and the Hepatitis C Virus (HCV) that are capable of causing human disease and are transmitted through human blood and tissues.

Containment is the method(s) used to reduce or eliminate exposure of workers and the environment to biohazardous materials or agents.

Center for Disease Control and Prevention is one of the thirteen major operating components of the U.S. Department of Health and Human Services (HHS).

Department of Transportation (DOT) is a Federal Cabinet-Level Department of the U.S. Government that is concerned with interstate transportation to keep the

[3] http://www.cdc.gov/biosafety/publications/bmbl5/index.htm
[4] http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html
[5] http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

traveling public safe and secure, increase their mobility, and have a transportation system that contributes to the nation's economic growth.

Decontamination is the reduction or inactivation of biological contaminants or components to an acceptable level to reduce or eliminate the possibility of transmission of pathogens to undesired hosts such as laboratory workers, the general public, and other organisms in the environment. Decontamination describes the processes or treatments that render a medical device, instrument, or environmental-surface safe to handle.

Disease is any deviation from or interruption of the normal structure or function of any body part, organ, or system that is manifested by a characteristic set of symptoms and signs and whose etiology, pathology, and prognosis may be known or unknown.

Disinfection is a level of decontamination that involves the elimination of nearly all recognized pathogenic, non-spore-forming microorganisms, but not necessarily all microbial forms (e.g. bacterial spores) from inanimate objects (e.g. work surfaces, equipment, etc.). Several parameters affect disinfection and influence effectiveness such as the kind and number of microorganisms, the amount of organic matter, the object or material to disinfect, temperature, concentration, and the chemical exposure time. Common disinfectants include household bleach or 70% isopropanol.

Exposure Control Plan (ECP) is a written document that defines work, hazards, and controls in accordance with the requirements of the OSHA Bloodborne Pathogens Standard[6] for work with or potential exposure to BBP materials.

Etiologic is an adjective that means disease-causing.

Export Controls are U.S. Federal Government Laws and Regulations that require federal agency approval before the export of controlled items, commodities, technology, software or information to restricted foreign countries, persons and entities (including universities). There are three federal government agencies responsible for implementing the export control regulations: the Department of Commerce, the Department of State and the Department of Treasury

Health and Human Services (HHS) is a cabinet department of the U.S. Government that contains the Public Health Services (PHS) and has the goal of protecting the health of all Americans and providing essential human services.

[6] http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

Hepatitis B Virus (HBV) is a pathogen that causes contagious liver disease (i.e. hepatitis B) in humans. HBV is a common BBP.

Human Immunodeficiency Virus (HIV) is a lentivirus (a member of the retrovirus family) that causes acquired immunodeficiency syndrome (AIDS), a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections. HIV is a common BBP.

Infectious Agents are agents capable of producing infection. Several factors are taken into consideration when evaluating risk, including pathogenicity of the organism, mode of transmission and host range, availability of effective measures, and availability of treatment.

Institutional Animal Care and Use Committee (IACUC) oversees the use of regulated animal species for research purposes under the Animal Welfare Act.

Institutional Biosafety Committee (IBC) provides oversight, administration, and review of policies and procedures involving research with biological materials that may pose safety, health, or environmental risks.

Institutional Review Board (IRB) is a HHS mandated committee that requires the use of established principles and requirements during the ethical review of proposed research projects involving human subjects, human-derived data, or human-derived tissues

Integrated Pest Management is a term used in the BMBL and the NIH Guidelines to describe a comprehensive program approach that integrates housekeeping, maintenance, and pest control services to prevent pest problems by managing the facility environment to make it less conducive to pest infestation.

International Air Transport Association (IATA) is an international industry trade group or airline that represents, leads, and serves the airline industry and publishes the Dangerous Goods Regulations used for airlines' shipping of hazardous materials, including infectious substances.

Large Scale is a term used to describe uses of and containment levels for organisms containing recombinant DNA molecules involving quantity of culture greater than ten liters[7].

[7] http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948480

Medical Waste is waste that is generated or produced as a result of diagnosis, treatment, or immunization of human beings or animals; research pertaining to the diagnosis, treatment, or immunization of human beings or animals; or the production or testing of biologicals

Occupational Safety and Health Administration (OSHA) is an agency of the U.S. Government that ensures the safety and health of U.S. workers (e.g. by setting and enforcing standards).

Office of Laboratory Animal Welfare is an office of the NIH that oversees compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.[8]

Other Potentially Infectious Materials (OPIM) are materials that are regulated by the OSHA Bloodborne Pathogens Standard[9] based on their potential to contain BBP. These materials do not include bloodborne pathogens, human blood, human blood components, or products made from human blood.

Pathogens are infectious microbial (e.g. bacteria, protozoa, fungi, viruses, etc.) or other agents that can cause disease in healthy host organisms such as humans, animals, or plants.

Personal Protective Equipment (PPE) is a device worn by workers to protect the body from injury to hazardous agents or materials. Examples of PPE include foot, hand, eye, face, body, and respiratory protection. PPE is one element of biosafety containment.

Principal Investigator (PI) is the individual(s) that is assigned authority and responsibility to direct a research experiment, project, or program that is typically funded by a grant. In addition, PI is responsible for oversee the lab and lab personnel.

Public Health Service is an umbrella organization in the U.S. Federal Government consisting of eight HHS health agencies, the Office of Public Health and Science, and the Commissioned Corps (a uniformed service of health professionals). NIH and CDC are agencies within the PHS.

Responsible Official (RO) is person that has the authority and responsibility to ensure compliance with CDC and US Department of Agriculture (USDA) regulations

[8] http://grants.nih.gov/grants/olaw/references/phspol.htm
[9] https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

for possession, use, or transfer of select agents and toxins, as specified in the regulations of UMass Lowell and EHS.

Risk is a chance of something going wrong. It is also the chance of exposure to something valued as a hazard, causing injury, damage, or loss.

Risk Group (RG) is a system (e.g. adopted by the CDC and NIH) for classifying biological agents by the degree of human hazard. There are four risk groups a higher RG number indicates a higher level of hazard or pathogenicity.

Risk of Infection is the state in which an individual has a chance to get invaded by an opportunistic or pathogenic agent.

Sanitization is a level of decontamination that involves the general reduction of microorganisms by the use of general cleaning agents.

Select Agents and Toxins are specific pathogenic agents and toxins strictly regulated by the CDC and USDA (i.e. under 7 CFR 331, 9CFR 121 and 42 CFR.73). These agents may be used as agents of mass destruction or pose a severe threat to human, animal, and plant health. Specific genetic elements, recombinant nucleic acids, and recombinant organisms that are related to the list of select agents and toxins are described in the regulations.

Standards are the external rules established by government, contract, funding regulations, and non-regulatory standards that form the requirements of the Biosafety Program at UMass Lowell (e.g. the Bloodborne Pathogens Standard, Standard Operation Procedures).

Stem Cells are undifferentiated cells of a multicellular organism that are capable of giving rise to indefinitely more cells of the same type, and from which certain other kinds of cells arise by differentiation. Stem cells are cells found in all multi-cellular organisms. They are characterized by the ability to renew themselves through mitotic cell division and differentiate into a diverse range of specialized cell types.

Sterilization is a level of decontamination utilizing a physical or chemical procedure that involves the complete destruction of all living microorganisms and viruses, including highly resistant bacterial endospores.

United States Department of Agriculture (USDA) is an agency of the U.S. government with the following types of mission areas: farm and foreign agricultural,

food, food safety, nutrition, natural resources, environment, research, education, economics, and rural development.

World Health Organization (WHO) is the agency of the United Nations that specializes in the attainment by all peoples of the highest possible level of health.

5.0 ROLES AND RESPONSIBILITIES

5.1 Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee (IBC) is a university-wide review body comprised of faculty staff and community members that oversees activities involving potentially hazardous biological agents. The IBC ensures that research activities using these materials and conducted at UML are in compliance with the NIH Guidelines, federal, state and local laws and regulations. UML is committed to ensuring the safe handling, storage, and disposal of potentially harmful biohazardous materials for research or instructional projects. The biohazardous materials of particular concern that are covered by the IBC include:

- Recombinant DNA (rDNA) or transgenic plants, animals, and microbes;
- Infectious agents [pathogenic or infectious bacteria, viruses, fungi, parasites, nucleic acids (prions), agents of unknown pathogenicity to humans, plants, or animals];
- Drug resistant bacteria, including those containing plasmids specifying drug resistance;
- Human tissue or body fluids and nonhuman primate materials (blood, blood components, tissues and body fluids and potentially infectious cultured human or animal cells);
- Tissues treated with pathogenic agents or transfected or otherwise treated with rDNA;
- Select agents and biologically derived toxins;
- Research that involves any of the above materials with animal and/or human subjects;
- Xenotransplantation;
- Stem cells.

IBC responsibilities are:

- Review policies regarding the use of biohazardous materials in research, teaching, and animal care activities;
- Review rDNA research for compliance with NIH Guidelines including:
    - Assessment of the containment levels required for the proposed research;
    - Assessment of the facilities, procedures, practices, training, and expertise of personnel involved in rDNA research;
- Review all IBC Registration applications and notify the PI of the results of the review;

- Set containment levels for experiments involving biohazardous materials;
- Periodically review institutional compliance with NIH Guidelines;
- Report any significant problems with or violations of the NIH Guidelines, and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/ Office of Biotechnology Activities (OBA) within 30 days.

5.2 Office of Institutional Compliance (OIC)

The OIC[10] has administrative oversight of IBC activities, including:

- Updating and revising policies and procedures;
- Setting up and recording meetings;
- Management and record keeping for all registrations;
- Coordinating other oversight committees such as the Institutional Animal Care and Use Committee (IACUC)[11], and the Institutional Review Board (IRB)[12] should an activity require oversight by more than one committee. Working closely with EEM-EHS to coordinate these activities;
- Responsibility for expert control compliance;
- Vetting and approval of international imports and exports.

Please refer all inquiries about international shipments to the OIC for assistance.

5.3 Environmental and Emergency Management/Environmental Health and Safety (EEM/EHS)

EHS has a comprehensive laboratory safety and compliance program and maintains a database of faculty and staff working with biological agents, chemicals, and other hazardous materials.

EHS requires all faculty and lab workers to attend Lab Safety and BBP/Biosafety Training annually prior to gaining access to UMass Lowell Laboratories. EHS provides monthly training regarding the proper handling, disposal, security and shipping of these materials, including export control and awareness training.

EHS maintains a biological and chemical inventory database that identifies the name of products and materials, quantity of products and materials, purchaser, location where

[10] http://www.uml.edu/Research/OIC/default.aspx
[11] http://www.uml.edu/Research/OIC/animal-use/default.aspx
[12] http://www.uml.edu/Research/OIC/human-subjects/default.aspx

such products and materials are stored and used on campus. Prior to purchase and delivery onto UMass Lowell campus, EHS and Radiation Safety Staff review and approve all chemical, biological, and radiological purchase requisitions. All deliveries of such materials are received at the EHS Hazardous Materials Receiving Stockroom. Upon arrival, all chemical and biological materials are bar coded by EHS for tracking purposes before the materials are distributed to the user. In addition, chemicals and biological agents are subject to many legal requirements including training sessions for packaging and shipping. EHS is available to assist members of the UMass Lowell community to comply with these laws and regulations.

5.4 Biosafety Officer

The Biosafety Officer (BSO) is a professional with comprehensive knowledge of biological sciences, microbiology, animal work and safety. At UMass Lowell, the BSO reports to the Director of EHS. He or she has responsibility for oversight of research and other activities involving the use of biohazardous materials, and assurance that containment levels are set in compliance to the NIH Guidelines, BMBL, and PHS/CDC/NIH. The BSO is a voting member of the IBC.

The BSO duties and responsibilities are:

- Advise and train the IBC members, faculty, and staff as necessary in the safe use and practices for working with potentially biohazardous materials;
- Review or pre-review registrations for the IBC, and provide recommendations to ensure that safe practices are followed;
- Inspect facilities and report results to the IBC on an annual basis;
- Review and inspect activities involving biohazardous materials in coordination with other EEM/EHS personnel such as the Safety Specialist, Radiation Officer, Life Safety and Emergency Response Manager;
- Provide assistance, input, and support required for emergency response;
- Develop emergency plans for containment, handling accidental spills of biological materials, and personnel contamination;
- Determine the necessity for health surveillance of personnel participating in projects that involve biohazardous substances;
- Provide technical advice to PIs on laboratory containment facilities, safety equipment, security, and research safety procedures;
- Report to the IBC and the Institutional Official (IO) any significant concerns, violations of the NIH Guidelines or UML Policies and Procedures, and research-related accidents or illnesses;

- If a biosafety violation occurs, then the IBC Chair will initiate an investigation with assistance from the BSO and/or EEM-EHS staff.

5.5 Deans and Department Chairs

Deans and Department Chairs are responsible for the implementation of safe practices and procedures by faculty and or investigators in their colleges and/or departments.

5.6 Principal Investigators

Principal Investigators (PIs) have the following responsibilities:

- Register his/her research work with the IBC, by submitting his/her research registration form(s) to the IBC for review and approval before commencing with any research activities using biohazardous substances;
- Complete a "Memorandum of Understanding and Agreement (MUA)" for all research proposals involving the use of biological agents;
- Accept direct responsibility for the health and safety of those working with biological materials in his/her laboratory;
- Identify potentially infectious and biohazardous materials proposed for use;
- Set example by attending all required training and ensures that all those working with biological materials in his/her laboratory are trained as required by the EEM/EHS in general Lab Safety and Biosafety/BBP;
- Implement necessary specific control procedures within their own laboratories, and ensure that students and staff working in his/her laboratory receive proper hands-on instruction and training in the potential hazards of the materials they are working with;
- Set an example by their own actions to ensure compliance with the regulations and procedures described in the UMass Lowell EEM/EHS Manuals (Exposure Control Plan, Chemical Hygiene Plan, Biosafety Manual), and provide directives and guidelines for the work they supervise;
- Notify the Offices of Institutional Compliance of any proposed activity using biohazards by indicating so on the Proposal Information Sheet accompanying a grant proposal;
- Ensure that reporting requirements are fulfilled and be accountable for any reporting lapses;
- Ensure that copies of approval letters are received by the funding agency or sponsor of any proposed research;
- Coordinate use and transport of biohazardous materials with EEM/EHS and refer to EHS-SOPs as necessary;

- Report any significant problems to the BSO after the project is initiated;
- Assist in any resulting decontamination and follow-up investigation or reporting that may be required;
- Report incidents promptly to the BSO or EEM/EHS office.

5.7 Researchers, Users or Employees

Are responsible for the following:

- Participate in mandated training and instruction;
- Become familiar with all biological agents being used in the lab and the potential risks associated with exposure;
- Follow all laboratory practices and protocols and comply with applicable guidelines and policies;
- Complete any necessary medical surveillance;
- Report all accidents, spills, or contamination incidents to supervisor;
- Report unsafe conditions to the PI, supervisor, or EHS;
- Seek guidance from their PI, supervisor, or EHS when uncertain how to handle, store or dispose of any hazardous or biohazardous material.

6.0 REGULATIONS, GUIDELINES AND PERMITS

6.1 National Institutes of Health (NIH)/Center for Disease Control and Prevention (CDC)

NIH Guidelines developed by the NIH[13] and the CDC[14] form the basis for the biosafety practices included in this manual. Compliance with these guidelines is a requirement to ensure the continuation of grant funds from federal agencies.

The NIH Guidelines have been amended to incorporate the use of synthetic nucleic acids since 2013. The completed NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules can be found at the Office of Biotechnology Activities (OBA) web site.[15]

The NIH Guidelines mandate the establishment of an IBC for the review and oversight of biological research; to outline roles and responsibilities for biosafety; and to establish the practices, procedures, and conditions under which recombinant DNA work must be conducted.

Biosafety in Microbiological and Biomedical Laboratories (BMBL)[16] is a practical guide that addresses the appropriate measures and facilities for work with all microbial agents**,** including bacteria, viruses, fungus, parasites and rickettsia agents.

6.2 OSHA Bloodborne Pathogens (BBP) Standard

In 1991, the Occupational Safety and Health Administration (OSHA) promulgated a standard to eliminate or minimize occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other bloodborne pathogens.[17]

This federal regulation "Occupational Exposure to Bloodborne Pathogens" mandates specific provisions to help control the health risk to employees that could result from exposure to human materials and other potential infectious agents. Specific requirements as combination of engineering and work practice controls, training, Hepatitis B Vaccination, and the use of PPE, can help to minimize and control the risk of exposure.[18]

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[13] www.nih.gov
[14] www.cdc.gov
[15] http://osp.od.nih.gov/office-biotechnology-activities/rdna/nih_guidelines_oba.html
[16] http://www.cdc.gov/biosafety/
[17] http://www.osha.gov/law-regs.html.
[18] http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

6.3 Center for Disease Control and Prevention (CDC)

Select agents are a group of agents, viruses, bacteria, and toxins that require stringent conditions and permits to work with them. The obtaining, possession, use, or transfer of any **select biological agent or toxin** is **strictly regulated** by federal code and regulations. It requires federal permits and inspection as well as significant measures of lab security, personnel training, and accurate record keeping regarding the status of possessed materials. Further information on select agents and toxins can be obtained at the CDC web site[19] or by contacting the Biosafety Officer at ext. 4-2618.

6.4 Mass Department of Environmental Protection (MDEP)

The Mass DEP regulates and monitors the disposal of biohazardous waste. EEM/EHS has developed Standard Operation Procedures (SOP) for handling and disposing biohazardous waste in compliance with the requirements of those regulations. See SOP Bio-001 to Bio-004 for additional information.

6.5 International Air Transportation Association/Department of Transportation (IATA/DOT)

Any person interested in shipping biological materials off campus should contact the EEM/EHS to confirm compliance with the regulations of IATA/DOT

6.6 Department of Commerce or State Department

The export of biological materials may require a license from the Department of Commerce or State Department. At UMass Lowell, all licenses for transport of any type of material outside the country have to be reviewed and authorized by the Office of Institutional Compliance (OIC).[20] Before any materials can be shipped, the person intending to ship the materials must submit a "Request to Export Materials Out of the U.S. Form" to the OIC. After review and approval, an "Export Compliance Clearance Form" is issued by OIC to the requester and a copy of the clearance is sent to EHS. The export of any controlled material is coordinated with the EHS Hazardous Materials Receiving Stockroom or through Radiation Safety.

[19] http://www.selectagents.gov/index.html
[20] http://www.uml.edu/Research/OIC/export-controls/default.aspx

6.7 U.S. Department of Agriculture (USDA) and Animal and Plant Health Inspection Service (APHIS)

USDA/APHIS permits are required for infectious agents of livestock and biological materials containing animal, particularly livestock, material. Tissue and cell culture techniques customarily use bovine fetal serum as a stimulant for cell growth. Tissue culture materials and suspensions of cell culture grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origin are controlled by the USDA due to the potential risk of introduction of exotic animal disease into the US.

7.0 BIOHAZARDS AND POTENTIALLY INFECTIOUS MATERIALS

7.1 Classification of Biohazardous Agents and Risk Groups

The World Health Organization (WHO) recommends a classification of four risk groups based on hazardous characteristics (described above) and the route of transmission of the natural disease. The four groups address the risk to both the laboratory worker and the community[21]

The NIH Guidelines *(*in Section II-A-1) establish a comparable classification and assign human etiological agents into four risk groups on the basis of hazard.[22]

Descriptions of the WHO and NIH risk group classifications are presented in Table 1. The risk groups (RG-) are classified 1 to 4 and although they correlate with biosafety level (BL-) 1 to 4, they do not necessarily equate to the four-biosafety levels.

It is necessary to perform a risk assessment in order to determine the degree of correlation between an agent's risk group classification and biosafety level.

[21] http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf.
[22] http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948312

Table 1: WHO and NIH Classification of Infectious Agents by Risk Group*[23]

Risk Group Classification	**NIH Guidelines for Research involving rDNA Molecules 2002**	**World Health Organization Laboratory Biosafety Manual 3rd Edition 2004**	**Examples**
Risk Group 1	Agents not associated with disease in healthy adult humans	(No or low individual & community risk) A microorganism unlikely to cause human or animal disease.	*Bacillus subtilis* AAV type 1-4 *E. coli-no O antigen* *E. coli K12*
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.	(Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.	*. Bacillus anthracis* *. Burkholderia* (formerly *Pseudomonas* species) *. Escherichia coli* - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including *E. coli* O157:H7 *. Blastomyces dermatitidis* *. Entamoeba histolytica* . Adenoviruses - all human . Herpesviruses - except Monkey B virus . Hepatitis A, B, C, D, E . Rabies virus - all strains
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).	(High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.	No Risk group 3 is used at UMass Lowell
Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).	(High individual & community risk) A pathogen that usually causes serious human or animal disease & can be readily transmitted, directly or indirectly, from one individual to another. Effective treatment and preventive measures are not usually available.	At the present, the State of Massachusetts doesn't allow work with Risk 4 group agents

[23] *BMBL 5th Edition, December 2009*

7.2 Categories of Biohazardous Agents

At UMass Lowell, working with any of the following biological agents requires registration of the research work with the Institutional Biosafety Committee:[24]

- Recombinant DNA (rDNA) or transgenic plants, animals, and tissues treated with pathogenic agents or transfected or otherwise treated with rDNA;
- Infectious agents like pathogenic or infectious bacteria, viruses, fungi, parasites, nucleic acids, or agents of unknown pathogenicity to humans, plants, or animals;
- Drug resistant bacteria, including those containing plasmids specifying drug resistance;
- Human tissue or body fluids; nonhuman primate materials including blood, blood components, tissues, and body fluids; and potentially infectious cultured human or animal cells;
- Select agents and biologically derived toxins regulated by Health and Human Services and Center for Disease Control (HHS/CDC) or United States Department of Agriculture (USDA);
- Undefined or other infectious agents, such as prions, and toxins (bacterial, fungal, plant);
- Infected animals and animal tissues derived from non-human primates (can transmit Herpes B Virus) or sheep (can transmit *Coxiella burnetii*, the causative agent of Q-fever);
- Human and animal stem cells;
- Research that involves any of the above materials with animal and/or human subjects.

7.3 Generation of rDNA

At UML, all research involving the generation of rDNA requires registration and approval by the IBC. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules is the definitive reference for rDNA research in the United States. For questions about any issue related to rDNA, particular host-vector system, or any biosafety issue contact the Biosafety Officer at biosafety@uml.edu or at ext. 4-2618.

[24] http://www.uml.edu/Research/OIC/biological-safety/default.aspx

7.4 Transgenic Animals and Plants

Investigators who work to create transgenic animals or plants by rDNA methods require registration with the IBC. The IBC has to approve the generation of the trans-gene, which is the DNA sequence that is going to be changed in the animal and that will be expressed in following generations. Additionally, the Institutional Animal Care and Use Committee (IACUC) will approve the manipulation of the animals to create the new strain of animal. The use of purchased transgenic animals requires IACUC approval but not IBC approval. The NIH Guidelines provide specific recommendation for plant-biosafety experiments involving the creation and/or use of genetically engineered plants.

At UMass Lowell, PIs doing research with any of the previous biohazardous agents must register his/her work with the IBC prior to initiation of research projects involving use of such materials or agents. The Biosafety Officer will guide any investigator through the process to register his/her work with the IBC.

7.5 Human Blood, Blood Products, Body Fluids, and Tissues

Biosafety Level 2 (BL-2) practices and procedures must be followed when handling human blood, blood products, body fluids, and tissues because of the infectious agents they may contain. Biosafety Level 2 practices and procedures are consistent with the concept known as Universal Precautions, requiring all specimens of human blood or other potentially infectious materials to be treated as if they are infectious.

7.6 Tissue Culture and Cell Lines

The CDC and OSHA recommend that all cell lines of human origin be handled at BL-2. The same requirement applies to cell lines derived from blood, lymphoid, tumor tissue, transformed cells, clinical and/or autopsy samples from human and non-human primates. At UMass Lowell, the IBC and EEM/EHS follow the CDC and OSHA recommendations. All commercial cell lines, independent of the classification of the vendor, should be handled at BL-2 containment and practices. It is difficult and costly to prove that the cells are free of all adventitious agents, all viruses, and mycoplasma-containing primate cell lines.

7.7 Use of Animals

The use of animals in research is reviewed and approved by the Institutional Animal Care and Use Committee (IACUC)[25] and must follow all local, state and federal regulations that govern the use of animals for research activities.

IBC approval is required for research involving the use of biohazardous materials and animals. The IBC registration serves to evaluate the materials used, ensures all personnel are aware of and informed of the hazards of the materials, adequate personal protective equipment is used and animal handling procedures are specified to protect animal facility workers.

The IACUC protocol[26] outlines the procedures used with animals. Specifically, it defines how the material will be used in animals, and the precautions necessary to protect persons handling animals and all byproducts. Approval is required BEFORE any activity may begin. Investigators who are uncertain how to categorize agents should contact the Biosafety Officer at biosafety@uml.edu or at ext. 4-2618.

7.8 Clinical Specimens

At UMass Lowell several research groups collaborate with outside institutions to send and receive human clinical specimens. The infectious nature of this material is largely unknown. In most circumstances, the initial processing of clinical specimens can be done safely at Biosafety Level 2. A primary barrier, such as a biological safety cabinet, is highly recommended.

All laboratory personnel who handle human source materials are required to comply with the OSHA Bloodborne Pathogens Standard as stated in the Exposure Control Plan. Universal Precautions must be followed when handling human blood, blood products, body fluids, or tissues.

The Customized Supplement Exposure Control Plan must be completed for each laboratory and be available to all lab workers.

[25] http://www.uml.edu/Research/OIC/animal-use/default.aspx
[26] http://www.uml.edu/Research/OIC/animal-use/forms.aspx

8.0 PRINCIPLES OF BIOSAFETY

8.1 Routes of Transmission

Infection requires a point of entry to the body through:

- Broken skin such as a puncture (sharp), lesion in the skin (rash, acne, cold sore, hang nail, etc.);
- Mucous membrane (eyes, mouth or nose);
- Inhalation;
- Ingestion.

Some laboratory procedures increase the potential for exposure depending of the route of transmission.

8.1.1 Contact with Broken Skin

Several procedures such us vortexing, mixing, decanting liquids, removal of screw caps, pipetting, as well as striking agar plates, and inoculation of animals can result in generation of infectious aerosol, droplet formation, or direct contact with infectious material and the broken skin. Use of sharps (needles and syringes) or contact with animals (bites or scratches) increases the risk of accidental inoculation.

8.1.2 Mucous Membrane Contact

Direct contact or splashing of eyes, nose, or mouth with contaminated gloves is a potential route of exposure. Splash can be generated by several of the methods described above such us vortexing, mixing, pipetting, and inoculation of animals.

8.1.3 Inhalation

Sonication, centrifugation and heating loops for inoculation are some of the procedures that can potentially produce fine aerosols that can easily be inhaled when working in the lab. Additionally, changing litter of infected animal cages will also produce aerosols that could be inhaled.

8.1.4 Ingestion

The highest risk for oral exposure or ingesting infectious agents in the laboratory setting used to be mouth pipetting, a procedure that has been forbidden for several years now. Storage of food drinks and utensils, and eating or drinking in the lab, can result in ingestion of infectious material.

8.2 Risk Assessment or Risk Evaluation

When performing a risk assessment or evaluating the risk of exposure, it is necessary to take into consideration the pathogenicity of the organism, route of transmissions, host range, effective protective measures, and the availability of treatment.

8.3 Containment

Containment describes the physical environment within which infectious agents are handled. It also applies to the methods to manage the infectious agents for handling, maintenance, and storage.

The purpose of containment is to reduce or eliminate exposure of laboratory workers, other people, and the outside environment to potentially hazardous agents.

The protection of personnel and the immediate laboratory environment from exposure to infectious agents (sometimes secondary containment) is provided by good microbiological techniques and the use of appropriate safety equipment.

The three elements of containment include laboratory practice and techniques, safety equipment, and facility design. Facility design may include such features as negative airflow, air filtration, impermeable flooring, and use of biological safety cabinets.

8.4 Laboratory Practices and Techniques

An important element of biological safety is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required for handling such material safely. The PI or laboratory supervisor is responsible for providing or arranging for appropriate training of personnel. The BMBL[27] published by the CDC contains all appropriate methods to follow when working with biological agents.

Laboratory activities must be directed by a scientist trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with the handling of infectious agents.

[27] http://www.cdc.gov/biosafety/publications/bmbl5/

The PI is responsible for selecting additional safety practices to address hazards associated with the agent or procedure.

Appropriate facility design and engineering features, safety equipment, and management practices are a complement to personnel safety, practices, and techniques.

8.5 Safety Equipment or Engineering Controls (Primary Barriers)

Safety equipment includes biological safety cabinets (BSC), enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials. The BSC is the principal device used to provide containment of infectious splashes or aerosols generated by microbiological procedures.

Safety equipment also includes personal protective equipment (PPE) such as respirators, face shields, lab coats, safety glasses or goggles. PPE is often used in combination with other safety equipment when working with biohazardous materials. In some situations, personal protective clothing may form the primary barrier between personnel and the infectious materials.

8.5.1 Facility Design (Secondary Barriers)

The design of a facility is important in providing a barrier to protect people working inside and outside the laboratory, and to protect people or animals in the community from infectious agents that may be accidentally released from the laboratory. Facilities must be commensurate with the laboratory's function and the recommended biosafety level for the agent being manipulated.

The recommended secondary barrier(s) will depend on the risk of transmission of specific agents. For example, the exposure risks for most laboratory work in Biosafety Level 1 and 2 facilities will be direct contact with the agents, or inadvertent contact exposures through contaminated work environments. Secondary barriers in these laboratories may include separation of the laboratory work area from public access, availability of a decontamination facility (e.g. autoclave), and hand washing facilities.

As the risk for aerosol transmission increases, higher levels of primary containment and multiple secondary barriers may become necessary to prevent infectious agents from escaping into the environment. Such design features could include specialized ventilation systems to assure directional airflow, air treatment systems to

decontaminate or remove agents from exhaust air, controlled access zones, airlocks at laboratory entrances, or separate buildings or modules for isolation of the laboratory.

8.6 Biosafety Levels

There are four biosafety levels (BL- or BSL-) which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each possible combination must be the appropriate for the operation to be performed, and consider key factors such as the Risk Group of the infectious agent, the route of transmission and the laboratory function or activities. The recommended biosafety level for an organism represents the conditions under which the agent can be ordinarily handled in a safe manner.

8.6.1 Biosafety Level 1 (BL-1)

BL-1 is appropriate for work done with Risk Group 1 (RG-1) agents that are characterized strains of viable microorganisms not known to cause disease in healthy adult humans. The BL-1 laboratory represents a basic level of containment that depends on standard microbiological practices with no special engineering controls, other than a sink for hand washing.

8.6.2 Biosafety Level 2 (BL-2)

BL-2 is applicable to work done with RG-2 agents, a broad-spectrum moderate-risk agents present in the community and associated with human disease of varying severity, but for which there is effective medical treatment. Agents can be used safely on the open bench, provided the potential for producing splashes or aerosols is low. Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures or ingestion of infectious materials. Procedures with high aerosol or splash potential must be conducted in primary containment equipment such as a biosafety cabinet. Primary barriers such as splash shield face protection, lab coat, and gloves should be used as appropriate. Hand washing and waste decontamination facilities must be available in the BL-2 laboratory.

8.6.3 Biosafety Level 3 (BL-3)

BL-3 is applicable to work done with indigenous or exotic agents (RG-3) with a potential for respiratory transmission and that may cause serious and potentially lethal infection. There may or may not be effective treatment for these group of

agents. Primary hazards to personnel working with these agents (i.e. *Mycobacterium tuberculosis*, St. Louis encephalitis virus, *Coxiella burnetii, among others*) include autoinoculation, ingestion, and exposure to infectious aerosols.

Greater emphasis is placed on engineering controls or special equipment (primary barriers) to protect personnel in adjoining areas, the community and the environment from exposure to infectious aerosols. For example, all laboratory manipulations should be performed in biological safety cabinet or other enclosed equipment. Secondary barriers include controlled access to the laboratory and a specialized ventilation system that minimizes the release of infectious aerosols from the laboratory.

8.6.4 Biosafety Level 4 (BL-4)

BL-4 is required for working with dangerous and exotic agents (RG-4), that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, and for which there are no vaccines or treatments.

Primary hazards to workers include respiratory exposure to infectious aerosols, mucous membrane exposure to infectious droplets, and autoinoculation. All manipulations of infected materials and isolates pose a high risk of exposure and infection to personnel, the community, and the environment. Isolation of aerosolized infectious materials is accomplished primarily by working in a Class III biological safety cabinet or a full-body, air-supplied positive pressure personnel suit. The facility is generally a separate building or a completely isolated zone within a complex, with specialized ventilation and waste management systems to prevent release of viable agents to the environment.

There are no BL-3 or BL-4 facilities or laboratories at UMass Lowell. Furthermore, there is no active BL-4 laboratory in the State of Massachusetts.

The level of containment designated in ascending order (BL-1 to BL-4) correlates with the Risk Group (RG-1 to RG-4) of the infectious agent involved in the work, as well as the degree of protection required for the work. Nonetheless, the Biosafety Officer should perform a safety analysis and a risk assessment of the complete work to assure the safety of personnel, environment, and community.

Complete descriptions of Biosafety Levels 1 through Level 4 may be found in the Appendix G of the NIH Guidelines.

The essential elements of the four-biosafety levels for activities involving infectious microorganisms are summarized in Table 2.

8.7 Vertebrate Animal Biosafety Levels

There are four animal biosafety levels, designated Animal Biosafety Levels (ABS- or ABSL-) 1 through 4, for work with infectious agents in mammals. The levels are combinations of practices, safety equipment and facilities for experiments on animals infected with agents that produce or may produce human infection. In general, the biosafety levels recommended for working with a specific infectious agent *in vivo* and *in vitro* are comparable. As with Biosafety Levels, increasing levels of protection to personnel and the environment are provided as the order of *in vitro* work ascends. At UMass Lowell, there is no work with animals that could be categorized as ABS-3.

Complete descriptions of Animal Biosafety levels 1 (ABSL-1) through 4 (ABSL-4) are found in Appendix Q of the NIH Guidelines and the BMBL 5th Ed.[28]

[28] http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf

Table 2: Recommended Biosafety Levels for the Use of Infectious Agents

Biosafety Level	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary barriers)
BL-1	Not known to cause disease in healthy adults	Standard microbiological practices	None required	Open bench-top and sink required
BL-2	Associated with human disease. Route of exposure: autoinoculation, ingestion, mucous membrane exposure	**BL-1 practices plus:** limited access biohazard warning signs sharps precautions biosafety manual defining waste decontamination or medical surveillance policies	**Primary barriers**: Class I or II biosafety cabinets or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE: laboratory coats, gloves, face protection as needed	**BL-1 Facility plus:** autoclave available
BL-3*	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	**BL-2 practices plus:** controlled access, decontamination of all waste, decontamination of clothing before laundering, baseline serum recommended	**BL2-equipment plus:** Primary barriers: Class I or II biosafety cabinets or other physical containment devices used for all manipulations of agents; PPE: protective lab clothing, gloves, respiratory protection as needed	**BL-2 plus:** physical separation from access corridors, self-closing, double door access, exhausted air not recirculated, negative airflow into laboratory

*At UMass Lowell there is no BL-3 or ABL-3 Laboratories.

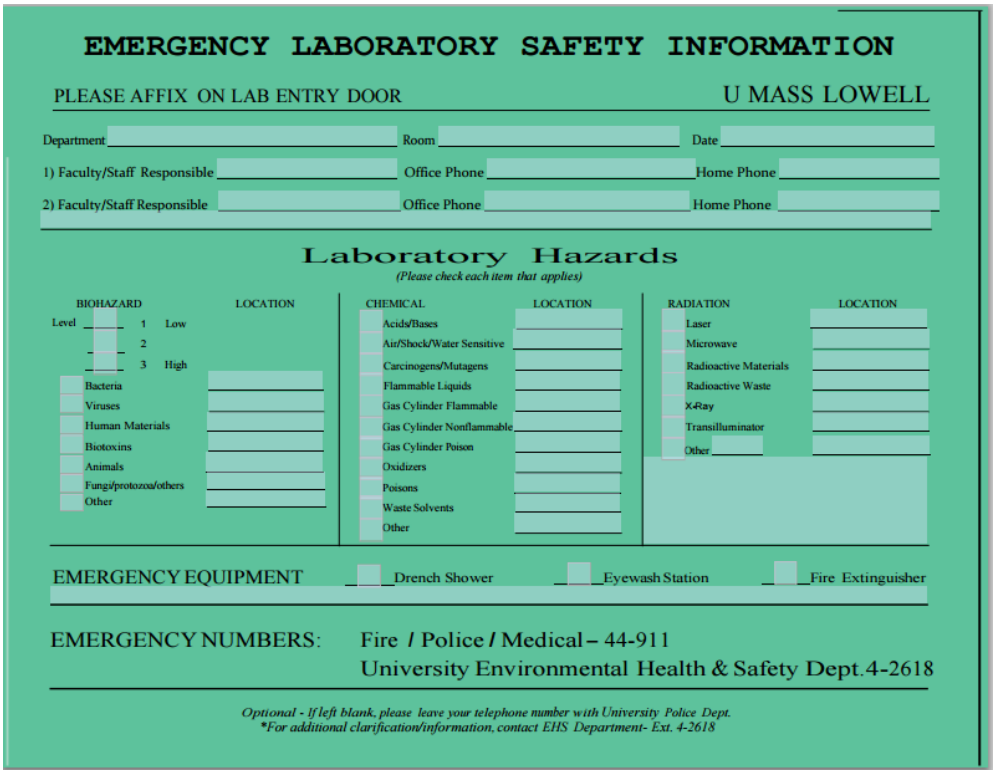
9.0 LABORATORY PRACTICES AND PROCEDURES

9.1 Administrative Controls

9.1.1 The Emergency Green Card

At UMass Lowell, each laboratory has an Emergency Green Card. These signs (cards) provide safety information to visitors, service and emergency response personnel.

Room signs must contain contact information designations for all laboratory hazards in use within the laboratory (chemicals, carcinogens, acutely toxic agents, reproductive hazards, biohazards, radioactive materials, lasers and magnetic fields). Contact the Biosafety Officer at biosafety@uml.edu or call the EEM office at ext. 4-2618 for more information.


EMERGENCY LABORATORY SAFETY INFORMATION

PLEASE AFFIX ON LAB ENTRY DOOR U MASS LOWELL

Department Room Date

1) Faculty/Staff Responsible Office Phone Home Phone

2) Faculty/Staff Responsible Office Phone Home Phone

Laboratory Hazards

(Please check each item that applies)

BIOHAZARD LOCATION

Level 1 Low

2

3 High

Bacteria
Viruses
Human Materials
Biotoxins
Animals
Fungi/protozoa/others
Other

CHEMICAL LOCATION

Acids/Bases
Air/Shock/Water Sensitive
Carcinogens/Mutagens
Flammable Liquids
Gas Cylinder Flammable
Gas Cylinder Nonflammable
Gas Cylinder Poison
Oxidizers
Poisons
Waste Solvents
Other

RADIATION LOCATION

Laser
Microwave
Radioactive Materials
Radioactive Waste
X-Ray
Transilluminator
Other

EMERGENCY EQUIPMENT Drench Shower Eyewash Station Fire Extinguisher

EMERGENCY NUMBERS: Fire / Police / Medical – 44-911

University Environmental Health & Safety Dept. 4-2618

Optional - If left blank, please leave your telephone number with University Police Dept.
**For additional clarification/information, contact EHS Department- Ext. 4-2618*

Figure 1: The Emergency Green Card[29]

[29] http://www.uml.edu/docs/Template%20Emergency%20Green%20Card%20Placard_tcm18-85686.pdf

9.1.2 Biohazard Warning Signs and Posting

All areas and laboratories which contain biohazardous agents must be posted with a biohazard sign. The sign must be red/orange in color with a biohazard symbol and should be located on lab doors, fridges, freezers (-20 and -80 degrees), storage and transportation containers and over all equipment used with biohazard materials.

Figure 2: Universal Biohazard Symbol

9.1.3 Medical Surveillance

Medical surveillance is the systematic assessment of employees exposed or potentially exposed to occupational hazards. The purpose of medical surveillance is for the early identification of conditions that could present an increased risk of adverse health effects related to the task being performed. Medical surveillance is recommended based on the type of work being performed, including consideration of factors such as the duration of the task, the materials being used, and the potential for exposures. Medical surveillance is recommended in the case of work with animals. Participation in a medical surveillance program is offered to those personnel having substantial direct animal contact.

Occupational Health Services are provided by Lowell General Hospital, Chelmsford Campus (978-458-6868) located at 10 Research Place and AllOne Health, 600 West Cummings Park, Suite 3400 Woburn, MA 01801 (781-935-4646). For additional information contact the Biosafety Officer at biosafety@uml.edu or call EEM-EHS at ext. 4-2618.

9.1.4 Engineering Controls or Safety Equipment

Engineering controls are equipment or tools designed to act as a barrier between the hazard and the worker. Examples of engineering controls can be a simple forceps to

pick up broken glass, a sharp container, or sophisticated equipment like the biosafety cabinet (BSC).

9.1.5 Biological Safety Cabinets (BSCs)

Biosafety cabinets (BSCs) are hoods with high-efficiency particulate air (HEPA) filters that provide personnel, environmental and product protection when appropriate practices and procedures are followed. Safety equipment including BSCs, PPE, or other physical containment devices (e.g. safety centrifuge cups) must be used whenever procedures with a potential to create infectious aerosols or splashes are conducted or whenever high concentrations or large volumes of infectious agents are used. Examples of such procedures include pipetting, centrifuging, grinding, blending, shaking, mixing, vortexing, sonicating, opening containers with pressure differentials, or harvesting infected tissues. The BSC is the principal BL-2 device used in laboratories to provide such containment.

Three types of BSCs (Class I, II and III) are used in microbiological laboratories. Open-fronted Class I and Class II BSCs are partial containment devices that provide a primary barrier, offering significant levels of protection to laboratory personnel and to the environment when used in combination with good microbiological techniques.

9.1.6 Class I BSC

This cabinet is suitable for work involving low to moderate risk agents, where there is a need for containment but not for product protection. It provides protection to personnel and the environment from contaminants within the cabinet. The Class I BSC does not protect the product from "dirty" room air.

9.1.7 Class II BSC

The Class II BSC protects the material being manipulated inside the cabinet (e.g. cell cultures, microbiological stocks) from external contamination. It meets requirements to protect personnel, the environment and the product. There are different types of Class II BSCs: Type A (A1, A2), Type B1 ant Type B2. The major differences between these types are in the percent of air that is exhausted or recirculated, and the manner in which exhaust air is removed from the work area. Type A1 and A2 are small cabinets, non-ducted, and the air is exhausted to the laboratory area. Type B1 and B2 are BSCs ducted that can exhaust the air removed outside the laboratory area, outside the facility. Although Type B1 is ducted, 40% of the air is recirculated and 60% removed or exhausted. BSCs Class II Type B2 are ducted with 100% of the air exhausted outside the facility.

9.1.8 Class III BSC or Glove Box

Class II BSC or glove box provides the highest attainable level of protection to personnel, the environment and the product. It is the only cabinet, which provides a total physical barrier between the product and personnel. It is for use with *high-risk* biological agents and is used when absolute containment of highly infectious or hazardous material is required. Additional information on the proper use and selection of a BSC is found on the BMBL.

9.1.9 Work Practices

The following Standard Microbiological Practices should be followed on campus:[30]

- Access to the laboratory is limited or restricted to trained personnel at the discretion of the Principal Investigator when experiments are in progress;
- Work surfaces are decontaminated by trained personnel once a day, and after any spill of viable material;
- All contaminated liquid or solid wastes are decontaminated before disposal;
- Mechanical pipetting devices are used. Mouth pipetting is prohibited;
- Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for this purpose only;
- Lab personnel wash their hands after removing PPE when they were handling materials involving organisms containing infectious materials, recombinant DNA molecules, or animals, and before exiting the laboratory;
- All procedures are performed carefully to minimize the creation of aerosols;
- Facilities should have hand washing sink, emergency eye wash and safety showers, and personal protective clothing (e.g. uniforms, laboratory coats) that are appropriate for the risk of exposure to viable organisms containing rDNA molecules shall be provided;
- Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable, leak-proof container that is closed before being removed from the laboratory;
- An insect and rodent control program is in effect at UMass Lowell. Contact Operations and Services/Facilities for more information at (978) 934-2601.

[30] SOP Bio-012 Biosafety Level 2 Practices, http://osp.od.nih.gov/sites/default/files/nih_guidelines.html#_toc351276355

9.2 Safe and Effective Use of the Biosafety Cabinet

All BSCs should be certified when they are installed, after they are moved, after full decontamination, and annually thereafter. EEM-EHS provides annual certification of all BSCs in UMass Lowell. EHS and the BSO coordinate the annual certification and repair of all equipment as needed. The following are some important reminders on how to use the BSC.

- Make sure that you understand how your cabinet works;
- Review SOP Bio-010 Use and Cleaning of the BSC;
- Plan your work;
- Do not disrupt the protective airflow pattern of the BSC. Rapidly moving your arms in and out of the cabinet, people walking rapidly behind you and open lab doors may disrupt the airflow pattern and reduce the effectiveness of the BSC;
- Minimize the storage of materials inside and around the BSC;
- Always leave the BSC running during use;
- Before using, wipe work surface with 70% alcohol. Wipe off each item you need for your procedures and place them in the cabinet;
- DO NOT place objects over the front air intake grille;
- DO NOT block the rear exhaust grille;
- Segregate clean and dirty (or contaminated items). Always work from "clean to dirty";
- Place a pan with disinfectant and/or a sharps container inside the BSC for pipette discard;
- It is not necessary to flame items. This creates turbulence in airflow and will compromise sterility. Heat buildup may damage the filters;
- Move arms slowly when removing or introducing new items into the BSC;
- If you use a piece of equipment that creates air turbulence in the BSC (such as a centrifuge, vortex, or blender), place equipment in the back third of the cabinet and stop other work while equipment is operating;
- Protect the building vacuum system from biohazards by placing a cartridge filter between the vacuum trap and the source valve in the cabinet;
- Clean up all spills in the cabinet immediately. (Follow SOP Bio-008). Wait 10 minutes before resuming work;
- When cleanup is finished, remove all materials used and dispose of them in a biohazardous waste container;
- Clean all interior surfaces with 70% alcohol;
- Run cabinet 10 minutes after cleanup, before resuming work, or turning cabinet off;
- Remove lab coat and gloves, wash hands thoroughly before leaving laboratory.

9.2.1 Use of Pipettes and Pipetting Aids

Pipettes are used for volumetric measurements and the transfer of fluids that may contain infectious or other hazardous materials. Laboratory associated infections have occurred from oral aspiration of infectious materials, mouth transfer via a contaminated finger, and inhalation of aerosols. Exposure to aerosols may occur when liquid from a pipette is dropped onto the work surface, when cultures are mixed by pipetting, or when the last drop of an inoculum is blown out. A pipette may become a hazardous piece of equipment if improperly used.

Safe pipetting techniques are required to minimize the potential for exposure to biological hazardous materials. The following must be followed;

- Always wear appropriate PPE in the lab
- Never mouth pipette. Always use a pipetting aid;
- If working with biohazardous solutions, confine pipetting operations to a biosafety cabinet;
- If working with chemical or toxic fluids work in a chemical fume hood or ducted BSC;
- Always use cotton plugged pipettes when pipetting biohazardous or toxic materials, even when safety pipetting aids are used;
- Do not prepare biohazardous materials by bubbling expiratory air through a liquid with a pipette;
- Do not forcibly expel biohazardous material out of a pipette;
- Never mix biohazardous or toxic material by suction and expulsion through a pipette;
- When pipetting, avoid accidental release of infectious droplets;
- Do not discharge material from a pipette at a height. Whenever possible, allow the discharge to run down the container wall;
- For re-usable pipettes, place contaminated pipettes, horizontally in a pan containing enough liquid disinfectant (freshly prepared 10% bleach) to completely cover them. Do not place pipettes vertically into a cylinder. Autoclave the pan and pipettes as a unit before processing them for re-use;
- Discard contaminated disposable pipettes in an appropriate container that can be disposed of by autoclaving or incineration;
- If possible, pans or containers for contaminated pipettes should be placed inside the biosafety cabinet to avoid moving one's arms outside the BSC.

9.3 Use of Syringes and Needles Sharps Policy

Syringes and hypodermic needles are dangerous instruments. The use of needles and syringes should be restricted to procedures for which there is no alternative.

Blunt cannulas should be used as alternatives to needles wherever possible (i.e. procedures such as oral or intranasal animal inoculations). Needles and syringes should never be used as a substitute for pipettes.

Follow these recommendations when using syringes and needles with biohazardous or potentially infectious agents:

- For disposal of sharps, follow the SOP (Bio-002);
- Before using any sharp, be sure to have a convenient size sharp container;
- Never recap a needle;
- Minimize the use of reusable syringes and needles. Bending, recapping, clipping, or removal of needles from syringes is prohibited;
- Use disposable needle locking syringe units whenever possible;
- Whenever possible, work in a biosafety cabinet if you are handling biological material and sharps;
- Wear appropriate PPE (gloves, safety glasses, and lab coat);
- Fill the syringe carefully to minimize air bubbles;
- Expel air, liquid, and bubbles from the syringe vertically into a cotton moistened with 70% alcohol;
- Wrap the needle and stopper in cotton moistened with disinfectant when removing a needle from a rubber-stoppered bottle;
- Use a separate pan of disinfectant for reusable syringes and needles;
- If it is essential that a contaminated needle be removed from a syringe, use a mechanical device or the one-handed scoop method;
- The use of needle nipping devices is prohibited and the devices must be discarded as infectious waste;
- Do not use a syringe to mix infectious fluid forcefully;
- Do not contaminate the needle hub when filling the syringe in order to avoid transfer of infectious material to fingers;
- Do not place sharps in pans containing pipettes or other glassware in order to eliminate sorting later;
- Used disposable needles and syringes must be placed in appropriate sharps disposal containers and discarded as infectious waste;
- Never overfill a sharps container. Only fill container until it is ¾ full.

9.3.1 Use of Cryostats

Frozen sections on unfixed human tissue or animal tissue infected with an etiologic agent pose a risk. Freezing tissue does not necessarily inactivate infectious agents. Freezing propellants under pressure should not be used for frozen sections as they may cause spattering of droplets of infectious material. Gloves should be worn during preparation of frozen sections.

When working with biohazardous material in a cryostat, the following practices are recommended:

- Consider the contents of the cryostat to be contaminated and decontaminate it frequently with 70% ethanol;
- Consider trimmings and sections of tissue that accumulate in the cryostat to be potentially infectious and remove them during decontamination;
- Defrost and decontaminate the cryostat with a tuberculocidal hospital disinfectant once a week and immediately after unknown tissue, *M. tuberculosis*, or other infectious agents is cut;
- Handle microtome knives with extreme care. Stainless steel mesh gloves should be worn when changing knife blades;

9.3.2 Use of Centrifuge Equipment

Hazards associated with centrifuging include mechanical failure and the creation of aerosols. To minimize the risk of mechanical failure, handle and maintain the centrifuge according to the manufacturer's instructions. Users should be properly trained, and operating instructions that include safety precautions should be prominently posted on the unit.

Aerosols are created by practices such as filling centrifuge tubes, removing plugs or caps from tubes after centrifugation, removing supernatant, and re-suspending sediment pellets. The greatest aerosol hazard is created if a tube breaks during centrifugation. To minimize the generation of aerosols when centrifuging biohazardous material, the following procedures should be followed:

- Use sealed tubes and safety buckets that seal with O-rings. Before use, inspect tubes, O-rings, and buckets for cracks, chips, erosions, bits of broken glass, etc. Do not use aluminum foil to cap centrifuge tubes because it may detach or rupture during centrifugation;

- Fill and open centrifuge tubes, rotors, and accessories in a BSC. Avoid overfilling of centrifuge tubes so that closures do not become wet. After tubes are filled and sealed, wipe them down with disinfectant;
- Add disinfectant to the space between the tube and the bucket to disinfect material in the event of breakage during centrifugation;
- Always balance buckets, tubes, and rotors properly before centrifugation;
- Do not decant or pour off supernatant. Use a vacuum system with appropriate in-line reservoirs and filters;
- Work in a BSC when re-suspending sedimented material. Use a swirling rotary motion rather than shaking. If shaking is necessary, wait a few minutes to permit the aerosol to settle before opening the tube;
- Small low-speed centrifuges may be placed in a BSC during use to reduce the aerosol escape. High-speed centrifuges pose additional hazards. Precautions should be taken to filter the exhaust air from vacuum lines, to avoid metal fatiguing resulting in disintegration of rotors, and to use proper cleaning techniques and centrifuge components. Manufacturers' recommendations must be meticulously followed to avoid metal fatigue, distortion, and corrosion;
- Avoid the use of celluloid (cellulose nitrate) tubes with biohazardous materials. If celluloid tubes must be used, choose only new tubes. Celluloid centrifuge tubes can stand high speeds (like 10^5 g) but they are highly flammable and prone to shrinkage with age and distort at high temperatures. Cellulose tubes never should be autoclaved since they are highly explosive. Chemical disinfection (e.g. 10% house bleach) can be used to decontaminate tubes before disposal.

9.4 Devices that Increase Aerosol Production

Equipment such as blenders, ultrasonic cell disrupting, grinding and vortex may create aerosol production and thus the tubes used with these types of equipment must be capped and the activity must be conducted inside a bio-safety cabinet.

9.4.1 Safety Blenders

This equipment is designed to prevent leakage from the bottom of the blender jar, providing a cooling jacket to avoid biological inactivation and to withstand sterilization by autoclaving.

- If blender rotors are not leak proof, they should be tested with sterile saline or dye solution prior to use with biohazardous material;
- The use of glass blender jars is not recommended because of the breakage potential. If they must be used, glass jars should be covered with a polypropylene jar to prevent spraying of glass and contents in the event the blender jar breaks. A towel moistened with disinfectant should be placed over the top of the blender during use;
- Before opening the blender jar, allow the unit to rest for at least one minute to allow the aerosol to settle;
- These devices should be decontaminated promptly after use. Follow "SOP Bio-005 Decontamination of Reusable Labware, Work-Surfaces, and Equipment."

9.4.2 Lyophilizers

Depending on lyophilizer design, aerosol production may occur when material is loaded or removed from the lyophilizer unit. If aerosol formation does occur, the material must be loaded in the BSC.

The vacuum pump exhaust should be filtered to remove any hazardous agents or alternatively, the pump can be vented into a BSC. After lyophilization is completed, all surfaces of the unit that have been exposed to the agent should be disinfected. Follow SOP Bio-005.

If the lyophilizer is equipped with a removable chamber, the equipment should be closed off and moved to a BSC for unloading and decontamination. Handling of cultures should be minimized and vapor traps should be used wherever possible.

9.4.3 Ampoules

Opening ampoules containing liquid or lyophilized culture material should be performed in a BSC to control the aerosol produced

- Gloves must be worn: WARNING[31];
- To open, nick the neck of the ampoule with a file, wrap it in disinfectant soaked towel, hold the ampoule upright and snap it open at the nick;
- Reconstitute the contents of the ampoule by slowly adding liquid to avoid aerosolization of the dried material;

[31] Ampoules used to store biohazardous material in liquid nitrogen have exploded, causing eye injuries.

- Mix the contents without bubbling and withdraw it into a fresh container;
- Discard the towel and ampoule top and bottom as infectious waste.

9.4.4 Alternatives to the Use of Glass Ampoules

The use of polypropylene tubes eliminates this hazard. These tubes are available dust-free or pre-sterilized, and are fitted with polyethylene caps with silicone washers. Heat sealable polypropylene tubes are also available.

9.4.5 Loop Sterilizers and Bunsen Burners

Avoid using the technique of sterilization of inoculating loops or needles in an open flame as it may generate small-particle aerosols which may contain viable microorganisms. The recommended approach is using a shielded electric incinerator that minimizes aerosol production during loop sterilization.

Alternatively, disposable plastic loops and needles may be used for culture work where electric incinerators or gas flames are not available. The loops are semi-quantitative and can be used for counting bacteria. Discard contaminated loops as bio-hazardous waste.

Continuous flame gas burners should not be used in BSCs. These burners can produce turbulence, which disturbs the protective airflow patterns of the cabinet, and the heat produced by the continuous flame may damage the HEPA filter.

Bunsen burners may also cause a fire in the cabinet. If a gas burner must be used, one with a pilot light should be selected.

9.4.6 Housekeeping

Good housekeeping in laboratories is essential to reduce risks and protect the integrity of biological experiments. Routine housekeeping must be relied upon to provide work areas free of significant sources of contamination. Housekeeping procedures should be based on the highest degree of risk to which personnel and experimental integrity may be subjected.

Laboratory personnel are responsible to clean laboratory benches, equipment and areas that require specialized technical knowledge.

Additional housekeeping consideration:

- Keep the laboratory neat and free of clutter. Surfaces should be clean and free of infrequently used chemicals, biological materials, glassware and equipment;
- Hazardous materials must be sealed/closed, labeled, and properly stored in appropriate storage areas such as flammable or corrosive cabinets, freezers and or refrigerators.
- Access to sinks, eyewashes, emergency showers and fire extinguishers must not be blocked;
- Maintain a workplace that is free of physical hazards. Aisles and corridors should be free of tripping hazards;
- Remove unnecessary items on floors, under benches or in corners. Do not accumulate cardboard boxes.
- Dispose of hazardous waste properly;
- Never use fume hoods for storage of chemicals or other materials;
- Unused containers of chemicals can be shared with other laboratories. Call the HazMat Manager at 4-2543, or EEM-EHS office at 4-2618 for details. If you have question about biosafety issues contact the Biosafety Officer at biosafety@uml.edu or EEM-EHS at ext. 4-2618.

9.4.7 Practices Not-permitted in Labs When Doing Custodial Cleaning

- Dry sweeping and dusting that may lead to the formation of aerosols is not permitted;
- The usual wet or dry industrial type vacuum cleaner is a potent aerosol generator and unless equipped with high-efficiency particulate air (HEPA) filter, must not be used in the biological research laboratory. Their use is prohibited in order to protect personnel and the integrity of the experiment. Wet and dry units with HEPA filters on the exhaust are available from a number of manufacturers;
- Operations and services shall not schedule activities such as floor washing while active research or teaching takes place. This activity must be scheduled during off hours.

10.0 PERSONAL PROTECTIVE EQUIPMENT (PPE)

PPE is used to protect personnel from contact with hazardous materials and infectious agents. Appropriate clothing may also protect the experiment from contamination. PPE includes items for personal protection such as gloves, lab coats, gowns, shoe covers, boots, respirators, face shields, safety glasses or goggles. Lab personnel working with biohazards must wear appropriate PPE for the type of biohazard, the activity to be performed, and the containment of the laboratory. PPE is provided without cost to personnel. The following PPE is recommended for regular use: safety glasses, gloves, and lab coat.

10.1 Eye and Face Protection

Goggles or safety glasses along with a face shield are required for anticipated splashes, sprays or splatters of infectious or other hazardous materials to the face. Information on the availability of low cost prescription safety eyewear may be obtained by calling EEM-EHS at ext. 4-2618. Wearing of contact lenses is allowed as long as safety glasses are also used.

10.2 Laboratory Clothing – Lab Coats

This category includes lab coats, smocks, scrub suits, and gowns. Long sleeved garments should be used to prevent the contamination of skin or street clothes and to reduce shedding of microorganisms from the arms. In circumstances where it is anticipated that splashes may occur, the garment must be resistant to liquid penetration to protect clothing from contamination. If the garment is not disposable, it must be capable of withstanding sterilization, in the event it becomes contaminated.

Additional criteria for selecting clothing are: comfort, appearance, closure types and location, antistatic properties and durability. Protective clothing must be removed and left in the laboratory before leaving for non-laboratory areas. Disposables should be available for visitors, maintenance, and service workers in the event it is required.

10.3 Lab Coat Program at UMass Lowell

The EEM/EHS Department operates a Lab Coat Program. Two white full length lab coats are provided per employee. The lab coats have embroidered UMass Lowell Logo on the left upper side and the lab worker's full name embroidered in script on upper right side. As important to providing lab coats, for safety purposes, is the need to provide a professional laundering service to assure that nobody at UMass Lowell takes lab coats home to launder.

Once per week (every Monday) soiled lab coats will be "picked-up" by the supplier and professionally laundered and returned to the University. This Lab Coat program is provided at no cost to the employee, department or researcher.

For more information, please contact the EEM/EHS office at (978)934-2618.

10.4 Gloves

These must be selected based on the hazards involved and the activity to be conducted. Gloves must be worn when working with biohazards, toxics and other physically hazardous agents. Temperature resistant gloves must be worn when handling hot material or dry ice. Delicate work requiring a high degree of precision dictates the use of thin walled gloves. Protection from contact with toxic or corrosive chemicals may also be required. For assistance in glove selection, call EEM-EHS at x 4-2618.

When working with hazardous materials, the lower sleeve and the cuff of the laboratory garment should be overlapped by the glove. A long sleeved glove or disposable arm-shield may be worn for further protection. In some instances, double gloving may be appropriate. If a spill occurs, hands will be protected after the contaminated outer gloves are removed. Gloves must be disposed of when contaminated, removed when work with infectious materials is completed, and not worn outside the laboratory. Disposable gloves must not be washed or reused.

Gloves should be used only in the lab. If you need to transfer any biological material outside the lab, you should use an unbreakable secondary container. Spray 70% ethanol, over the container surface, wait 1 minute and dry the container with paper towels. Never use one glove or gloves when carrying containers outside of the lab.

10.5 Respirators

In certain instances, additional PPE may be required. Respirator selection is based on the hazard and the protection factor required. Personnel who require respiratory protection must contact the Sr. Safety Specialist, at EEM/EHS for fitting of equipment and training in its proper usage.

11.0 CLEAN-UP PROCEDURES AFTER WORKING WITH BIOLOGICAL MATERIALS

11.1 General Considerations

- All infectious materials and all contaminated equipment or apparatus must be decontaminated before being washed, stored, or discarded. Follow SOP Bio-006 Use of the Autoclave for Sterilization of Materials and Biological Waste;
- Autoclaving is the preferred method for sterilizing biological waste. Training is necessary to work with an autoclave;
- Autoclaves should not be operated unattended or by untrained personnel;
- Special precautions should be taken to prevent accidental removal of material from an autoclave before it has been sterilized or simultaneous opening of both doors on a double door autoclave;
- Residual bleach, hypochlorite, or any other strong oxidizing material, must not be autoclaved with organic materials such as paper, cloth, or oil.

11.2 Cleaning Procedures

The following SOPs, described in Section IV from this Biosafety Guide, are related with this chapter:

- SOP BIO-005 Cleaning and Decontamination of Reusable Labware, Work Surfaces and Equipment
- SOP BIO-006 Use of Autoclave for Sterilization of Materials and Biological Waste
- SOP BIO-007 Cleaning Biological Spill inside the Centrifuge
- SOP BIO-008 Cleaning and Decontamination of Small Spills in the Lab or BSC
- SOP BIO-009 Cleaning Instruments and Materials Used for Handling Potentially Prion Infected Neural Tissue
- SOP BIO-010 Usage and Cleaning of Biosafety Cabinet

12.0 CLEANING-UP BIOHAZARD SPILLS

12.1 Spill Clean-Up inside the BSC

- Wear lab coat, safety glasses, and gloves during cleanup;
- Allow cabinet to run during cleanup;
- Apply disinfectant and allow a minimum of 20 minutes contact time;
- Wipe up spillage with disposable disinfectant-soaked cloth;
- Wipe the walls, work surface and any equipment in the cabinet with a disinfectant-soaked cloth;
- Discard contaminated disposable materials in appropriate biohazardous waste container to be decontaminated by autoclave or picked up by EHS;
- Place contaminated reusable items in biohazard bags to be autoclaved;
- Expose non-autoclavable materials to disinfectant, 20-minute contact time, before removal from the BSC;
- Run biosafety cabinet for 10 minutes after cleanup before resuming work or turning cabinet off;
- Remove gloves and discard into biohazard waste container, then remove lab coat and wash hands thoroughly before leaving laboratory.

12.2 Spill Clean-up Outside the BSC and Inside the Lab

- Clear area of all personnel and wait for aerosol to settle before entering spill area;
- Asses size of spill and notify 44911 if EEM/EHS support is necessary;
- Remove any contaminated clothing and place in biohazard bag to be autoclaved;
- Wear a disposable gown, safety glasses, and gloves during clean-up;
- Initiate cleanup with disinfectant as follows;
    a. Soak paper towels in disinfectant and place over spill;
    b. Encircle the spill with additional disinfectant being careful to minimize aerosolization while assuring adequate contact;
    c. Decontaminate all items within the spill area;
    d. Allow 20 minutes contact time to ensure germicidal action of disinfectant;
    e. Wipe equipment with 1:10 bleach followed by water then 70% alcohol;
    f. Place disposable contaminated spill materials in appropriate biohazardous waste container(s) for autoclaving;
    g. Place contaminated reusable items in biohazard bags to be autoclaved.

12.3 Spill Clean-Up inside Centrifuge

- Review and follow SOP Bio-007 Cleaning Biological Spills Inside a Centrifuge;
- Clear area of all personnel and wait 30 minutes for aerosol to settle before attempting to clean-up spill;
- Wear a lab coat, safety glasses, and gloves during clean-up;
- Remove rotors and buckets to nearest biological safety cabinet for clean-up;
- Thoroughly disinfect inside of centrifuge;
- Remove contaminated debris after disinfection, place in appropriate biohazardous waste container(s) and autoclave before disposal as infectious waste.

12.4 Spill Clean-up Outside Lab and During Transport

- Transport biohazardous material in an unbreakable well-sealed primary container placed inside of a second unbreakable lidded container (cooler, plastic pan or pail) labeled with the biohazard symbol;
- Should a spill occur in a public area, do not attempt to clean it up without appropriate personal protective equipment;
- As an interim measure, wear gloves and place paper towels, preferably soaked in disinfectant, directly on spilled materials to prevent spread of contamination;
- To assure adequate contact, surround the spill with disinfectant, if available, taking care to minimize aerosols;
- If you cannot handle the clean-up, call the UMass Police at 4-4911.

13.0 BIOHAZARDOUS WASTE MANAGEMENT

13.1 Biohazardous Waste Definitions

Infectious waste as defined by the Commonwealth of Massachusetts, Department of Public Health is a physically dangerous medical or biological waste such as: sharps; blood and blood products; pathological wastes; cultures and stocks of infectious agents; contaminated animal carcasses, body parts and bedding.

Blood and blood products are discarded bulk human blood products in free draining, liquid state; body fluids contaminated with visible blood; and materials saturated/dripping with blood.

Pathological waste consists of human anatomical parts, organs, tissues, and body fluids removed and discarded during surgery or autopsy, or other medical procedures and specimens of body fluids and their containers.

Culture and stocks of infectious agents and associated biologicals such as the following

- All discarded cultures and stocks of infectious agents and associated biologicals;
- Biotechnological by-product effluents (any discarded preparations made from genetically altered living organisms and their products);
- Cultures of specimens from medical and pathological laboratories;
- Cultures and stocks of infectious agents from research laboratories;
- Wastes from the production of biologicals, and discarded live attenuated vaccines intended for human use.

Contaminated Animal Carcasses, Body Parts and Bedding of all research animals known to be exposed to pathogens

Sharps are discarded medical articles that may cause puncture or cuts, including but not limited to all used and discarded hypodermic needles and syringes, Pasteur pipettes, broken medical glassware, scalpel blades, disposable razors, and suture needles.

13.2 Handling Biohazardous Waste

All infectious waste from university laboratories must be managed appropriately. The preferred disposal technique is inactivating the bio-hazard by autoclaving when the equipment is available. If autoclaving equipment is not available, the EEM/EHS Department shall provide bio-waste incineration boxes for the collection of bio-hazardous solid waste. Please refer to standard operating procedure Bio-003 for further information. Any treatment of infectious waste, other than by autoclaving, must be

reviewed by the EEM-EHS Department. Contact the Biosafety Officer at biosafety@uml.edu or ext. 4-2618 if you have any questions about biological waste disposal or any other biosafety issue.

The primary responsibility for identifying and disposing of infectious material rests with the PI or laboratory supervisors. This responsibility cannot be shifted to inexperienced or untrained personnel.

IMPORTANT: Glass Disposal
The glass containers should be used for dispose any type of glass that does not contain biohazardous material or "clean glass" following **SOP Bio-001 Disposal of Glass**.

Potentially infectious and biohazardous waste must be separated from the general waste stream at the point of generation (i.e. the point at which the material becomes a waste) by the generator into the following three classes:

- Used Sharps
- Liquid Infectious Waste
- Solid Infectious Waste

13.2.1 Disposal of Used Sharps

All used sharps must be segregated into sharps containers that are non-breakable, leak proof, impervious to moisture, rigid, tightly lidded, puncture resistant, red in color, and marked with the universal biohazard symbol. Call Hazards Materials Manager at x 42543 to request pick up and new sharp containers. To dispose of used sharps, follow SOP Bio-002.

13.2.2 Disposal of Liquid Infectious Waste

The disposal of liquid waste is described in the SOP Bio-004 For Decontamination and Disposal of Liquid Biohazardous Waste. This SOP applies to the disposal of any liquid biohazardous waste like, but not limited to, culture media or any effluent that has been in contact with cells, viable organisms or their parts.

All liquid biological waste should be collected in bottles or plastic containers that contain 100 ml of household bleach for each liter of liquid waste. The bottles should be labeled as hazardous waste and stored in the Satellite Accumulation Area (SAA) according to the disposal of hazardous waste described in the CHP.

The University prohibits sink disposal of all hazardous materials. PIs can fill out a Non Hazardous Waste Determination Form[32] to determine if the bleached liquid can be flushed into the sanitary sewer system. The pouring of those wastes should be accompanied by large amounts of water after EHS approval.

13.3 UMass Lowell Monitoring Autoclave Program

The process of autoclaving is monitored to assure the efficacy of the treatment method. Each autoclave operator uses a chemical monitor strip. EEM-EHS provides every autoclave user with Class-5 Vapor line Steam Integrator to validate each run and load of autoclaved material. This vapor indicator verifies that the proper conditions of temperature, vapor, and pressure have been obtained during the autoclaved process.

EEM-EHS offers testing and validation of all autoclaves located at the university and performs a monthly Bio-test using spores from *Geobacillus stearothermophilus* at standard conditions. Autoclaved ampules are incubated for 62ºC for 24 hours with a non-autoclaved ampule used as control.

The Biosafety Officer maintains a data base with monthly testing results.

13.4 Incinerating Biological Waste

Certain infected materials cannot be autoclaved and should be disposed of directly in a burn box lined with a red biohazard bag and marked with the biohazard symbol. Infectious waste must be properly packaged prior to off-site transport for incineration by a State approved facility and vendor.

IMPORTANT: Contact the Biosafety Officer at biosafety@uml.edu if you have any questions related to disposal of biological waste.

13.5 Mixed Waste

Some lab processes generate mixed waste. Procedures must be in place for the disposal of waste mixed with multiple hazards, e.g. biological waste or potentially infectious substantially contaminated with toxics, carcinogenic, nanomaterial and other compounds, including radioactive materials. The most common mixed waste at UMass Lowell is of biological materials (human or animal cells in culture, bacteria plates etc.)

[32] https://www.uml.edu/docs/Non-Hazardous-Waste-Determination-Form_tcm18-87560.pdf

with chemical substances. The disposal of each case of mixed waste generated will depend on the components of the mixture. The rule of thumb is to inactivate or decontaminate the biological material and then dispose accordingly as chemical or radiological materials. It is important to consider the reactivity of the chemicals involved in the mixed waste, as well as the half- life of the radioactive material.

Autoclaving mixed waste is not permitted.

Contact the Biosafety Officer at biosafety@uml.edu regarding the disposal of these wastes. The BSO, together with the HazMat Manager, the Safety Specialist, and the Radiation Safety Officer will decide the steps to follow in each particular case.

13.6 Small Whole Animals, Parts, and Carcasses

Discarded animals and animal parts are considered infectious waste and must be discarded as described in SOP Bio-003. The IBC and EEM-EHS must approve the disposal procedure.

13.7 Embalmed Cadaver and Animal Parts Used in Teaching Labs

EEM-EHS provides faculty with special containers for disposal of embalmed cadaver parts and animal parts. Faculty should contact in advance the BSO to discuss procedures and request the containers for disposal of these materials.

13.8 Storage

Infectious waste must not be allowed to accumulate. Contaminated material should be inactivated and disposed of daily or on a regular basis as required. If the storage of contaminated material is necessary, it must be done in a rigid container away from general traffic.

Infectious waste, excluding used sharps, may be stored at room temperature until the storage container is full, but no longer than 30 days from the date of generation. In addition, it can be refrigerated for up to 30 days or frozen for up to 90 days from the date of generation. Infectious waste must be dated when refrigerated or frozen for storage. Storage of infectious waste in a freezer must be approved by EEM-EHS.

If infectious waste becomes putrescent during storage, it must be moved off site within 24 hours for processing and disposal. Sharps containers may be used until 3/4 full, at which time they must be disposed of as infectious waste.

14.0 PACKAGING AND SHIPPING OF BIOLOGICAL AND BIOMEDICAL MATERIALS

The federal and state government recognizes all etiologic agents, infectious materials and vectors that may contain them as hazardous materials and packaging and shipping of biomedical material must meet federal requirements.

14.1 Definitions Related to Packaging, and Shipping Biological and Biomedical Materials

Biomedical Materials that are known to contain or could contain etiologic agents are divided into two groups: "diagnostic specimens and biological products" and "materials containing certain etiologic agents".

Etiologic Agents are those viable microorganisms that cause disease in humans and include bacteria, bacterial toxins, viruses, fungi, rickettsia, protozoans and parasites. These disease-causing microorganisms may also be referred to as infectious agents or infectious substances.

Infectious Substances are those substances containing viable microorganisms or their toxins which are known or are suspected to cause disease in animals or humans.

Diagnostic Specimens are any human or animal material including but not limited to, excreta, blood and its components, tissue, tissue fluids, etc. which the shipper reasonably believes may contain an etiologic agent and that is being shipped for purposes of diagnosis.

Biological Product means a product prepared in accordance with regulations that govern the manufacture of vaccines, reagents, etc.

Materials Containing Etiologic Agents mean materials known to contain or reasonably believed by the shipper to contain an etiologic agent from a list included in the regulation. The list contains most of the Class 2, 3 and 4 agents but any etiologic agent should be handled according to the regulation even if it is not on the list. Patient specimens that are expected to contain an etiologic agent should be shipped according to these requirements.

14.2 Packaging of Materials Containing Etiologic Agents

The packaging of etiologic agents or materials containing them varies depending on the volume shipped. Packaging should be such that the package will withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation. Contents should not leak to the outside of the shipping container, even if leakage of the primary container occurs. Packages should be able to withstand rough handling and passage through cancellation machines, sorters, conveyers, etc.

14.3 Packaging of Materials with Volumes Not Exceeding 50 ml

The material to be shipped must be placed in a securely closed, watertight primary container. The primary container must be placed in a durable, watertight secondary container. Several primary containers may be placed in a single secondary container, so long as the total contents does not exceed 50 ml. Absorbent material must be placed in the spaces between the primary and secondary containers, so that there is enough absorbent to absorb the entire contents of the primary container(s) should breakage or leakage occur. Each set of primary and secondary containers must be placed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood or other material of equivalent strength (Figure 3).

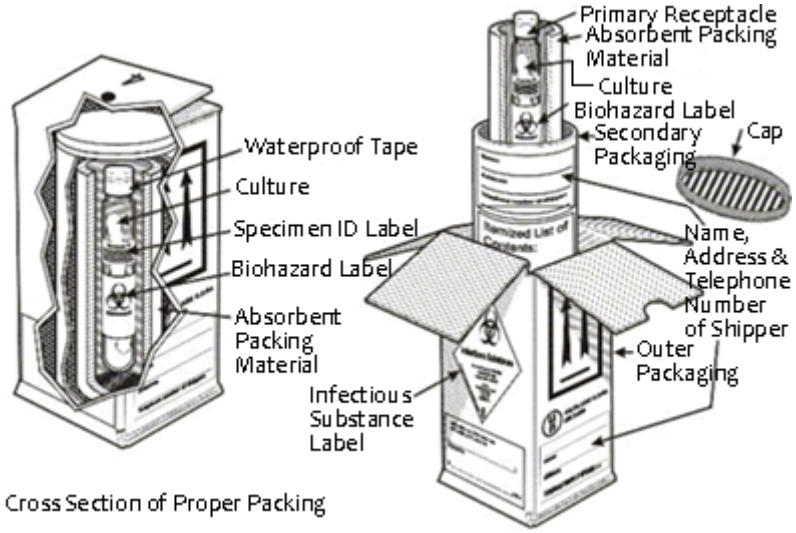


Figure 3: Package and container for infectious agents (under 50 ml)[33]

[33] http://www.mass.gov/eohhs/docs/dph/laboratory-sciences/div-6-2-infectious-substance-shipping-guide.pdf

14.4 Packaging of Materials with Volumes Greater Than 50 ml

Packaging of these larger volumes must comply with the above-mentioned requirements. In addition, shock absorbent material in volume at least equal to that of the absorbent material must be placed between the secondary container and the outer shipping container. Single primary containers must not contain more than 1 Liter (L) of material. However, two or more primary containers whose volumes do not exceed 1 L may be placed in a single secondary container. The maximum amount of etiologic agent that may be enclosed within a single outer shipping container may not exceed 4 L.

14.5 Dry Ice

If dry ice is used, it must be placed between the secondary container(s) and the outer shipping container and the shock absorbent material placed so that the secondary container(s) does not become loose within the outer shipping container as the dry ice sublimates.

A special label for dry ice and one for infectious substances, illustrated below, must be placed on the outer shipping container. These labels identify the package as containing etiologic agents in dry ice and direct anyone observing damage to the package or leakage of its contents to the call the CDC

Figure 4: Labels for dry ice and infectious substances[34]

Certain etiologic agents require special handling in addition to that stated above. They must be shipped by registered mail or an equivalent system, which requires or provides for sending notification of receipt to the sender immediately upon delivery. When this

[34] https://www.federalregister.gov/articles/2011/07/20/2011-17687/hazardous-materials-miscellaneous-amendments

notice of receipt is not received within 5 days following anticipated delivery, the sender must notify the CDC.

Questions pertaining to proper shipping and packaging of etiologic agents at UMass Lowell should be directed to the Biosafety Officer at biosafety@uml.edu or contact the EEM-EHS at x 4-2618.

14.6 Export Control

At UMass Lowell, the Office of Institutional Compliance (OIC)[35] is responsible for developing and implementing the export compliance program.[36]

Export controls are United States laws that regulate and restrict the release of critical technologies, technical data, software code, equipment, chemical and biological materials, and other materials information and services to foreign nationals and foreign countries for reasons of foreign policy and national security. Export control laws apply to all activities – not just sponsored research projects.

An export is:

- Shipment of a controlled commodity, equipment, material, or software outside of the U.S.;
- Disclosing controlled technology or technical data to a foreign national, whether in the U.S. or abroad;
- Performing technical assistance or defense services for or on behalf of a foreign national, whether in the U.S. or abroad;
- Exports within the U.S. are considered to be a "deemed" export to the foreign national's home country.

At UMass Lowell, the shipment out of the U.S. requires review and approval by the OIC) to meet Export Compliance Program Guidelines.

Contact the OIC for assistance and to determine whether a license is required or if an exemption may apply.

[35] http://www.uml.edu/Research/OIC/default.aspx
[36] http://www.uml.edu/Research/OIC/export-controls/default.aspx

14.7 Import of Etiologic Agents

Import of infectious materials, etiologic agents and vectors that may contain them is governed by federal regulation. This includes but is not limited to bacteria, viruses, rickettsia, parasites, yeasts, and molds. In some instances, an agent that is suspected of causing human disease also requires a permit. When an etiologic agent, infectious material, or vector containing an infectious agent is being imported to the United States, an importation permit issued by the United States Public Health Services (US PHS) must accompany it. Importation permits are issued only to the importer, who must be located in the United States. The importation permit, with the proper packaging and labeling, will expedite clearance of the package of infectious materials through the US PHS Division of Quarantine and release by U.S. Customs.

Shipping labels contain the universal biohazard symbol, the address of the importer, the permit number, and the expiration date are issued to the importer with the permit. The importer must send the labels and one or more copies of the permit to the shipper. The permit and labels inform the U. S. Customs Service and the U.S. Division of Quarantine personnel of the package contents. The importer bears responsibility for assuring that the foreign shipping personnel pack and label the infectious materials according to US PHS regulations. Transfers of previously imported material within the United States also require a permit.

In some cases, instead of an importation permit, the issuing officer may issue a “Letter of Authorization” after review of an "Application to Import an Etiological Agent". The letter is issued for materials that are judged noninfectious, but which might be construed to be infectious by U. S. Customs inspection personnel. “Letters of Authorization” may be issued for items such as formalin fixed tissues, sterile cell cultures, clinical materials such as human blood, serum, plasma, urine cerebrospinal fluid, and other tissues or materials of human origin when there is no evidence or indication that such materials contain an infectious agent. Letters of Authorization are in effect for two years, and do not require a shipping label to be issued by CDC.

14.8 New Changes on Import Regulations for Biological Agents, Infectious Substances and Vectors

The Federal Register/Vol. 78, No. 23/Monday, February 4, 2013/Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
[Docket No. CDC–2011–0007]
42 CFR Part 71
RIN 0920–AA37
Foreign Quarantine; Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors

Agency: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

Action: Final rule[37]

Summary: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) is issuing this final rule amending the regulations regarding the importation of infectious biological agents, infectious substances, and vectors. The amendments improve HHS/CDC's ability to prevent the introduction, transmission, or spread of communicable diseases into the United States.

Dates: The final rule is effective April 5, 2013.

Questions pertaining to import of any biological agents, infectious substances, or vectors by any member of UMass Lowell should be directed to the Biosafety Officer at biosafety@uml.edu or EEM-EHS at x 4-2618.

[37] http://www.gpo.gov/fdsys/pkg/FR-2013-02-04/pdf/2013-02391.pdf

15.0 SELECT AGENTS

Select agents are a group of microorganisms or toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. The National Select Agents Registry (NSAR) Program[38] currently requires registration of facilities, including government agencies, universities, research institutions, and commercial entities that possess, use or transfer "select" biological agents and toxins. The use and possession is controlled by Federal Agencies such as the CDC or the USDA. Select agents are also controlled for export purposes. EEM-EHS is responsible for the Select Agents Program at UMASS Lowell.

Any UMass Lowell, the PI that plans to use any of the listed select agents in research or teaching needs to contact the Biosafety Officer at biosafety@uml.edu or call ext. 4-2618 to get all paperwork, permits and registration with the NSAR in place before any use of these agents begins. Please note that this process can take several weeks and we advise all investigators to contact the BSO as soon as possible.

Some of the select agents are exempt depending on the amount in possession of the investigator. The list of exclusions is showed on Table 3[39]

15.1 Requirements for the Use of Select Agents at UMass Lowell

In addition to IBC approval for the use of the select agent, the Office of Institutional Compliance[40] must be consulted before any quantities of select agents may be acquired or used at UMass Lowell.

[38] http://www.selectagents.gov/index.html
[39] http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html
[40] http://www.uml.edu/Research/OIC/default.aspx

15.2 Federal Exempt Quantities of Toxins

The following toxins listed in Table 3[41] are not regulated if the amount under the control of a PI, treating physician or veterinarian, or commercial manufacturer or distributor does not exceed, at any time, the amounts indicated in Table 3.

Table 3: HHS Non-Regulated Quantities of Toxins

HHS (NIH/CDC) Toxins	Amount (mg)
Abrin	100.0
Botulinum neurotoxins	0.5
Clostridium perfringens epsilon toxin	100.0
Conotoxin	100.0
Diacetoxyscirpenol (DAS)	1000.0
Ricin	100.0
Saxitoxin	100.0
Shiga-like ribosome inactivating proteins	100.0
Shigatoxin	100.0
Staphylococcal enterotoxins	5.0
T-2 toxin	1000.0
Tetrodotoxin	100.0

[41] http://www.selectagents.gov/PermissibleToxinAmounts.html

16.0 REFERENCES, RESOURCES AND WEBSITE LINKS FOR SUPPORTING INFORMATION

1. The OSHA Bloodborne Pathogen Standard 29CFR 1910.1030
   http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051
   http://osha.bloodbornepathogens.us/OSHAreg.html

2. CDC/NIH, "*Biosafety in Microbiological and Biomedical Laboratories*", Fifth Edition, December 2009
   http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf

3. CDC HIV
   http://www.cdc.gov/hiv/basics/whatishiv.html

4. NIH Guidelines for Research Involving Recombinant DNA Molecules
   http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

5. 105 CMR 480.00 "*Storage and Disposal of Infectious or Biological Wastes: State Sanitary Code*" Chapter VIII
   http://www.mass.gov/eohhs/docs/dph/regs/105cmr480.pdf

6. Public Health Agency of Canada
   This site contains Pathogens Safety Data Sheet (PSDS), the equivalent of MSDS for microorganisms.
   http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php

7. EPA Approved Disinfectants
   http://www.epa.gov/oppad001/chemregindex.htm

8. UML Environmental Emergency Management – Environmental Health and Safety
   http://www.uml.edu/eem/

9. UML EHS – Biosafety Program
   https://www.uml.edu/EEM/EHS/Biosafety/default.aspx

10. UML – Office of Institutional Compliance
    http://www.uml.edu/Research/OIC/default.aspx

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11. UML Institutional Biosafety Committee(IBC)
    http://www.uml.edu/Research/OIC/biological-safety/default.aspx

12. UMass Lowell Institutional Animal Care and Use Committee (IACUC)
    http://www.uml.edu/Research/OIC/animal-use/default.aspx

13. EEM-EHS Lab Coat Program
    https://www.uml.edu/EEM/EHS/Lab-Safety.aspx

14. EEM-EHS training schedule for BBP/Biosafety and Lab Safety
    https://www.uml.edu/EEM/Training-schedule/Training-Schedule-EHS.aspx