ENVIRONMENTAL AND EMERGENCY MANAGEMENT
ENVIRONMENTAL HEALTH AND SAFETY

I. EXPOSURE CONTROL PLAN

Compliance with OSHA Bloodborne Pathogen Standard
29 Code of Federal Regulations 1910.1030

2013
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I. UML-EXPOSURE CONTROL PLAN POLICY

The University of Massachusetts Lowell (UML) is committed to providing a safe and healthy work environment for students, faculty and staff. In pursuit of this goal, the following Exposure Control Plan (ECP) is provided as an administrative control to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with Occupational Safety and Health Administration (OSHA) Standard 29 Code of Federal Regulation (CFR) 1910.1030.

Purpose

The purpose of the UML-ECP is to eliminate or minimize student, faculty and staff occupational exposure to blood, body fluids or other potentially infectious materials (Appendix One). This plan is a key document to assist the UML administration to comply with the OSHA Bloodborne Pathogen (BBP) Standard and to protect the UML community.

Responsibilities

Environmental and Emergency Management-Environmental Health & Safety (EEM-EHS)

1. Provide guidance and supervision to ensure compliance with the implementation of the Exposure Control Plan;
2. Provide support to departments, schools, laboratories and facilities in determining those employment positions or tasks that qualify for reasonable anticipation of exposure to bloodborne pathogens;
3. Assist departments, schools, laboratories and facilities in determining appropriate personal protective equipment (PPE), work practices, engineering controls, and housekeeping schedules;
4. Support schools, laboratories and facilities to establish a program for evaluating sharps with safety devices designed to eliminate or minimize occupational exposure;
5. Provide training programs for all employees who have potential occupational exposure to bloodborne pathogens and maintain a master file of employees trained in this program;
6. Coordinate Hepatitis B vaccinations for all persons covered by the UML-ECP;
7. Manage and coordinate biowaste disposal according to federal and state regulations;
8. Supervise and coordinate emergency response to accidental exposure to blood or other potential infectious material (OPIM);
9. Maintain, review and update the UML-ECP annually and whenever necessary to include new or modified tasks and procedures.
Department Heads, Directors, Managers, and Supervisors

1. Identify those employment positions considered at risk of "occupational exposure" to bloodborne pathogens within each department and specify those tasks or procedures in which occupational exposure is likely to occur;
2. Customize the ECP by adding supplementary information for each department, school, laboratory, facility that is not covered in the general UML-ECP (e.g., tasks, procedures, PPE, and training specific to the agent used in that facility);
3. Provide and maintain all necessary PPE for all persons (faculty, staff and student) working in settings where potential exposure can occur;
4. Enforce all elements of the ECP within the work setting;
5. Ensure that all existing and new employees are informed and trained in all elements of the ECP.

Faculty, Supervisors, Lab Directors, Managers and Principal Investigators (PIs)

1. Customize the Exposure Control Plan for specific work done in his/her laboratory;
2. Ensure that all personnel working under their supervision follow the UML-ECP;
3. Provide training to their respective students in specific techniques;
4. Provide workers and students with appropriate PPE;
5. Report incidents and/or accidents involving exposures to infectious materials within 24 hours to Human Resources (HR), Student health Services and EEM-EHS.

Employees

1. Attend required training sessions on controlling exposure to bloodborne pathogens in the workplace;
2. Comply with all elements of the ECP that apply to work-related tasks and procedures with potential for exposure;
3. Report all exposure incidents to work supervisors or other responsible parties.

UML Institutional Biosafety Committee (UML-IBC)

> Review and approve all research or teaching activities involving blood or other potentially infectious materials.

Licensed Healthcare Professionals

AllOne Health

1. Provide the Hepatitis B vaccination to faculty and staff referred by EEM-EHS;
2. Evaluate employees reporting exposure incidents and provide appropriate diagnostic tests, treatment, and follow-up evaluation;
3. Maintain employee records relative to the Hepatitis B vaccination and post-exposure incidents and treatment.
Office of Student Health Services

1. Provide services for all UML-students;
2. Evaluate students reporting exposure incidents and provide appropriate diagnostic tests, treatment, and follow-up evaluation;
3. Maintain students' records relative to the Hepatitis B vaccination and post-exposure incidents and treatment.
DEFINITIONS/GLOSSARY

**Blood** means human blood, human blood components, and products made from human blood.

**Bloodborne Pathogens (BBP)** means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). Additional information can be found in Appendix One.

**Clinical Laboratory** means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

**Contaminated** means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

**Contaminated Laundry** means laundry that has been soiled with blood or other potentially infectious materials.

**Contaminated Sharps** means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

**Decontamination** means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

**Engineering Controls** means controls (e.g., handwashing facilities, biological safety cabinets, sharps disposal containers, self-sheathing needles, and other safer medical devices such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens or sharps hazard from the workplace.

**Exposure Incident** means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that result from the performance of an employee's duties.

**Handwashing Facilities** means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

**Licensed Healthcare Professionals** are professionals who are legally permitted to independently perform the activities required for hepatitis B vaccination and post-exposure evaluation and follow-up.

**HBV** means hepatitis B virus.

**HIV** means human immunodeficiency virus.

**Needleless Systems** means a device that does not use needles for:
1. The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;
2. The administration of medication or fluids; or
3. Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps

**Occupational Exposure** means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.
Other Potentially Infectious Materials (OPIM) means

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Person(s) in the UML-ECP means all individuals, faculty, staff and students working in settings where potential exposure can occur.

Personal Protective Equipment (PPE) is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be PPE.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Lab means a laboratory where human materials or other potential infectious materials are used.

Sharps with Engineered Sharps Injury Protections means a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).
REFERENCES, RESOURCES AND WEBSITE LINKS FOR SUPPORTING INFORMATION

   & p_id=10051
   http://osha.bloodbornepathogens.us/OSHAreg.html

2. CDC - HIV
   http://www.cdc.gov/hiv/resources/ga/definitions.htm

   http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf

4. NIH Guidelines for Research involving recombinant DNA Molecules


6. 105 CMR 480.00 “Storage and Disposal of Infectious or Biological Wastes: State Sanitary Code” Chapter VIII

7. UML Environmental Health and Safety
   www.uml.edu/ehs

8. UML EHS-Biosafety Program
   http://www.uml.edu/EHS/Programs/bio/Biosafety.html

9. UML Institutional Biosafety Committee (IBC)
   www.uml.edu/ora/institutionalcompliance

10. Public Health Agency of Canada
    This site contains Pathogens Safety Data Sheet (PSDS, the equivalent of MSDS for microorganisms)

11. EPA approved disinfectants
    http://www.epa.gov/oppad001/chemregindex.htm
II. EXPOSURE DETERMINATION AND IDENTIFICATION OF EMPLOYEES AT RISK

The Occupational Safety and Health Administration (OSHA) requires the identification of all employees who are considered at risk of occupational exposure to bloodborne pathogens. Anyone who has a reasonable chance of encountering human blood, body fluids and other potentially infectious materials while performing their normal job duties is covered by the standard.

Risk Determination at UMass Lowell
Workers at risk are identified at UML, based on their job classification and the tasks performed on the job. A screening tool (Appendix Two) is recommended to be used at the first orientation meeting for new employees or at time of BBP training. The screening questionnaire can also be used any time that an employee considers that his/her job scope has changed.

Job Classification and Related Task with Potential Risk for Exposure
Personnel, staff, faculty and students holding the following positions are considered at risk for potential exposure to human material.

1. Clinical personnel from Student Health Services, providing first aid to students in emergency situations;
2. Emergency medical technicians (EMT), administering first aid, responding to spills and other emergencies;
3. Environmental Health and Safety personnel, handling OPIM and biohazardous waste;
4. Faculty/Staff with approved IBC registration handling human materials (tissue, cell lines);
5. Students, Assistants working in labs where blood or OPIM are handled;
6. Graduate Assistants working in labs where blood or OPIM are handled;
7. Animal Care staff, working with or in areas housing infected animals with bloodborne pathogens or human materials;
8. Athletic Trainers, providing initial assistance, in case of accident;
9. Camp Recreation staff, providing initial assistance in case of accident;
10. Custodial staff, cleaning places (laboratories, bathrooms, others) where human materials could be present (also responding to clean small spills involve blood or OPIM);
11. Faculty with clinical assignments, with potential contact with clinical samples;
12. Nursing laboratory professional technicians (phlebotomy, blood processing);
13. Plumbers repairing sanitary systems, labs, pools;
14. University Police responding to emergencies;

Personnel participating in the program will receive training, adequate personal protective equipment (PPE) and be offered the Hepatitis B vaccination at no cost to them. Please note that the vaccination is not obligatory, however if declined, a declination form must be signed (Appendix Three).
III. METHODS OF COMPLIANCE

1. Universal Precautions

Universal Precautions is an approach to infection control where all blood and other potentially infectious materials are treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens.

At UML, Universal Precautions will be observed by all employees and students in order to prevent exposure to blood or other potentially infectious materials.

2. Facilities and Containment

Laboratory facilities are the primary barrier to protect people working inside and outside the laboratory, and to protect people or animals in the community from infectious agents, which 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 level of containment 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. Although there are four levels of containment, table 1 in Appendix Four contains the principal characteristics of Biosafety one to three. In the State of Massachusetts, there are no active BL-4 laboratories. At UMass Lowell all labs are BL-1 or BL-2 containment.

3. Engineering Controls

Engineering controls are the primary barriers designed to remove or minimize exposure to biological hazards. They must be examined, analyzed and maintained on a regular schedule to ensure their effectiveness.

a. Handwashing facilities

Handwashing facilities must be located near the exit of the lab with soap and paper towels available.

b. Biosafety Cabinets (BSCs)

The BSC is the principal device used to provide containment of infectious droplets or aerosols generated by many procedures using blood and human materials. BSCs are designed to provide personnel, environmental and product protection when appropriate practices and procedures are followed.
EEM-EHS has a specific program to routinely inspect, test and certify all BSCs by trained personnel following strict protocols to verify that they are working appropriately. Most BSCs use "high efficiency particulate air" (HEPA) filters in the exhaust and supply systems.

Three kinds of biological safety cabinets, designated as Class I, II and III, have been developed to meet varying research and clinical needs.

Class I BSCs
This BSC provides personnel and environmental protection but not product protection. It does not have HEPA filtered supply air, but the HEPA filter is in the exhaust system to protect the environment. It is commonly used to enclose equipment (e.g. centrifuges, harvesting equipment) or for procedures that generate aerosols like animal cage dumping.

Class II BSCs
This is the most common type of BSCs for working with biological materials. There are several types: A1, A2, B1, and B2. The class II BSC provides protection from external contamination of the materials (e.g., cell cultures, microbiological stocks) being manipulated inside the cabinet, in addition to the protection for the worker and the environment. The supply air flows through a HEPA filter and provides a particulate-free air to the work surface. The exhausted air also goes through a HEPA filter. Depending of type of BSC, the air will recirculate in the lab or will be exhausted to the environment. A summary with information on characteristic of Class II BSCs is in the table-2 of Appendix Four.

Class III BSC
This is a gas-tight BSC; it provides enclosure with a non-opening view window. It also provides the highest attainable level of protection to personnel and the environment. Class III BSCs are used when working with highly infectious organisms.

c. Sharps Disposal Containers and Needle Safe Devices
Standard Operation Procedures (SOP) for the disposal of sharps is explained in the SOP Bio 002 Sharp disposal Policy and Procedures.

Sharps containers must be closable, puncture-resistant, leak-proof on all sides and bottom and the universal biohazard symbol must be on the containers. All sharps containers should be size appropriate and located in areas where sharps such as needles are being used.

EEM-EHS provides sharps containers to all laboratories, and will pick up the containers when they are 75% full. To request a new sharps container, or a pick-up of a full container (75% full) call Peter Bergeron at extension 4-2543.
The following list are examples of sharps: needles, scalpels, razor blades, lancets, glass Pasteur pipettes, glass capillary tubes, contaminated broken glass, and contaminated microscope slides and cover slips. Those sharps are disposed following the SOP Bio-002 Sharps disposal policy and procedures.

UML recommends the use of needle safety devices to avoid needle stick injuries. Examples of safer needle devices are self-blunting needles, self-sheathing needles, and devices with safety locks. Needles should be disposed immediately after use or as soon as feasible in a labeled sharps container. Do not shear, bend, break, or re-cap by hand any needle or sharps. Also, do not put items in the sharps container that are not sharps.

Any person who encounters improperly disposed needles should notify the police department (extension 4-4911) or EEM-EHS (extension 4-2618). When reporting about improperly disposed needles, give your name and the location where you found the needles. In addition, the appropriate authorities at the location shall be notified (i.e., lab manager, PI, Faculty).

4. Work Practices
Work practice controls will be utilized to eliminate or minimize exposure to students and employees working at UML.

a. Best Practices
See Appendix Five for the complete list of the Standard Microbiological Practices

1. No eating, drinking, smoking, applying cosmetics or lip balm, or handling contact lenses is allowed in a work area where there is a reasonable likelihood of occupational exposure;
2. No food or drinks shall be kept in refrigerators, freezers, cabinets, shelves, or on counter tops or bench tops;
3. Persons must wash their hands immediately (or as soon as feasible) after removal of gloves or other personal protective equipment;
4. Employees must perform all procedures involving blood or other potentially infectious materials in such a manner as to minimize splashing, spraying, splattering, and generation of droplets of these substances;
5. Specimens of blood or other potentially infectious materials must be placed in a labeled or color-coded container which prevents leakage during collection, handling, processing, storage, transport or shipping;
6. Secondary containers (puncture resistant) should be used during storage, transport or shipping;
7. Persons must wash their hands or other skin area with soap and water, or flush mucous membranes with water, as soon as possible following an exposure incident (such as a splash of blood to the eyes or an accidental needle stick injury) with copious amounts of water for at least 15 minutes.
5. Personal Protective Equipment (PPE)

Minimum PPE required in a lab is labcoat, safety glasses and appropriated gloves. Principal Investigators, faculty and department supervisors shall provide gloves, lab coats, face shields, eye protection, and aprons in appropriate sizes at no cost to students and employees. Also the University will replace or repair PPE as necessary at no cost to students and employees. All personal protective equipment will be chosen based on the anticipated exposure to blood or other potentially infectious materials.

PPE will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employee's clothing, skin, eyes, mouth, or mucous membranes under normal conditions of use and for the duration of time for which the protective equipment will be used.

EEM-EHS offers to all staff, faculty, students working in labs two personalized lab coats, under the UML-Lab coat Program. Contact Kathi Lyon to get your lab coat (kathi_lyon@uml.edu). And obtain more information about the lab coat program at www.uml.edu/EEM/lab-Safety.aspx

Use of PPE by Students and Employees

1. Wear PPE such as lab coat, safety glasses, and gloves all the time when working in lab where occupational exposure situations can occur;
2. Remove garments that become contaminated by blood or other potentially infectious material immediately or as soon as feasible;
3. Replace all garments that are torn, punctured, or lose their ability to function as a barrier to bloodborne pathogens;
4. Remove all PPE before leaving the work area;
5. Place all garments in the appropriate designated area or container for storage, cleaning, decontamination, or disposal;
6. Wash hands immediately or as soon as feasible after removing gloves or other PPE.

6. Emergency Response: Spills and Decontamination

Spills

1. Personnel are required to report spills of any hazardous material including blood or other potentially infectious materials by contacting UML Police Dispatch at x 4-4911;
2. Small spills may be cleaned by personnel at the time of release if personnel have an understanding of the hazards associated with the material, have appropriate training and spill cleanup materials are available;

3. Personnel should be vaccinated for HBV and must have the appropriate PPE, tools, and materials to safely absorb and disinfect all surfaces. Spill debris must be collected in biohazard waste bags;

4. Spills should be reported to EHS using the Incident Report Form (Appendix Six). Additional information is described in the SOP Bio-008 Cleaning and Decontamination after Spill in the Lab or inside BSC;

Decontamination

1. Wear PPE when decontaminating and cleaning small blood spills or other potentially infectious material spills. PPE should include latex or nitrile gloves, eye protection, and lab coat;

2. Use a freshly, daily prepared 10% (minimum) solution of sodium hypochlorite (household bleach) in water. Since a solution of bleach and water loses its strength quickly, it should be prepared daily before each clean-up to make sure it is effective;

3. Lysol or other EPA-registered disinfectants may also be used depending on the organism of concern;

4. The freshly made bleach solution or disinfectant must be left in contact with the contaminated work surfaces, tools, objects, or potentially infectious materials for at least twenty (20) to thirty (30) minutes before cleaning;

5. All contaminated work surfaces, tools, objects, etc. will be decontaminated immediately or as soon as feasible after any contact with blood or other potentially infectious materials (SOP Bio-005);

6. Equipment that may become contaminated with blood or other potentially infectious materials will be examined and decontaminated before servicing or use;

7. Do not pick up broken glassware directly with your hands. Use hand tools and/or sweep or brush materials into a dust pan. Collect this material into a sharps container;

8. Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner that would expose employees to the risk of percutaneous injury;

9. All equipment and exercise mats associated with Athletics and Campus Recreation shall be wiped clean after each use with an EPA registered disinfectant such as Lysol® or Virex®.

7. Housekeeping
   The PI or supervisor is responsible for ensuring that the work is maintained in a clean and sanitary condition.

Laundry

1. Wear the following PPE when handling and/or sorting contaminated laundry: lab coat, gloves and safety glasses;

2. Handle contaminated laundry as little as possible, with minimal agitation;

3. Place wet contaminated laundry into leak-proof and labeled containers
before transport. Use red biohazard bags for this purpose;
4. At UML, Aramark is used as a provider for laundering labcoats under the EEM-EHS Labcoat Program (Kathi_lyon@uml.edu). For more information about the labcoat program visit: www.uml.edu/EEM/lab-Safety.aspx

8. Regulated Waste

Chemical toxic waste and Biohazard toxic waste are regulated waste. The following are some important consideration about regulated waste.

1. The disposal of solid biological waste follows the SOP Bio-003;
2. Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled, and closed prior to removal to prevent spillage or protrusion of contents during handling;
3. The waste must closed before removal to prevent spillage or protrusion of contents during handling, storage, or transport;
4. In the event that outside contamination of the waste container occurs, it must be placed within a secondary container that is leak-proof and puncture resistant;
5. PPE contaminated with blood or other potentially infectious material shall be handled as little as possible. Such PPE should be placed in a biohazard waste container;
6. Incineration of biohazard waste shall be handled by a certified biological waste contractor. At UML, this process is coordinated by EEM-EHS;
7. Red bags are used as required for regulated waste and contaminated equipment;
8. Employees are to notify EEM-EHS if they discover regulated waste containers, containing blood or OPIIM, that are not labeled with the biohazard sign;
9. To remove biohazard waste bags, boxes or sharps containers, contact the EEM-EHS HazMat Manager Peter Bergeron at extension 4-2543.

If you have any questions contact the Biosafety Officer at ruth_medina@uml.edu.
IV. HEPATITIS B VACCINATION PROGRAM

The Hepatitis B (Hep B) vaccine is safe and effective. Three injections are required for full protection. The second injection is given one month after the first and the third is given five months later. This vaccine only provides protection against Hepatitis B virus. Long term protection is provided in 90% of the individuals who complete the vaccination series.

1. The Hepatitis B vaccination is available at no cost to all employees and students who have the potential for occupational exposure unless the person has previously received the complete series, antibody testing has revealed that the person is immune, or the vaccine is contraindicated for medical reasons;

2. The Hepatitis B vaccination is available after the employee or student has received the EEM-EHS BBP training and within 10 working days of initial assignment;

3. If the person initially declines the Hepatitis B vaccination, but at a later date decides to accept the vaccination, the vaccination is then made available;

4. All persons who decline the Hepatitis B vaccination offered shall sign the OSHA-required waiver indicating their refusal (Appendix Three). These declaration forms will be kept at the office of EEM-EHS;

5. If a routine booster dose of Hepatitis B vaccine is recommended by U.S. Public Health Service or a licensed physician at a future date, such booster doses shall be made available at no cost to the employee and coordinated by EEM-EHS;

6. The Hepatitis B Vaccine is offered to all custodial staff, plumbers, University police, nursing laboratory professional technicians, animal care staff, clinical personnel from Student Health Services, EEM-EHS staff, EMT Emergency Responders, faculty with clinical assignments and faculty/staff with approved IBC registrations;

7. Depending on their job situation and likelihood of exposure, the vaccine is also offered to preventive maintenance personnel, trades persons, PIs, faculty, lab technicians and other personnel as necessary;

8. EHS will provide training to employees on hepatitis B vaccinations, addressing safety, benefits, efficacy, methods of administration, and availability;

9. Vaccination for all UMass Lowell personnel, under the BBP Program will be provided by:
   AllOne Health at
   600 West Cummings Park, Suite 3400
   Woburn, MA 01801
   The phone number is 781-935-4646.
   The satellite office is located at 85 Pankhurst Road, Chelmsford, MA 01824

Contact the Biosafety Officer Ruth_medina@uml.edu for additional information.
V. POST-EXPOSURE EVALUATION AND FOLLOW-UP

1. All exposure incidents shall be reported, investigated, and documented on an Incident Report Form provided by EEM-EHS (Appendix Six). It can also be downloaded from the EHS website;

2. When an employee sustains an exposure incident, it shall be reported immediately to their supervisor, EEM-EHS at extension 42618 and the Human Resources at extension 43560;

3. When a student experiences an exposure incident, it shall be reported immediately to their Faculty, PI, Clinical Preceptor, EEM-EHS at extension 42618 and the Student Health Services Director at extension 44991;

4. The exposed individual may decline medical evaluation or seek medical attention from their own primary care physician if they so choose;

5. All laboratory tests must be conducted by an accredited laboratory at no cost to the employee;

6. Cost for post-exposure evaluation and follow-up will not be the responsibility of the worker;

7. Following a report of an exposure incident, the University recommends that the exposed worker go for a confidential medical evaluation and follow-up, to any of the following places:
   a. AllOne Health,
   b. Lowell General Hospital, or
   c. Saints Medical Center
   d. Students should go to the Office of Student Health Services.

a. Healthcare Professional offices

Staff, Faculty and Graduate Students:
   a. AllOne Health
      600 West Cummings Park, Suite 3400
      Woburn, MA 01801
      Phone: (781) 935-4646
      (Satellite Office located at 85 Parkhurst Road, Chelmsford, MA 01824)
   b. Lowell General Hospital
      295 Varnum Avenue
      Lowell, MA 01854-2134
      Phone: (978) 937-6000
   c. Saints Medical Center
      1 Hospital Drive
      Lowell, MA 01852
      Phone: (978) 458-1411

Undergraduate students:
   d. Office of Student Health Services
      University of Massachusetts Lowell
      McGauvran Student Center, Room 355, Suite 5
      71 Wilder Street
      Lowell, MA 01854-3091
      Phone: (978) 934-4991-Extension 44991
b. Information provided by Human Resources Office to the Healthcare Professional that evaluates individuals exposed to Bloodborne Pathogens

UML will provide the healthcare professional evaluating the employee after an exposure incident with the following information:

1. A description of the employee’s duties and the circumstances under which the exposure occurred;
2. Documentation of the route(s) of exposure, date and time;
3. Results of the source individual’s blood testing, if available. (Identification is not required if the employer can establish that identification is impossible or prohibited by state or local law);
4. The collection and testing of the source individual’s blood for HBV and HIV serological status will occur as soon as feasible after consent is obtained in order to determine HBV and HIV infectivity;
5. Results of the source individual’s testing will be made available to the exposed employee;
6. All medical records relevant to the appropriated treatment of the employee, including vaccination status;
7. Description of any PPE used or to be used.

c. Healthcare Professional’s written opinion post-exposure evaluation

The report from the Healthcare Professional post-exposure evaluation and follow-up should be limited to the following information:

1. The employee has been informed of the results of the evaluation;
2. The employee has been told about any medical condition resulting from exposure to blood or OPIM which require further evaluation or treatment;
3. The employee has been informed of the recommended limitations upon use of PPE;
4. All other findings or diagnoses will remain confidential and should not be included in the written report;
5. Copy of this report will be kept at the Human Resources Office. All medical records will be kept in accordance with 29 CFR 1910.1020.

d. Accidents or incidents at different institutions other than UMass Lowell

Faculty, staff or students doing work at different institutions should follow the guidelines of the institution where accident/incident could occur. An incident report on the UMass Lowell-EHS Incident Report form (Appendix Six) should be sent to EHS.
VI. TRAINING AND COMMUNICATION OF HAZARDS TO EMPLOYEES

1. Training

UMass Lowell and the Department of Environmental Emergency Management/Environmental Health and Safety, are committed to provide a safe and healthy work environment for students, faculty and staff by developing safety programs and providing adequate training to all members of the UMass Lowell community. Annual training in OSHA-Bloodborne Pathogens, lab safety and general Biosafety are a requirement by federal regulations and university policies.

Bloodborne Pathogens (BBP) and Biosafety training

OSHA-BBP Training is offered to employees, student, faculty and staff that will work with human blood, body fluids or other potentially infectious materials. Those workers are identified at risk of occupational exposure to BBP, and require training, adequate personal protective equipment (PPE) and be offered the Hepatitis B vaccination at no cost to them. OSHA-BBP Training is valid for one year and workers at risk must attend training annually.

The Biosafety-BBP training is offered to all laboratory workers that will handle any kind of biological agents.

This training is offered each month from January to December and the scheduled is posted at http://www.uml.edu/EHS/Training_Schedule.htm

b. Contents of the OSHA BBP Standard Training

The training program will include the following components:

1. An accessible copy of the regulatory text of 29 CFR 1910.1030 and an explanation of its contents;
2. A general explanation of the epidemiology and symptoms of bloodborne diseases;
3. An explanation of the modes of transmission of bloodborne pathogens;
4. An explanation of the UML-ECPF and the means by which the employee can obtain a copy of the written plan;
5. Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, and the benefits of being vaccinated;
6. An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood or other potentially infectious materials;
7. An explanation of the use and limitations of methods that will prevent or reduce exposure, including appropriate engineering controls, work practices, and personal protective equipment;
8. Information on the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment;
9. An explanation of the basis for selection of personal protective equipment;
10. Awareness of the term and intent of "Universal Precautions";
11. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the follow up that will be made available;
12. Information on the post-exposure and evaluation follow up provided for the employee following an exposure incident;
13. Explanation of signs and labels or color-coding used to communicate a biological hazard;
14. A question and answer period with the person conducting the training session.

c. Labels and Signs

1. All areas and equipment used when performing a task that involves the potential exposure to human material must be labeled with the universal biohazard label;
2. The orange biohazard sign should be located on doors, equipment, refrigerators and freezers to indicate the presence of biological hazards;
3. The label should be fluorescent orange-red with lettering and symbols in contrasting color as shown below;
4. Employees are to notify EEM-EHS if they discover refrigerators or freezers containing blood or OPIM, or contaminated equipment that are not labeled with the biohazard.
VII. RECORDKEEPING

1) Training Records

OSHA BBP Training is valid for one year and workers at risk must attend training annually. Training records will be kept at the EEM-EHS and contain the following information:

a. Name and title of training instructor;
b. Instructor affiliation: EEM-EHS Department;
c. Attendees: employee name, job title and signatures;
d. Date of training

2) Immunization Status Records

Immunization records will be maintained in accordance with OSHA Standards. These records will be kept confidential, and must be maintained for at least the duration of employment plus 30 years. All UML employee medical records will be kept at the Human Resources Office and students records at Students Health Services Office.

3) BBP- Incident Report Records

All incidents reports will be kept at the EEM-EHS office and in the Human Resources office for at least three years.
VIII. APPENDICES

Appendix One  Bloodborne Pathogens Agents

Appendix Two  Exposure Determination and Identification of Employees at Risk Form

Appendix Three  Hepatitis B Vaccination-Declination Form

Appendix Four  Characteristics of Containment (table-1) and Class II Biosafety Cabinets (table-2)

Appendix Five  Standard Microbiological Practices for BL-1 and BL-2 Laboratories

Appendix Six  Incident Report Form
Appendix One

Bloodborne Pathogens Agents

Bloodborne pathogens (BBP) are microorganisms that are infectious and may be present in blood, body fluids and tissues from human and non-human primates.

Hepatitis B Virus (HBV)

The hepatitis B virus belongs to the Orthohepadnavirus genus and the Hepadnaviridae family. HBV causes a disease that affects the liver. HBV poses great risk for infection among health care providers and laboratory researchers because it can be easily transmitted through parental inoculation (needle stick), and droplet exposure of mucous membrane. Unprotected sexual contact is also a mode of transmission.

Half of all people infected with the hepatitis B virus have no symptoms and for those who do get sick, symptoms usually develop within 1 to 4 months after exposure to the virus. The initial symptoms are often similar to the flu: appetite loss, tiredness, nausea, vomiting, itching all over the body, pain over the location of the liver, jaundice (skin and whites of the eyes turn yellow) and dark color urine.

The virus is present in blood or blood products, urine, semen, cerebrospinal fluid (CSF) and saliva. The virus may be stable in dried blood or blood components up to seven days.

An effective vaccine for HBV is available and is offered free of charge to all workers who have potential for exposure when performing certain tasks during work.

Hepatitis C Virus (HCV)

HCV belongs to the Hepacivirus genus in the Flaviviridae family. This virus causes serious inflammatory disease in the liver and occasionally can be fatal. It is spread predominantly by parenteral (blood contact) route. HCV is present in blood, serum and less frequently in saliva.

It is rarely present in urine and semen. The virus is unstable at room temperature and only lives outside the body from few hours up to three days.

Although hepatitis C damages the liver, 80% of people with the disease do not have symptoms. In those who do, symptoms may not appear for 10-20 years, or even longer. A minority of people have symptoms during the early acute phase of the infection. These symptoms typically develop 5-12 weeks after exposure to HCV and are described as being flu-like (appetite loss, tiredness, nausea, vomiting, body itching, pain over the location of the liver, jaundice [skin and whites of the eyes turn yellow] and dark color urine). These symptoms are indistinguishable of those developed in patients infected with HBV. The symptoms may last a few weeks or months.
HCV infection can occur in a laboratory setting. The prevalence of antibody to this virus (anti-HCV) is slightly higher in medical care worker than the general population. There is no vaccine available for use in humans against the HC virus.

**Human Immunodeficiency Virus (HIV)**

The human immunodeficiency virus belongs to the family Retroviridae, sub-family Orthoretrovirinae, genus Lentivirus and species HIV-1 and HIV-2. HIV suppresses the immune system leaving the infected individual vulnerable to opportunistic infections and cancers. These infections become increasingly severe and eventually can lead to death.

Scientists and medical authorities agree that HIV does not survive well in the environment, making the possibility of environmental transmission remote. CDC studies have showed that drying high concentrations of HIV reduces the number of infectious viruses by 90 to 99 percent within several hours. HIV is sensitive to fluctuations in temperature and the presence of oxygen. One place that HIV has been known to survive in is drug injection syringes since these are airtight and often contain blood from the injector.

Occupational risk for workers is primarily through exposure to infected-blood and other human body fluids such as semen, feces, saliva, urine, tears, sweat, vomitus, and human breast milk. The use of personal protective equipment, engineering controls and good laboratory practices can reduce the potential for exposure to this and other bloodborne pathogens.

The symptoms of HIV infection vary, depending on the phase of infection. When first infected with HIV, the person may not have signs or symptoms at all, although he/she is able to transmit the virus to others. Many people develop a brief flu-like illness two to four weeks after becoming infected. Signs and symptoms may include: fever, headache, sore throat, swollen lymph nodes and rash.

Some people can remain symptom-free for years. But as the virus continues to multiply and destroy immune cells, the person may develop mild infections or chronic symptoms such as: swollen lymph nodes (often one of the first signs of HIV infection) diarrhea, weight loss, fever, cough and shortness of breath. The disease typically progresses to AIDS in about 10 years if no treatment is provided.

There is no vaccination against HIV. Drug prophylaxis such as Azidothymidine (AZT) is available, although its efficacy is debated within the medical community. Protease inhibiting drugs have slowly become a part of the treatment process and seem to hold some promise according to some medical experts.
Additional Bloodborne Pathogens

In addition to HIV, HBV, and HCV; other viruses, bacteria and parasites may also be present in blood, tissues or body fluids.

1. Bacteria and Parasites
   The bacterial and parasitic diseases listed below are treatable with antibiotics or other therapy. At present, at UMass Lowell, there is no research involving the pathogens listed below:
   1) *Plasmodium* species - Malaria;
   2) *Treponema pallidum* - Syphilis;
   3) *Babesia microti* - Babesiosis;
   4) *Brucella* species - Brucellosis;
   5) *Leptospira interrogans* - Leptospirosis.

2. Viruses
   Below are some examples of viruses and the disease that they produce. At present, at UMass Lowell, there is no research involving the virus listed below:
   1) Simian Immunodeficiency Virus (SIV) - SIV Infection;
   2) Arboviruses - Encephalitis;
   3) Hemorrhagic viruses - Viral Hemorrhagic Fever Ebola, Marburg, Lassa fever.

Other Potentially Infectious Materials (OPIM)

Body Fluids:
Semen; Pleural fluid; vaginal secretions; amniotic fluid; cerebrospinal fluid; saliva in dental procedures; synovial fluid; body fluids visibly contaminated with blood; peritoneal fluids in situations where it is impossible to differentiate fluids; pericardial fluids.

Cells, Tissues, Infected Animals
Cell lines or tissue cultures containing HIV, HBV or HCV; Culture media or other solutions which contain HIV, HBV or HCV; Primary human cell and tissue cultures; Human T-lymphocyte cultures; Blood and tissues from experimental animals infected with HIV, HBV or HCV; Animals that have been experimentally infected with HIV, HBV or HCV.

Neural Tissue and Prions
Although rare, neural tissue, particularly brain can be infected with Prions. Prions are abnormal, very stable proteins that produce rare forms of diseases called prion diseases. There is not treatment for this type of diseases. Creutzfeldt-Jakob disease (CJD) is one of them. Any work involving human brain or other neural tissue has to be discussed with the Biosafety Officer to set safety parameters in place. Additional information on prions can be found at http://www.cdc.gov/biosafety/publications/bmbi5/BMBL.pdf

Transmission of Bloodborne Pathogens
Direct contact of infected materials with broken or non-intact skin e.g. rash, hang nail, cut, abrasion, acne and cold sore. Broken skin can occur in accidents with sharps as through needle sticks, punctures, etc. Splashes and aerosols contact with mucosa from eyes, mouth and nose.
The Occupational Safety and Health Administration (OSHA) requires the identification of all employees who can be considered at risk of occupational exposure to bloodborne pathogens (BBP), found in human blood and other potential infection materials (OPIM) like human body fluids and secretions.

Please print the following information and respond by marking YES or NO to all the questions according to the tasks performed on your job.

1. (name) __________________________ Date__________________________
2. Job title __________________________ Department _______________________
3. Supervisor __________________________ Building/Room # _______________________
4. E-mail __________________________

YES NO Work as a responder to accidents providing first aid and/or other emergency medical procedures (e.g. Police Officers, EMT, Sports Trainers, Coaches and EHS personnel)

YES NO Works in the laboratory and perform any tasks where anticipated exposure to infectious materials could occur such as (handling or transporting human material or other infectious materials)

YES NO Enter areas where others may handle infectious materials and it is reasonably anticipated that the employee can be at risk of occupational exposure due to his/her job tasks:
- Laboratory cleaning where research with human materials is done
- Fixing plumbing in a laboratory where human material is present,
- Work in areas or clean areas where there is blood due to an accident with sharp objects (glass bottle broken in a fight) or a fall or a wet surface

YES NO Handle human blood or blood components (plasma, serum, and cells), blood products, clinical samples when doing research or working in clinical laboratories.

YES NO Handle sharps when working with human materials. Handle waste containing sharps or waste that contains human materials. Perform any I.V. blood drawing (e.g. Phlebotomist, Clinical Laboratory Technician, and Clinical Laboratory Trainee)

YES NO Work with animals infected with human material (e.g. Animal Care Technician, Research Assistant and Research Trainees)

If ANY of the above responses is "YES", the employee must be considered at occupational risk of exposure to bloodborne pathogens. In compliance with the OSHA BBP the employee must be offered the HepB vaccine (at no cost), appropriate BBP training and must be provided with personal protective equipment.

If you have any questions contact the Biosafety Officer at ruth.medina@uml.edu or call EEM at x 42816
EEM-EHS BLOODBORNE PATHOGEN PROGRAM (29 CFR 1910.1030)

HEPATITIS B VACCINATION/DECLINATION FORM (29 CFR 1910.1030 (f)(1) and (f)(2)(iv)

The University of Massachusetts Lowell in compliance with the OSHA “Bloodborne Pathogen Standard” offers the Hepatitis B Vaccine (HepB) to employees with potential for exposure to bloodborne pathogens.

As a UMass Lowell employee, you have the option to receive the HepB at no cost to you.

Please print your name and indicate your interest in receiving HepB by checking one of the boxes below. Sign and date the bottom of the form and return to the Training Instructor or send it by interoffice mail to: Ruth Medina, EHS. 175 Cabot St.-Wannalancit Suite 311, Lowell, MA 01854

Print Name: __________________________________________

Job Title/Department: ________________________________________

e-mail: ______________________________________________________

_____ N/A - My job does not involve contact with blood or other human body fluids

_____ Yes, I want to receive the HepB vaccination

_____ I have already received the HepB vaccination

_____ No, I am not interested in receiving the HepB vaccination. I understand that due to my occupational exposure to blood or other infectious materials that I may be at risk of acquiring Hepatitis B virus infection. I have been given the opportunity to be vaccinated with the Hepatitis B vaccine at no charge to myself. However, I decline the Hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want the Hepatitis B vaccine, I can receive the vaccine series at no charge to me. 29 CFR 1910.1030(f)(2)(iv)

Signature: ____________________________ Date: ______________

Note: EEM-EHS personnel will coordinate HepB Vaccination for employees covered by the UMass Lowell-Exposure Control Plan. If you have any questions contact the UMass Lowell- Biosafety Officer ruth_medina@uml.edu, or the EEM office (978-934-2618).
# Appendix Four

## Table-1

**Characteristics of Containment BL-1 and BL-2***

<table>
<thead>
<tr>
<th>Containment</th>
<th>Agents</th>
<th>Practices</th>
<th>Safety Equipment (Primary Barriers)</th>
<th>Facilities (Secondary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL-1</td>
<td>Not known to consistently cause disease in healthy adults</td>
<td>Standard Microbiological Practices</td>
<td>None required</td>
<td>Open bench top sink required</td>
</tr>
<tr>
<td>BL-2</td>
<td>Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure</td>
<td>BSL-1 practice plus:</td>
<td>Primary barriers = Class I or II BSC or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials;</td>
<td>BSL-1 plus: Autoclave available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Limited access</td>
<td>PPE: laboratory coats; gloves; face protection as needed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Biohazard warning signs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• &quot;Sharps&quot; precautions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BL-3**</td>
<td>Indigenous or exotic agents: with potential for aerosol transmission; disease may have serious or lethal consequences</td>
<td>BSL-2 practice plus:</td>
<td>Primary barriers = Class I or II BCS or other physical containment devices used for all open manipulations of agents;</td>
<td>BSL-2 plus:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Controlled access</td>
<td>PPE: protective lab clothing; gloves; respiratory protection as needed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Decontamination of all waste</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Decontamination of lab clothing before laundering</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Baseline serum</td>
<td></td>
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</tbody>
</table>

*(BMBL-5th edition, 2009), ** No BSL-3 Laboratories at UMass Lowell*
Appendix Four

Table-2

Class II Biosafety Cabinets*

<table>
<thead>
<tr>
<th>Class II Biosafety Cabinet</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>- 70% air recirculated; 30% exhausted from a common plenum to the room; 75FPM intake; may have biologically contaminated positive pressure plenum</td>
</tr>
<tr>
<td>A2</td>
<td>- 70% air recirculated; 30% exhausted from a common plenum to the room; 100FPM intake; biologically contaminated plenum under negative pressure or surrounded by negative pressure</td>
</tr>
<tr>
<td>A3</td>
<td>- 70% air recirculated; 30% exhausted from a common plenum to a facility exhaust system; 100FPM intake; biologically contaminated plenum under negative pressure or surrounded by negative pressure</td>
</tr>
<tr>
<td>B1</td>
<td>- 40% air recirculated; 60% exhausted from cabinet; exhaust air pulled through dedicated exhaust duct into facility exhaust system; 100FPM intake; all biologically contaminated plenums are negative to the room or surrounded by negative pressure plenums</td>
</tr>
<tr>
<td>B2</td>
<td>- 0% air recirculated; 100% exhausted from cabinet; exhaust air pulled through dedicated exhaust duct into facility exhaust system; 100FPM intake; all ducts and plenums are under negative pressure; all contaminated ducts are under negative pressure or surrounded by directly exhausted negative pressure ducts or plenums</td>
</tr>
</tbody>
</table>

*At UMass Lowell, all BSC are inspected once a year by EEM-EHS. Contact the Biosafety Officer if you have any questions related to your BSC, ruth_medina@uml.edu.
Appendix Five

Standard Microbiological Practices

Biosafety Level 1 (BL1)\(^1\)


Appendix G-II-A. Biosafety Level 1 (BL1)


Appendix G-II-A-1-a. Access to the laboratory is limited or restricted at the discretion of the Principal Investigator when experiments are in progress.

Appendix G-II-A-1-b. Work surfaces are decontaminated once a day and after any spill of viable material.

Appendix G-II-A-1-c. All contaminated liquid or solid wastes are decontaminated before disposal.

Appendix G-II-A-1-d. Mechanical pipetting devices are used; mouth pipetting is prohibited.

Appendix G-II-A-1-e. 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.

Appendix G-II-A-1-f. Persons wash their hands: (i) after they handle materials involving organisms containing recombinant or synthetic nucleic acid molecules and animals, and (ii) before exiting the laboratory.

Appendix G-II-A-1-g. All procedures are performed carefully to minimize the creation of aerosols.

Appendix G-II-A-1-h. In the interest of good personal hygiene, facilities (e.g., hand washing sink, shower, changing room) and protective clothing (e.g., uniforms, laboratory coats) shall be provided that are appropriate for the risk of exposure to viable organisms containing recombinant or synthetic nucleic acid molecules.

Appendix G-II-A-2. Special Practices (BL1)

Appendix G-II-A-2-a. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.

Appendix G-II-A-2-b. An insect and rodent control program is in effect.

Appendix G-II-A-3. Containment Equipment (BL1)

Appendix G-II-A-3-a. Special containment equipment is generally not required for manipulations of agents assigned to BL1.

\(^1\) (NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*)- Last Amendment to include the use of synthetic Nucleic Acids to be updated in March 2013. Appendix G. Physical Containment. (See Appendix G-III-M, Footnotes and References of Appendix G)

Appendix G-II-A-4. Laboratory Facilities (BL1)

Appendix G-II-A-4-a. The laboratory is designed so that it can be easily cleaned.
Appendix G-II-A-4-b. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
Appendix G-II-A-4-c. Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are accessible for cleaning.
Appendix G-II-A-4-d. Each laboratory contains a sink for hand washing.
Appendix G-II-A-4-e. If the laboratory has windows that open, they are fitted with fly screens.
Biosafety Level 2 (BL2)

Appendix G-II-B. Biosafety Level 2 (BL2)

Appendix G-II-B-1. Standard Microbiological Practices (BL2)

Appendix G-II-B-1-a. Access to the laboratory is limited or restricted by the Principal Investigator when work with organisms containing recombinant or synthetic nucleic acid molecules is in progress.

Appendix G-II-B-1-b. Work surfaces are decontaminated at least once a day and after any spill of viable material.

Appendix G-II-B-1-c. All contaminated liquid or solid wastes are decontaminated before disposal.

Appendix G-II-B-1-d. Mechanical pipetting devices are used; mouth pipetting is prohibited.

Appendix G-II-B-1-e. 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.

Appendix G-II-B-1-f. Persons wash their hands: (i) after handling materials involving organisms containing recombinant or synthetic nucleic acid molecules and animals, and (ii) when exiting the laboratory.

Appendix G-II-B-1-g. All procedures are performed carefully to minimize the creation of aerosols.

Appendix G-II-B-1-h. Experiments of lesser biohazard potential can be conducted concurrently in carefully demarcated areas of the same laboratory.

Appendix G-II-B-2. Special Practices (BL2)

Appendix G-II-B-2-a. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.

Appendix G-II-B-2-b. The Principal Investigator limits access to the laboratory. The Principal Investigator has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

Appendix G-II-B-2-c. The Principal Investigator establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms.

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2 (NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)- Last Amendment to include the use of synthetic Nucleic Acids to be updated in March 2013. Appendix G. Physical Containment. (See Appendix G-III-N, Footnotes and References of Appendix G)
Appendix G-II-B-2-d. When the organisms containing recombinant or synthetic nucleic acid molecules in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door to the laboratory work area. The hazard warning sign identifies the agent, lists the name and telephone number of the Principal Investigator or other responsible person(s), and indicates the special requirement(s) for entering the laboratory.

Appendix G-II-B-2-e. An insect and rodent control program is in effect.

Appendix G-II-B-2-f. Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory. Before exiting the laboratory for non-laboratory areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.

Appendix G-II-B-2-g. Animals not involved in the work being performed are not permitted in the laboratory.

Appendix G-II-B-2-h. Special care is taken to avoid skin contamination with organisms containing recombinant or synthetic nucleic acid molecules; gloves should be worn when handling experimental animals and when skin contact with the agent is unavoidable.

Appendix G-II-B-2-i. All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.

Appendix G-II-B-2-j. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of fluids containing organisms that contain recombinant or synthetic nucleic acid molecules.

Note: Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal.

Note: Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably autoclaved, before discard or reuse.

Appendix G-II-B-2-k. Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Institutional Biosafety Committee and NIH/OBA. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

Appendix G-II-B-2-l. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically depending on the agents handled or the function of the facility.

Appendix G-II-B-2-m. A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.
Appendix G-II-B-3. Containment Equipment (BL2)

Appendix G-II-B-3-a. Biological safety cabinets (Class I or II) (see Appendix G-III-L, Footnotes and References of Appendix G) or other appropriate personal protective or physical containment devices are used whenever:

Appendix G-II-B-3-a-(1). Procedures with a high potential for creating aerosols are conducted (see Appendix G-III-O, Footnotes and References of Appendix G). These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of materials whose internal pressures may be different from ambient pressures, intranasal inoculation of animals, and harvesting infected tissues from animals or eggs.

Appendix G-II-B-3-a-(2). High concentrations or large volumes of organisms containing recombinant or synthetic nucleic acid molecules are used. Such materials may be centrifuged in the open laboratory if sealed beads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

Appendix G-II-B-4. Laboratory Facilities (BL2)

Appendix G-II-B-4-a. The laboratory is designed so that it can be easily cleaned.
Appendix G-II-B-4-b. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
Appendix G-II-B-4-c. Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning.
Appendix G-II-B-4-d. Each laboratory contains a sink for hand washing.
Appendix G-II-B-4-e. If the laboratory has windows that open, they are fitted with fly screens.
Appendix G-II-B-4-f. An autoclave for decontaminating laboratory wastes is available.