University of Prince Edward Island

Biosafety Program Standard

March 2024

Contents

Abbreviations Used

AAF-A, AAF-B	Aquatic Animal Facility A, Aquatic Animal Facility B
AQC2	Aquatic Containment Level 2
BHM	Biohazardous material
BSC	Biological Safety Cabinet
BSO	Biosafety Officer
CBH	Canadian Biosafety Handbook
CBS	Canadian Biosafety Standard
CL	Containment Level
CFIA	Canadian Food Inspection Agency
ERP	Emergency Response Plan
HEPA	High Efficiency Particulate Air
HPTA	Human Pathogens and Toxins Act
IBC	Institutional Biosafety Committee
LAI	Laboratory Acquired Infection
MSDS	Material Safety Data Sheet
RG	Risk Group
PPE	Personal Protective Equipment
PHAC	Public Health Agency of Canada
PI	Principal Investigator
PSDS	Pathogen Safety Data Sheet
WHMIS	Workplace Hazardous Material Information System

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Introduction

The University of Prince Edward Island (the University; UPEI) is a research and teaching institution in which laboratory-based programs are a vital component. On a daily basis, staff, faculty, and students engage in experimental work, diagnostic service, and teaching involving biohazardous material (BHM). Providing a safe environment in the University's laboratories is a shared responsibility of all those involved in laboratory programs, including the University Administration, area leaders, departmental Chairs, Deans, laboratory supervisors, staff, and students. The UPEI Laboratory Safety Manual provides health and safety regulations and guidelines to employees and students. The present **UPEI Biosafety Program Standard** (referred to as the 'Program Standard' in this document) provides more detailed information on the use of BHM in research, service, and teaching, and is to be used as a required University reference for those working with these materials. It also refers to the Administrative Oversight Plan, an overarching document describing the various controls in place to ensure that biological risks are managed, which is available from the Biosafety Officer (BSO). All individuals must read this Program Standard prior to beginning any laboratory work or teaching involving BHM.

The University is required to maintain a biosafety program to protect people, animals, and the environment from exposure to the BHM worked with at the University. All those who handle BHM must conduct their work in such a way to protect themselves, other laboratory personnel, animals, and the environment from accidental exposure. They must comply with all applicable federal, provincial, and municipal legislation, the UPEI Biosafety Policy, and the UPEI Medical Surveillance for Research Involving Biohazardous Materials Policy (hereafter referred to as the UPEI Medical Surveillance Policy). Principal Investigators (PIs) should refer to the UPEI Institutional Biosafety Committee Terms of Reference if additional detail is needed. This Program Standard will help guide the user to these documents and associated regulations and provide detailed information on how these are to be followed at UPEI.

This Program Standard is not intended to be a replacement for the Canadian Biosafety Standard (CBS) or the Canadian Biosafety Handbook (CBH), but rather is an initial introduction to these valuable resources. The reader is directed to the CBS and the CBH for further information on areas of specific concern. Other federal standards are available for aquatic and plant pathogen containment. Those working with these BHM must be familiar with these standards, noted in the following section.

Biosafety rules and regulations are subject to change. Every attempt will be made to keep this document current and up to date.

The BSO works with the Health, Safety and Environment Manager, within UPEI Administration and Finance, to incorporate health and safety practices for all personnel working with BHM at UPEI. To contact these individuals, please see the preceding page for email addresses and phone numbers.

1. Overview

1.1 Federal Regulating Bodies

The following federal agencies have legislation pertaining to the use of Risk Group 2 (RG2) BHM (section 2.1) that apply to research, service, and teaching labs at our University:

The **Public Health Agency of Canada (PHAC)** has responsibility for terrestrial pathogens, both human and animal. It administers and enforces the Human Pathogens and Toxins Act (HPTA) and the Human Pathogens and Toxins Regulations (HPTR). The University of Prince Edward Island is currently licensed under the HPTA, providing the opportunity for UPEI researchers to work with RG2 human and terrestrial animal pathogens and toxins and RG2 terrestrial animal pathogens.

The **Canadian Food Inspection Agency (CFIA)** covers plant and aquatic animal pathogens, emerging diseases, and foreign animal diseases. Biosafety and biosecurity requirements are available for aquatic animal pathogens in the CFIA publication 'Containment Standards for Facilities Handling Aquatic Animal Pathogens'.

CFIA also provides a similar publication for those facilities working with plant pathogens in the 'Containment Standards for Facilities Handling Plant Pests'.

The CFIA and the PHAC have worked together to create the 'Canadian Biosafety Standard, Third Edition (2023)' and the 'Canadian Biosafety Handbook' for facilities handling terrestrial, animal and human pathogens, biological toxins, and prions. These are the central guides to working with BHM.

Environment Canada administers the Canadian Environmental Protection Act (CEPA) and the New Substances Notification Regulations (Organisms). The purpose of the latter is to ensure that "new" living organisms, such as genetically modified or synthetic organisms, are assessed for potential risks to both the environment and human health. For further information on this regulation, please contact the BSO.

Transport Canada (TC) administers the Transportation of Dangerous Goods Regulations which defines the requirements for shipping infectious substances and other hazardous materials within Canada. Training and certification are required for anyone packaging, transporting, or receiving infectious substances. TC is also responsible for ensuring that infectious material leaving Canada complies with the International Civil Aviation Organization regulations.

The University has its own regulations, in the form of the UPEI Biosafety Policy and UPEI Medical Surveillance Policy. The use of BHM/toxins must comply with these Policies. The UPEI Administrative Oversight Plan (AOP) supports our HPTA license by describing our University's Biosafety Program in the context of ten elements as required by the PHAC. It is an overview, without the degree of detail described in this Program Standard. Please contact the BSO for a copy of the AOP.

1.2 Biohazardous Material (BHM)

BHM is any biological organism, or material produced by a biological organism, which is potentially harmful to humans, animals, plants, and/or the environment. Materials that are classified as BHM at UPEI include microorganisms (bacteria, mycoplasma, viruses [including viral vector systems]), parasites, fungi, algae, prions, and genetically altered or synthetic organisms with the ability to harm humans, animals, plants, and/or the environment, biological toxins, human and animal blood, cells, tissues, body fluids, and waste, diagnostic specimens, cell lines, and other tissue cultures. Certain types of nucleic acids, such as DNA, derived from pathogenic organisms, human oncogenes, or transformed cell lines, are also considered to be BHM. Research using certain vaccines or synthetic DNA and synthetic biology are developing fields that may be included.

Any cases where it is uncertain whether or not the material is biohazardous should be referred to the BSO, or one of the members of the UPEI Institutional Biosafety Committee (IBC).

1.3 Use of BHM at UPEI

BHM is classified by Risk Group (RG), described in more detail in section 2.1 of this Program Standard. Work involving RG1 or RG2 BHM can be conducted at the University. No work with RG3 or RG4 pathogens can be conducted at the University.

Anyone using a RG1 or RG2 BHM must apply for and receive a biosafety permit before the work can be undertaken. Work with RG1 or RG2 BHM that is seen as service or diagnostic in nature also needs a biosafety permit.

Permit holders must be faculty members at the University or otherwise approved by the IBC. The application deadline for a biosafety permit is the last Friday of the month for consideration at the next month's meeting. IBC meetings are held in the third week of the month. Meetings may not always be held in the month of December. Please refer to the UPEI Institutional Biosafety Committee Terms of Reference for more information.

If you have any questions about biosafety permits, please see section 3.2 or contact the BSO.

2. Working with BHM and Risk Assessments

Federal legislation requires that all work with BHM be subjected to a risk assessment prior to its initiation to ensure the work is carried out as safely as possible. This is done to ensure the safety of not only the lab worker, but of the wider community and the environment.

Organisms are classified according to risk group (RG), the determination of which is based on several factors, including: pathogenicity, virulence, infectious dose, mode of transmission, host range, communicability, presence of vectors, and availability of effective treatment or preventative measures. Whether or not the pathogen is indigenous to Canada and the potential economic impact of the organism are also considered in this determination. Pathogen Safety Data Sheets (PSDS) are available on the PHAC website for many infectious agents and include the risk group to which it is assigned, and the containment level required for work with it. If there is uncertainty as to which RG a given organism belongs to, please contact the BSO. The four RGs are described below.

2.1 Risk Groups

Risk Group 1 (RG1): Biological agents that are unlikely to cause disease in healthy individuals are classified as RG1. They pose a low individual and low community risk. These organisms are not regulated by federal agencies. However, the IBC requires that biosafety permits be in place for work with RG1 BHM to ensure safe work practices are followed.

Risk Group 2 (RG2): These pathogens can cause disease but are unlikely to be a serious hazard to lab workers under normal laboratory situations. Disease could be caused due to laboratory exposure, but effective treatments are generally readily available. There is a moderate individual risk but a low community risk. Biosafety permits for RG2 BHM must be approved through the IBC before work can be initiated.

Risk Group 3 (RG3): These pathogens usually cause serious disease or may result in significant economic loss, but they are not usually spread readily from one individual to another. While there is a high risk to the individual there is still a low community risk. Treatments for bacterial or parasitic diseases caused by pathogens in this RG are available. No work with agents in this RG can be done at UPEI.

Risk Group 4 (RG4): These pathogens pose a high individual and high community risk as they are readily spread from one individual to another or even from human to animal or animal to human through direct or indirect contact. This category is composed solely of viruses. Currently, there are no aquatic pathogens in this risk group. No work with agents in this RG can be done at UPEI.

Only RG1 and RG2 BHM can be used in research, service, and/or teaching at the University. As the required facilities for work with higher risk groups do not exist at UPEI, work with RG3 or higher BHM is strictly prohibited.

2.2 Containment Levels

Laboratory containment levels, in general, correlate with the risk group category of the BHM. However, the risk group category does not take into consideration the research activities that may be undertaken and, as a result, the containment level under which that organism might be handled could be different from the RG. Containment levels describe the minimum requirements for safe handling of the BHM in a laboratory setting. Containment is achieved through facility design, the use of appropriate safety equipment, and the implementation of specific operational practices. Four containment levels (CLs) exist. At UPEI, there are only CL1 and CL2 laboratories. To remain compliant, CL2 labs must be inspected annually by the BSO. For details on the physical and operational requirements of the four containment levels, please see the CBS.

Containment Level 1 (CL1): A basic, functional laboratory where work may be done on the open bench. Containment is achieved through normal biological laboratory practices with RG1 BHMs that pose no risk to healthy individuals. Cleanable work surfaces are decontaminated according to the materials being used, good microbial practices are employed, appropriate PPE is worn, and training is provided to lab staff.

Containment Level 2 (CL2): These laboratories generally work with RG2 pathogens, where the usual route of infection is not aerosol. However, care must be taken not to generate aerosols in the manipulation of these agents. Biological safety cabinets (BSC) are frequently used. Access to these labs is restricted, training is required, and other operational protocols must be in place to maintain containment. The CFIA has established standards for those working with aquatic pathogens. An aquatic environment poses an added concern, in that the water can be contaminated and thus cannot be allowed to leave the facility without being adequately treated to prevent release of the pathogen. As a result, the requirements for aquatic containment level 2 (AQC2) *in vivo* labs differ from those required for terrestrial *in vivo* labs.

Containment Level 3 (CL3): Agents handled at this level are generally spread via the aerosol route. There are stricter rules for the primary and secondary containment of the agents. Design requirements and engineering controls are stricter and primary containment devices are utilized to ensure biocontainment. Operational protocols are likewise more detailed to deal with the increased risk of the materials manipulated. There are no CL3 facilities at UPEI.

Containment level 4 (CL4): This is the maximum containment level utilizing the strictest facility design and operational protocols. The RG4 agent is completely isolated from the worker, either by a positive pressure suit or a Class III BSC. There are no CL4 facilities at UPEI.

2.3 Containment Facilities at UPEI

UPEI limits work with BHM to RG1 and RG2 only. No work with RG3 BHM can occur. From time to time, it is possible that clinical cases involving RG3 organisms are encountered. When an RG3 organism is suspected or identified, any further laboratory work must be done at a reference laboratory with a higher level of containment.

The University has *in vitro* CL1 and CL2 labs and *in vivo* labs of similar containment for terrestrial animals. There is an aquatic facility (AAF-A) that is for non-pathogen work only, and an aquatic facility (AAF-B) that is certified by the CFIA as AQC2 *in vivo* for work with pathogens and aquatic animals from off-Island. AAF-B has added requirements for effluent decontamination.

It is not uncommon for some pathogens to be categorized as RG2 *in vitro* but when used *in vivo*, especially in an aquatic environment, to be categorized as RG3 organisms. This prohibits their use *in vivo* in AAF-B. Please contact the BSO if you have any questions about this.

Prions and other specified risk material are not currently included in the biosafety program at UPEI. These materials require special provisions for decontamination.

Research laboratories working with human blood, tissue, fluids, and waste do so under CL2 conditions. These labs will be inspected annually by the BSO. There are a number of requirements for working with human samples – please see section 5.1 for more details.

Most of the teaching labs at UPEI are CL1 laboratories. They utilize carefully chosen RG1 surrogates to provide the same learning opportunity for students as the RG2 pathogens but at a decreased risk to the individual. There are two CL2 teaching labs at the Atlantic Veterinary College (AVC).

2.4 Risk Assessments

Risk Assessments are required to determine the appropriate containment level for the proposed work. One must consider the agent(s) to be used, the host, lab worker handling the agent, procedures to be carried out, and the space in which the work will be done.

Assessing the BHM involves determining the RG to which it belongs. This includes consideration of factors such as pathogenicity, virulence, infectious dose, mode of transmission, host range, communicability, presence of vectors, endemicity, and availability of effective treatment or preventative measures. For many microorganisms, this information is readily available, and the designated RG is well accepted. For other material, such as clinical submissions and environmental samples, it may not be as clear. Unfixed human blood, tissues, cells, bodily fluids, and fecal material are considered RG2 materials. All human cell lines are therefore also considered to be RG2 BHM. Additionally, primary cell lines from any species are considered to be RG2 BHM at UPEI. Samples taken from animals could be RG1 or RG2 depending on the source. Blood samples drawn from healthy captive animal populations, such as laboratory rodents housed at the University and under the care of the University Veterinarian, would be considered RG1. The same samples taken from wild source rodents would be RG2, as wild rodents (and other wild animals) can be hosts or carriers for many human and animal pathogens. For additional help please contact the BSO.

The PHAC provides a searchable risk group database called ePATHogen (http://health.canada.ca/en/epathogen) which is helpful in determining RG. The American Biological Safety Association has a risk group classification database which can also be useful (https://absa.org/). When materials are obtained from vendors such as the American Type Culture

Collection (ATCC), they may provide information on the RG. Note that the RG assigned in other countries may differ from that assigned by Canadian regulators. Always check with the BSO if you have any questions or uncertainty.

Once the RG has been determined, the activities planned with the BHM must be examined. Hazards may arise from the proposed work and mitigation must be considered. This may be through substitution or elimination, engineering and/or administrative controls, and personal protective equipment (PPE). For example, aerosols can be generated by procedures such as homogenizing, sonicating, lyophilizing, and centrifugation. This can lead to the deposition of BHM on surrounding surfaces, providing a potential source of exposure to the laboratory worker, even though the BHM is not technically spread via the aerosol route. Administrative and engineering controls must be considered. If large volumes are to be used, the risk is greater. For example, cultures of 10 litres or more are considered large scale, and special facilities and operational protocols are required.

The laboratory containment level (CL) required for a given project can be determined by knowing the RG of the BHM to be used, and considering how the planned work impacts the biohazardous risk.

One must also consider the risks of the procedure to human health. If human or zoonotic pathogens are involved, or the work involves the manipulation of human tissue, fluids, or waste, protection of human health must be a priority. Education of all laboratory workers on the possible consequences of exposure, the provision of all required PPE, and the process of required reporting of a Laboratory Acquired Infection (LAI) is necessary. Some personal medical conditions (such as pregnancy, immunocompromisation, etc.) might put one at an increased risk depending on the BHM worked with. These situations should be discussed in confidence with the supervisor. Please see section 4.11 on Medical Surveillance for more details.

At UPEI, the biosafety permit application helps fulfill the laboratory-based risk assessment, as the PI indicates the BHM to be used, type of work proposed, potential for aerosol generation, PPE and engineering controls to be in place, and any other information related to the use of BHM in the work. This is then reviewed by the IBC, at which point further refinements may be required. Risk mitigation may be achieved by substituting an infectious pathogen with one of lesser risk, or by the inclusion of equipment and/or operational practices that would improve safety. PPE may be added to improve safety, but one must remember that PPE is a last line of defense and other safety procedures should also be implemented. Once approved, the project will be issued a biosafety permit and the work may begin. Please keep a copy of the approved biosafety permit application form and attached materials available in the laboratory for reference and training purposes, serving as part of the site-specific training requirement. If the lab is a shared space, others using the space must be notified of the biohazardous work that is about to begin in that space. The permit will be in effect for two years. If in that period of time, there are planned changes to the protocol that might affect the risk assessment, such as changes to the research activities, changes to the BHM in use, change in location of the work, or addition of new people to the project, then an amendment application must be completed and submitted to the IBC for review. For roles and responsibilities of laboratory personnel please see section 3.1.

3. Biosafety Program at UPEI

The biosafety program at UPEI is based on Federal regulations and guidelines, and is outlined in the UPEI Biosafety Policy and UPEI Medical Surveillance Policy, both found on the UPEI policy page. Details of related roles and responsibilities follow.

3.1 UPEI Biosafety Administration; Roles and Responsibilities

3.1.1 Vice-President, Academic and Research (VPAR)

At UPEI, the VPAR is responsible for ensuring that a BSO is in place. It is the VPAR, or delegate, who appoints and administers the IBC and is responsible for the UPEI Biosafety Policy, the UPEI Medical Surveillance Policy, the Biosecurity Plan, the Administrative Oversight Plan, and the Overarching Risk Assessment. The VPAR is the License Holder under the HPTA.

3.1.2 UPEI Institutional Biosafety Committee (IBC)

The IBC is appointed and administered by the VPAR or delegate and is responsible for policy and procedure development governing the use of BHM at UPEI. It reviews biosafety permit applications and monitors activities and laboratories to ensure compliance with all applicable regulations, both internal and external to the University. The IBC meets a minimum of 11 times per year. For submission deadlines and meeting dates, please contact the Research Compliance Coordinator at researchcompliance@upei.ca. The IBC is composed of faculty members, technical staff, a graduate student, and a representative of the NRC facility on campus. Ex officio members include: the VPAR, the BSO, the Health, Safety and Environment Manager, the Central Services Senior Technologist, and the University Veterinarian. The IBC may invite comments from subject matter experts when reviewing permit applications. While the IBC serves as a resource to researchers, it is also responsible for investigating reports of UPEI Biosafety Policy non-compliance and has the authority to suspend activities and communicate with supervisors and University Administration on compliance concerns. Additional information regarding role and responsibilities of the IBC can be found in the UPEI Institutional Biosafety Committee Terms of Reference.

3.1.3 UPEI Biosafety Officer (BSO)

The BSO works closely with and through the IBC to ensure the biosafety program appropriately addresses risk and is compliant with all relevant regulations, and to oversee its daily operation. Duties and responsibilities include, but are not necessarily limited to:

- Promote and monitor compliance with all requirements applicable to the licensed facility;
- Act as the main point of contact between the University and the PHAC, the CFIA, and other government agencies as necessary;
- Notify the PHAC in the event of any necessitating situation, as described in the HPTA (inadvertent procession, loss in transit);

- Provide advice in advance of biosafety permit application submission, when requested;
- Deliver and/or coordinate and document biosafety, biosecurity, and blood borne pathogen training;
- Perform annual laboratory inspections for compliance and report these findings to the IBC and the VPAR;
- Report any unresolved non-compliance issues to the IBC and the VPAR;
- Assist in the development and maintenance of the UPEI Biosafety Policy, UPEI Medical Surveillance Policy, UPEI Institutional Biosafety Committee Terms of Reference, UPEI Biosafety Program Standard, and related standard operating procedures;
- Oversee the movement of incoming and outgoing pathogens and toxins from the University;
- Conduct internal investigations of incidents and near misses involving BHM, such as inadvertent release or production of BHM, missing or stolen BHM, potential laboratory acquired illness, with the Health, Safety and Environment Manager, the University Veterinarian, or others with specialized training (e.g., medical professionals) if needed;
- Assist with decommissioning procedures for CL2 laboratories;
- Serve as a member of other relevant committees, such as the UPEI Animal Care Committee (ACC) and the UPEI Joint Occupational Health and Safety Committee (JOHSC);
- Act as the Responsible Official (RO) under the UPEI Biosecurity Plan;
- Verify the accuracy and completeness of applications under the HPTA.

3.1.4 Deans, Department Chairs, and Facility Directors

These individuals must be knowledgeable of activities in their areas that involve BHM and play an important role in educating department or facility members on and encouraging compliance with regulations, notably the UPEI Biosafety Policy and UPEI Medical Surveillance Policy, as relevant. If non-compliance issues arise, Deans, Chairs, and/or Directors, or equivalent, may be included in communication from the IBC to PIs regarding the non-compliance and associated requests, requirements, and recommendations.

3.1.5 Principal Investigators (PIs)

PIs have the primary responsibility for the implementation of and adherence to the UPEI Biosafety Policy and UPEI Medical Surveillance Policy, if and as they apply to their research, and for ensuring that their laboratories are safe for themselves, their staff, and the public at large. The following section summarizes the roles and responsibilities of the PI. As supervisors, PIs also hold responsibility for their laboratory staff and students working with BHM. Additional responsibilities may be required in certain circumstances, as detailed in relevant sections of this Program Standard.

- **Regulatory Compliance:**

- Remain current and compliant with the UPEI Biosafety Policy, UPEI Medical Surveillance Policy, if relevant, IBC Terms of Reference, and this Program Standard;
- Ensure compliance of their research program with the regulations as required by federal, provincial, and municipal agencies, as well as with other University policies and procedures;
- Consult with the Biosafety Officer, University Veterinarian, IBC or Animal Care Committee, as appropriate, on the application of this policy to the proposed research;
- Obtain biosafety permit application approval from the IBC for all work that uses BHM prior to the acquisition of the material and/or the initiation of the work by submitting the appropriate documentation (new permit application, renewal, or amendment form, and all additional attachments required for the given work) to the IBC by the posted submission deadline. This is to be done at least two months prior to the expected start date to allow time for IBC review and PI completion of any requested revisions, and at least two weeks ahead for minor amendment applications (see section 3.2);
- Ensure that any proposed changes (e.g., altered protocols, personnel, pathogens) to an active biosafety permit are approved in advance by the IBC;
- Ensure that all other required certifications are in place (i.e., human ethics and/or animal care and/or radiation approval, etc.) before starting work;
- Cooperate with members of the IBC, the BSO, the Health, Safety and Environment Manager, and all other persons exercising duties imposed by regulatory agencies;
- Retain an easily accessible file of current biosafety permits;
- Appoint a designate PI if the main PI plans to be away for 30 days or more. The designate must be approved by the IBC. This is accomplished by submitting a temporary transfer form in the UPEI Researcher Portal;
- Submit a Biosafety Resume and remain up-to-date with required training;
- Create and regularly review (at least annually) a laboratory biosafety manual containing the SOPs for safe work practices;
- Create and regularly review (at least annually) an Emergency Response Plan.

➢ **Training:**

- Develop a training needs assessment for the laboratory and review annually, as required by the CBS. This is to include, for all laboratory personnel, UPEI Basic Biosafety Training before beginning to work in the lab, UPEI Biosafety Refresher Training every three years, WHMIS training, and any other training as required due to the nature of the work, such as blood borne pathogen training;
- Ensure all personnel are authorized to handle the biological/biohazardous material by attending the required training as identified in the assessment as well as site specific laboratory training. A form to document new lab worker site-specific training can be found on the biosafety webpage: https://files.upei.ca/research/biosafety_laboratory_worker_orientation.pdf;
- Ensure all authorized personnel are familiar with the contents of the UPEI Biosafety Program Standard, the Laboratory Biosafety Manual, the UPEI Laboratory Safety Manual, and all other documentation as appropriate for the containment level and research program of the laboratory;

- Keep training records of personnel on file. These are to be signed by both the trainer and the trainee. Records must be available at the time of lab inspection;
- Provide competent supervision of laboratory personnel.

➢ **Laboratory Access:**

- Maintain an up-to-date list of persons with authorized access to all Containment Level 2 labs for which the PI is responsible and share this list with UPEI Security and the BSO;
- Develop a visitor policy and ensure visitors are supervised;
- Ensure that minors are not permitted in CL2 laboratories without University permission and signed waivers. Depending on the risk assessment of the laboratory, minors may not be permitted in the lab.

➢ **Biohazardous Waste Management:**

- Ensure all biological waste is handled according to University guidelines, as per the UPEI Waste Disposal Protocol available on the HSE intranet;
- Communicate specific risks to the senior technologist of Central Services as appropriate.

➢ **Inventory Acquisitions and Maintenance:**

- Maintain an accurate inventory of all BHM used in active research, service, and /or teaching, as well as those in archival storage on the UPEI inventory database;
- Confirm annually to the BSO the security and complete inventory of all BHM being used or stored (active use and archival);
- Report any theft or loss of RG2 biological materials to the BSO and the Health, Safety and Environment Manager immediately upon discovery;
- Notify the BSO of your intention to bring a RG2 BHM (pathogen or toxin) into UPEI, to send a BHM off campus, or to transfer BHM to or receive BHM from a colleague on campus in advance of such activities. A Biohazardous Agent Transfer (BAT) form must be completed for this activity and submitted to the BSO prior to the acquisition or transfer of the BHM;
- Notify the BSO if the material does not arrive at the expected time or if it arrives in a damaged condition;
- Notify the BSO upon discovery of the inadvertent possession of a pathogen for which the University is not licensed.

➢ **Decommissioning**

- Ensure that the appropriate decommissioning procedures for CL2 zones are undertaken when necessary after consultation with the BSO;
- Ensure that any equipment or area used within a biohazardous work zone that requires service, transfer, or disposal is appropriately decontaminated (and labeled

as such) prior to any action taking place. Decommissioning sheets are available from the BSO or from AVC Biomedical Engineering.

- **Laboratory Safety Requirements**

  - Ensure that monthly inspections of CL2 laboratory facilities are completed to monitor for damage and other risks to biosafety and biosecurity (see section 3.5 for details);
  - Place a work order with Facilities Management when issues such as surface defects are noted and recorded so the problem is rectified in a timely fashion;
  - Ensure that all safety devices, including Biosafety Cabinets (BSCs), are present and certified as required;
  - Ensure that all required personal protective equipment listed on the IBC-approved biosafety permit is available to personnel, in good working order, and used as necessary;
  - Ensure that standard operating procedures are developed and implemented;
  - Ensure that biohazard warning labels are posted on equipment that may be contaminated (on BSCs, refrigerators, feeders, liquid nitrogen canisters, incubators, centrifuges, etc.);
  - Ensure that appropriate signage is in place at all lab entrances;
  - Ensure that all personnel, including non-project personnel in shared spaces, are informed of the proposed work that will take place, including the hazards, risks, and symptoms of exposure associated with the planned project, and that the required safety measures are implemented;
  - Ensure that in CL2 laboratories, the Laboratory Biosafety Manual, Plan for Post-Exposure Prophylaxis (PEP) to Bloodborne Pathogens and/or Human Pathogens if working with potentially infectious or RG2 human/zoonotic pathogens and biological toxins, and Safety Data Sheets and Pathogen Safety Data Sheets are available in the laboratory. The laboratory Biosafety Manual and the PEP must contain specific information, but must also be individualized to each lab and must be reviewed annually;
  - Report immediately all incidents, accidents, spills, known or possible exposures to pathogens, laboratory acquired infections, malfunction of biocontainment equipment, or biosecurity incidents in writing to the Health, Safety and Environment Manager for action by the IBC as appropriate, using the University's Incident Report Form. In cases of known exposure, diagnosed laboratory acquired infection, or serious incident, direct communication with the BSO must be made immediately.

- **Additional medical surveillance considerations**

  - Ensure precautionary medical practices for authorized personnel are in place as required before they begin the work; this may include rabies or hepatitis A vaccination or hepatitis B immunization and titre checks to provide evidence of a positive immune response;
  - Discuss, in confidence, any personal health issues self-identified by personnel that could increase personal risk as a result of exposure to the BHM and/or animal

allergens listed on the biosafety permit and discuss mitigating strategies that could be instituted. Inclusion of a medical professional recommendation may be required;
- Determine in advance the category of risk for any parenteral exposure to human blood/tissue/bodily fluids prior to working with these materials. PIs must be prepared to follow the plan for post exposure prophylaxis (PPEP) in the event of such any exposure occurring.

3.1.6 Authorized Personnel

Authorized personnel are those who have completed the required biosafety training and are named on an approved biosafety permit. Authorized personnel can be faculty, staff, contract personnel, graduate students, undergraduate students, or authorized visitors.

The health and safety of all personnel is extremely important. All personnel are expected to take a proactive role in educating themselves about the agents, materials, and equipment with which they are working. They will conduct their work in a safe and responsible manner so as to protect their own health and safety, as well as that of others who could be affected by their acts or omissions. Authorized laboratory personnel must:

- Comply with all applicable rules and regulations set forth by regulatory agencies and UPEI policy and procedures;
- Cooperate with their supervisor, members of the IBC, and all other persons exercising duties imposed by regulatory agencies;
- Complete and understand the appropriate training to safely and effectively perform their required duties, as determined by the laboratory training needs assessment and the IBC. This training will include, at a minimum, UPEI provided training for WHMIS, Biosafety and Biosecurity, as well as PI supplied training for the laboratory Emergency Response Plan and site-specific orientation;
- Participate in the Medical Surveillance program when applicable. Alternatively, in exceptional cases, obtain medical exemption documentation from a licensed medical professional, presenting this to the IBC for review, in consultation with the UPEI Health and Wellness Centre. Additional information or modifications may be requested as part of the review process;
- Notify their supervisor and submit an Incident Report Form when they become aware of any unsafe act, condition, or incident, accident, or spill.

3.1.7 Authorized Maintenance and Custodial Staff

These are University employees who are required to enter facilities where biological/biohazardous materials are being used. They must be informed of the hazards that may be encountered. They must be trained in general workplace safety, and any other practices or procedures required for the safe execution of their work. They must:

- Ensure they have received and understood appropriate safety training;
- Carry out their work in a safe and responsible manner;
- Notify the laboratory supervisor of their intent to enter the lab for non-routine maintenance and cleaning;

- Notify their supervisor when they become aware of any unsafe act or condition.

3.2 Biosafety Permits

Biosafety permits are required for all work at UPEI that involve either RG1 or RG2 BHM. This includes RG1 and/or RG2 microorganisms, unfixed animal or human blood, tissues, cells, bodily fluids, or fecal material, which may be biohazardous. The use of RG3 and RG4 biological materials is prohibited under the UPEI HPTA license issued by the PHAC. The PI submitting the application for a biosafety permit will hold a UPEI faculty appointment or be a person who is otherwise approved by the IBC to hold a biosafety permit.

The biosafety permit must be in place before work can begin. This requires that the application be submitted by the appropriate deadline, at least two months in advance of the anticipated start date. Submission deadlines are designed to allow IBC members time to pre-review the application before the meeting date. If concerns or questions arise at this point, and there is time, these can then be communicated to the PI who in turn can provide a response before the committee meeting, thus saving both the PI and the IBC time. A Biosafety Resume for Project Team Members must also be on file, and must be updated upon request. Other supporting documents, such as import permits, pathogen safety data sheets, proof of vaccination, etc., may be required, as determined for the individual project.

Applications can be considered by the IBC Chair and BSO for expedited review if a need exists and if the application meets certain parameters. Please see the UPEI Institutional Biosafety Committee Terms of Reference for these and further details. The PI must contact the Research Compliance Coordinator to request an expedited review.

The application form essentially provides a local risk assessment (LRA), in that it addresses risks identified in the project and the mitigation means the PI has planned to minimize these risks. Once the IBC approves an application and issues a permit, work can commence. Any changes to the project that could alter the risk must be submitted to the IBC in the form of an amendment application. This could include changes to the experimental protocol or procedures, changes in the BHM, or BHM quantity, etc., as each of these might increase risk. Any requests to amend a current biosafety permit must be submitted to the IBC on the Biosafety Amendment ‘event’ form in the UPEI Researcher Portal and approved following review by the IBC prior to the change coming into effect. If, during the course of the project, there are changes limited to the personnel involved or to the funding of the research, a minor amendment application form must be submitted. Minor amendment applications are normally reviewed by only the IBC Chair or designate and BSO or designate. If the amendment is approved then an approval notification will be sent to the PI. Minor amendments will be documented in the IBC meeting minutes. Minor amendment applications may be sent for full IBC review at the discretion of the IBC Chair and BSO.

Permits are valid for two years. They may be renewed once. When a renewed permit expires, a new application is required if the project is on-going.

Please note, the absence of a permit holder (PI) for a period of greater than 30 days requires a transfer of signing authority and responsibility for that period of time. If a permit holder will be unable to oversee the activities under their permit, they are responsible for finding a designate and submitting the 'Biosafety Temporary Transfer Request' event form in UPEI Researcher Portal for IBC review and approval.

3.2.1 Exceptions to the Requirement for a Biosafety Permit

There are some exceptions to the requirement for a biosafety permit:

- Human tissues, bodily fluids, and potentially infectious materials that are encountered in normal clinical practice in the UPEI Health and Wellness Centre are excluded from the requirement for biosafety permits.
- Animal tissues, bodily fluids, and potentially infectious materials that may be encountered during the conduct of normal clinical veterinary practice in the AVC Veterinary Teaching Hospital, AVC Farm Services, and AVC Equine Ambulatory Services are excluded from the requirement for biosafety permits.

If either human or animal clinical material will be used in a research study, then a biosafety permit is required.

- Unfixed animal blood or bodily fluids taken from healthy animals that are part of the resident animal population at the Atlantic Veterinary College (AVC) and under the medical supervision of the University Veterinarian, or such samples taken from healthy rodents supplied through certified providers, are not necessarily deemed biohazardous and may be exempt from this definition **if no other pathogen or toxin is involved in the research**. Please contact the BSO to confirm that your intended samples are exempt.
- Normal animal husbandry practices for animals housed at the AVC that include management of manure are exempt from the requirement for biosafety permits, **unless the material is to be used in a research project**.

Research uses of any other clinically-obtained human or animal samples require a biosafety permit. Any cases where it is uncertain whether or not the material is biohazardous should be referred to the BSO or to a member of the IBC.

3.3 Laboratory Signage

Signage must be present on all access points to the lab. University standard signage can be obtained from Facilities Management at: https://www.upei.ca/office-vice-president-administration-and-finance/facilities/signage-requests. Emergency contact names and phone numbers must be present. The containment level of the lab must be clearly displayed along with an indication of the nature of the BHM. All hazards in the lab must be represented by the corresponding WHMIS symbol(s) on the signs. Thus, all CL2 labs require at least the biohazard symbol.

3.4 Inventory of Biohazardous Agents

All BHM must be inventoried, whether part of an active research protocol or in storage as an archival sample. The UPEI electronic inventory must be kept up to date and confirmed on an annual basis when requested by the BSO. Access to the database is obtained through the BSO. Information required includes: the type of BHM (including genus, species, and form), RG, host range, source, storage location(s), quantities, uses, date of entry, and record of transfer or destruction.

If a new pathogen is obtained or identified in the course of diagnostic work, it must be entered into the inventory database within 30 days.

Day to day fluctuations in inventory during active research and diagnostic work is to be recorded in the laboratory notebooks or research logbooks. This information is not captured in the database. For example, cell culture and organism stock quantities must be inventoried but not the number of cell culture flasks or petri plates used on a daily basis. This information would be instead be captured in the research log books.

Inventories are subject to random spot checks by the BSO at the time of the annual laboratory inspection as well as at any other time throughout the year. Inventory discrepancies are an example of policy non-compliance and may be investigated by the BSO and IBC, potentially resulting in an in-depth inventory audit by the IBC.

3.5 Laboratory Inspections

The University has a program of general health and safety inspections carried out by the Joint Occupational Health and Safety Committee (JOHSC) for all areas of campus on a regular basis, with labs being inspected annually. In addition to this inspection, all CL2 labs are inspected on an annual basis by the BSO to monitor compliance, assist with compliance with any changes in regulations, and to aid in the continual improvement in the lab. There are national containment standards for plant, terrestrial animal, and human and aquatic pathogen containment. Compliance with these national standards is determined by a laboratory inspection by the BSO and the lab supervisor. A record of the inspection report, as well as a list of items that need attention, will be forwarded to the PI by the BSO soon after the inspection. Deficiencies identified shall be rectified within four (4) weeks or the time frame indicated in the report. Serious deficiencies shall be communicated to the PI and PI's department chair or facility director. Non-compliance issues will be discussed by the IBC and the appropriate action taken, as outlined in the UPEI Institutional Biosafety Committee Terms of Reference. The IBC has the authority to suspend associated work and communicate with supervisors and University Administration regarding compliance concerns. An annual report of all laboratory inspections will be forwarded to the VPAR.

In addition to the formal inspections of CL2 spaces, lab staff are required to perform monthly internal inspections to ensure the safety of themselves and others, and the timely submission of work orders to repair minor problems before they become significant issues. Records of these periodic inspections are to be maintained in the laboratory. A sample of a self-audit checklist is available from the BSO and may be adjusted to suit the specific laboratory.

For CL1 laboratories, annual self-inspections are requested. The PHAC document 'Containment Level 1: Physical Design and Operational Practices' can be used as a metric for laboratory supervisors to conduct their own lab inspections. A checklist based on this document, revised slightly to better reflect the labs at this University, is available on the Biosafety web page. A copy of the completed checklist is to be forwarded to the BSO upon completion and/or upon request.

3.6 Import, Export, and Transfer of BHM

Whether BHM is being transferred across the hall, across the country, or across national borders, legislative requirements must be met. Transfers do not only refer to import or export (i.e., crossing Canada's border). The sender or recipient of BHM must comply with this legislation. The first step is to alert the BSO of the intent to transfer or obtain a BHM **in advance of the transfer taking place**.

To import BHM under the HPTA or Health of Animals Act, a Biohazardous Agent Transfer Notification Form must be completed. To do so, the BSO must first be informed of your intention to import. The UPEI HPTA License number is then provided to the sender, who must package the material according to regulations and affix all required information to the outside of the package for the information of Canadian border security officers. The receiver must be aware of the approximate arrival time and be available to handle the material when delivered. If the material is late in arriving, the BSO must be notified as soon as possible.

Import permits must be acquired for materials regulated by the CFIA and may be obtained for either single or multiple entries of the material and are valid for one year. Anyone applying for a CFIA import permit must do so through the institutional UPEI MyCFIA portal. To obtain access to this portal, please contact the BSO or the Manager of Procurement Services. The PI must pay careful attention to any and all restrictions placed on the import permit. These usually include a restriction for *in vitro* work only, for work only within the labs listed on the import permit, and for use only by the importing faculty member. If at any time the importing faculty member wishes to give the imported material to another colleague, an official transfer must be arranged with the BSO and either PHAC or CFIA as relevant.

CFIA compliance letters for CL2 or plant pathogen containment may be required, depending on the material to be imported. CFIA compliance letters are required to obtain a Domestic Movement Control Permit.

Once the material is obtained, it must be logged into the UPEI inventory database.

Any questions on importing or exporting, including on obtaining a CFIA compliance letter, should be directed to the BSO, as consultation with the Agencies may be required.

Exportation of pathogens requires that the BSO is informed of the intended action and that the sender is in compliance with the HPTA. This requires a Biohazardous Agent Transfer Notification Form be completed before the export occurs.

3.7 Training Requirements

For relevant employees new to the University, the individual's supervisor must complete the Biosafety Laboratory Worker Orientation form available on the UPEI Biosafety website as part of the hiring process.

Each laboratory worker must also be provided with site-specific biosafety orientation when they begin work in the lab. The related form must be completed, signed by the trainer and trainee, and maintained in the training manual. Please add specific topics relevant to the given lab(s) to this form, available on the biosafety webpage.

Training for staff working in CL2 laboratories is to be completed before work with BHM commences. The IBC requires that basic biosafety training, provided by the BSO, be completed by all CL2 and CL1 lab staff (PI, lab technicians, graduate and undergraduate students, visitors, and anyone else handling the BHM). If UPEI-provided biosafety training is not scheduled until after one starts work in a CL2 lab, the BSO must be contacted. In these cases, the IBC may recommend alternate training modules for the short term, with required attendance at the next available session. Biosafety training requires a refresher course **every 3 years**. Please contact the BSO for information on future training dates.

Workplace Hazardous Materials Information System (WHMIS) training is also required. For further information, including a password to access the site, please contact the UPEI Health, Safety and Environment Office.

Blood Borne Pathogen Training is required for those working with human blood and/or fluids and/or body tissues. It must be renewed **every 5 years**.

All CL2 labs must have an **Emergency Response Plan** on which all lab personnel must be trained. Refresher training is required annually. It is suggested that this activity be planned by adding it to the lab's monthly safety checklist so that it will be accomplished in advance of the lab's annual inspection.

Each lab will also have a list of training requirements specific to their lab, to which lab staff must comply. This may include BSC training, first aid, respirator fit testing, animal user training, etc. The training required must be assessed annually and the review documented. Training needs assessment templates can be accessed by contacting the BSO.

All training must be documented and records stored for easy referral at the time of the lab inspection(s).

The PHAC has a training resource which is very helpful and informative. It provides videos on biosafety as well as online modules on a wide array of topics. Please visit: https://training-formation.phac-aspc.gc.ca/

3.8 Incident Reporting

Incident reporting and investigation is an important part of the laboratory's Emergency Response Plan. Incidents may include an actual event that caused injury, harm, or damage but they are not limited to these more obvious scenarios. Near misses – events that have the potential for negative outcomes but that do not actually cause any harm or damage, should be reported as well. While it was fortunate that there was no negative outcome, investigating why the incident occurred could be very useful in preventing it from happening again in the future, possibly with more serious results. Reportable incidents also include breaches in biocontainment or biosecurity. Investigation of reported incidents may identify biosafety and/or biosecurity weaknesses that, once addressed and corrected, will make the lab a safer place to work. All incidents should be reported, even if they seem minor at the time. The incident reporting process and subsequent investigation is undertaken to improve the safety of the working environment by identifying the root cause and is not meant to be punitive in nature.

Under the HPTA, all laboratory acquired infections (LAI) must be reported to the BSO who in turn reports the occurrence to the PHAC. This will be for informational purposes only – all information will be confidential, and no names will be submitted.

While one must submit an Incident Report Form, there are a few steps to first be taken in the moments after the accident. Immediately determine whether first aid and/or emergency services are required. Assess the severity of the situation, including the potential for a secondary incident to follow that might worsen the situation if preventative steps are not immediately taken. Notify the lab supervisor and the BSO right away if the incident involves the loss of biocontainment or a biosecurity breach. Follow lab specific procedures as described in the approved biosafety permit application to deal with the biological spill, if relevant.

- **To Report an Incident:**

    - call 911 (or 9-911 if calling from a UPEI phone) if any emergency or criminal situation is encountered;
    - Immediately notify the supervisor;
    - The BSO is to be notified immediately in cases of breach of biocontainment or biosecurity.
    - Some biosecurity issues may also require the notification of UPEI Security Services;
    - Should the incident be a very serious health concern, others require notification, including department Chairs or Faculty Deans, and the Health, Safety and Environment Manager;
    - A UPEI Incident Report Form (https://www.upei.ca/office-vice-president-administration-and-finance/health-safety-and-environment/incident-reporting) must be submitted as soon as possible, and no later than 24 hours after the incident. This form is to be completed for all incidents, regardless of the severity. Complete Workers Compensation Board forms for staff for any incident that could potentially cause a health problem in the future. This must be completed within three days of the incident. These forms are also found at the above link.

Following the report, cooperation is required from those involved in the incident during the follow up investigation. Once immediate/temporary corrective actions are taken, then an incident investigation should be conducted by the responsible supervisor/person. Incident investigations are designed to find the root cause of an incident. Once these root causes are identified, recommendations can be made to eliminate, or at a minimum reduce, the potential for recurrence. Supervisors need to complete the Incident Investigation Form within 72 hours of an incident occurring. The supervisor is responsible for incident investigation, but investigators can also include the BSO, Health, Safety and Environment Manager, and/or other individuals deemed essential depending on the situation.

3.9 Decommissioning

When vacating a CL2 laboratory (e.g., the PI is leaving the employment of the University, or relocating to another lab) or when extensive renovations are planned, the space must first be decommissioned to ensure that it is safe for the next user or renovation contractor. This process ensures, among other things, that all BHM, sharps, chemicals, etc. are removed from the lab. Equipment may need to be relocated, which may require decontamination prior to this move. The UPEI decommissioning form must be completed by the PI and signed by the department Chair. At this time, the BSO and a member of the IBC will visit the lab to ensure that all aspects of the checklist have been completed, making it safe for the next occupant of the space. The form can be found on the main biosafety webpage.

4. General Safety Considerations in a Laboratory Handling RG2 BHM

4.1 Good Microbial Practices

Good laboratory practices are essential to protecting one's health and the integrity of the experiment. The following points are requirements of a CL2 laboratory:

- A University-wide biosafety program is in place to oversee safety and containment practices, and must be followed;
- A local risk assessment (LRA) is to be conducted and documented to identify each activity, identifying risks and describing safe work practices;
- A laboratory biosafety manual must be developed, implemented, kept up to date, and made available to people in and outside of the containment zone. It must include the intent of the research program, outline the biosafety program, and briefly describe the physical operation and design of the CL2 containment zone. It also covers institutional policies, SOPs for safe work, including entry/exit procedures, PPE requirements, use of primary containment devices, decontamination, movement and transportation of BHM, incident reporting procedures, Emergency Response Plan (ERP), training program, biosecurity plan, laboratory medical surveillance as applicable, BSC use, and SOPs specific to the nature of the work in the lab. It should also contain a copy of the facility's biosecurity plan, medical surveillance plan (if applicable), training requirements and documentation of training, and any other lab specific SOPs that pertain to the work under the biosafety permit. Please contact the BSO for the SOP templates that have been developed for many of these topics. They are generic, and should be individualized for a specific lab and the work that occurs there;
- An ERP is to be developed, implemented, kept up to date, and training on it provided to all lab personnel. It is to include procedures for accidents, medical emergencies, fire, natural disasters, biological spills, power failure, BSC failure, emergency egress, loss of containment, incident follow up, and any other topics relevant to the lab and the work done in it;
- An inventory of infectious materials must be maintained, including those materials stored outside of the containment zone;
- A training needs assessment (TNA) must be done, and a training program developed based on it. TNAs are to be reviewed annually by the PI or designate, and any gaps in training identified, documented, and corrected. Documentation for all training is required and must be signed by both the trainer and the trainee;
- CL2 labs require specific signage on all entrances to inform of the risk;
- The door to the CL2 lab must remain closed at all times, and locked when not occupied;
- Access to the lab is limited to authorized personnel only. A list of these authorized individuals is to be sent to UPEI Security Services and the BSO. Personal belongings

are not to be brought into the lab. Visitors and others entering the lab must be provided with training and/or supervision with regards to their anticipated activities in the lab;

- Traffic flow patterns from clean to dirty areas are to be established and followed;
- Dedicated paperwork stations and computer work areas to be used for report writing must be kept away from BHM;
- Oral pipetting is prohibited;
- Hand washing is extremely important and proper protocol must be followed. Hands are to be washed after gloves are removed, after handling any material known or suspected to be contaminated, and before leaving the lab;
- It is forbidden to eat, drink, insert or remove contact lenses, or apply cosmetics in the lab. It is forbidden to store food or utensils in the lab;
- Long hair must be tied back so it cannot come into contact with hands, specimens, containers, or equipment. Jewellery that may become contaminated or compromise PPE is to be removed or covered prior to entering the containment zone;
- PPE (a minimum of lab coat and gloves) must be worn in the laboratory. PPE must be removed before leaving the lab. Lab coats are to be decontaminated before laundering;
- Eye and face protection is required when there is a known or potential risk of exposure by splashes or flying objects, including when contact lenses are worn;
- Gloves are to be worn whenever there is potential for direct skin contact with BHM or potentially infected animals. Gloves are always removed before leaving the laboratory. Open wounds, cuts, abrasions, etc. must be covered with waterproof dressings before donning gloves;
- Suitable footwear with closed toes and heels that provides full foot coverage must be worn in the lab;
- Extra street clothing (coats, sweaters, etc.) and personal items (knapsacks, purses) must be kept outside the lab;
- A BSC is to be used for procedures that may produce infectious aerosols, or procedures involving high concentrations or large volumes of BHM;
- Centrifugation should be done using sealed safety cups or rotors. Samples are to be unloaded in the BSC if inhalation is a primary route of infection for the pathogen;
- Samples of infectious material or toxins are to be opened only in containment zones that meet the containment level requirements to which that infectious material or toxin has been assigned;
- Emergency eyewash and emergency shower are to be available;
- If a known or suspected exposure occurs, it is to be reported to the lab supervisor immediately. If clothing has been contaminated, it must be decontaminated before laundering. An Incident Report Form must be completed and submitted;
- Care must be taken when working outside a BSC (i.e., on the bench) to prevent the generation of aerosols. Working in a BSC requires that written procedures must be followed to ensure product and personnel protection. Training on the correct use and operation of primary containment devices is required;
- The use of needles and other sharps is to be strictly limited. When used, they should not be recapped, bent, sheared, or separated from the syringe. If any of these is a

required procedure, an SOP must be developed to provide guidance on how to do this as safely as possible. Approved sharps containers must be available in the immediate vicinity of where the sharps are used;
- All contaminated material is to be decontaminated before disposal or reuse;
- A protocol for the daily decontamination of the working surfaces of the lab must be developed and followed;
- Transportation of contaminated materials to and from the lab must be done properly. Primary and secondary sealable, leak proof, and shatter proof containers must be used. They must both be surface disinfected before removal from the lab. Containers must be identified with lab information and a biohazards symbol;
- Experimentally infecting cells or other specimens derived from the person conducting the experiment is prohibited;
- Contact of the face or mucous membranes with items contaminated or potentially contaminated with pathogens or toxins is to be prevented.

4.2 Minimizing the Creation of Aerosols

Aerosol production in the laboratory is a potential means by which workers can be infected with pathogenic organisms. Aerosols are small particles of solids or liquids suspended in air. If the particles are 5 microns or less in diameter, they can remain airborne for long periods of time, can spread long distances, and are easily inhaled. If the aerosolized particle is larger than five microns in diameter, they tend to settle out rapidly, possibly contaminating skin and work or other nearby surfaces. This could lead to a laboratory exposure by routes other than inhalation.

To minimize aerosol production, it is important to recognise those procedures and devices that could create them.

Laboratory procedures that may produce aerosols include:

- **Pipetting:**

  - Never pipette by mouth;
  - Use “to deliver” pipettes to avoid blowing out the last drop, which creates aerosols;
  - Use pipettes with plugs to avoid contamination of the pipetting device;
  - Do not mix materials by alternate suction and expulsion through a pipette – use the proper piece of equipment for this procedure (i.e., a vortex mixer);
  - Drain pipettes gently with the tip against the inner wall of the receiving vessel;
  - After use, place reusable pipettes in a pan filled with enough disinfectant to completely cover the pipettes. Draw up liquid to fill the pipette before resting in the pan;
  - Work in a BSC whenever possible.

- **Plating and Using Loops:**

  - Flaming inoculating loops, needles, or slides can generate aerosols. To minimize this, use a micro incinerator rather than an open flame;
  - Do not insert a hot loop into the culture; use a cooled or sterilized, disposable loop;

- Be sure that the loop is completely closed;
- Use shorter rather than longer loops, as they will vibrate less and reduce risk;
- Using presterilized loops will increase safety;
- When plating, streak plates where the surface is smooth – avoid bubbles.

➢ **Use of Needles and Syringes:**

- Use luer lock syringes to prevent accidental separation;
- Filling a syringe from a stoppered bottle may lead to increased pressure in the container, and the release of liquid when the needle is withdrawn. To prevent contamination, wrap the needle and bottle cap in a disinfectant-soaked absorbent when withdrawing;
- Immediately dispose of the needle and syringe into a red biohazardous sharps container without any further manipulations (separation of needle and syringe and needle cutting devices release aerosols).

➢ **Breakage or dropping of Culture Containers:**

- Use plastic lab ware rather than glass, as it is less likely to break, which leads to the generation of aerosols. Plastic ware is also less likely to cause cuts and accidental inoculation;
- Have a spill clean-up protocol prepared and a completely stocked spill kit available in the lab, suitable for all BHM handled in the lab;
- When opening lyophilized cultures, ampules, etc., avoid hasty opening by snapping the neck, which can lead to the sudden in rush of air and dispersal of contents. Instead, make a file mark near the middle of the cotton plug and apply a red hot glass rod to crack the glass. Allow time for air to seep into the ampule and gently remove the top and plug;
- Add liquid for re-suspension slowly to avoid frothing.

➢ **Opening Tubes:**

- Avoid using tubes with push in closures (when opened, the film of liquid trapped between the tube and closure breaks and releases aerosols);
- Do not invert tubes; use a vortex mixer;
- Wait 30 seconds after shaking a tube before opening it.

➢ **Pouring Infectious Liquids:**

- Avoid pouring off supernatant; use pipettes instead;
- Pour infectious liquid material through a funnel with the end of the funnel below the surface of the disinfectant in the discard container. The funnel should be sized so that it rests securely in the discard container. Pour disinfectant through the funnel after use with infectious or potentially infectious material.

➢ **Spills and Splashes:**

- Work over an absorbent, plastic backed pad to avoid aerosol production from drops falling on a hard surface.

Other activities that may lead to aerosol production and thus require care when performed include, but are not limited to:

- Handling discharge from animals or ectoparasites;
- Necropsy;
- Cage cleaning, removal of animal bedding. The use of a cage change station, which employs a High Efficiency Particulate Air (HEPA) filter and is very similar to a BSC in function, can allow cage changes to occur without exposing personnel to pathogens or allergens;
- Harvesting infected material;
- Opening culture plates.

The operation of some laboratory equipment can certainly produce aerosols. It is important that the equipment is designed for the purpose for which it will be used, and that safe work practices are followed. While the most significant piece of equipment to protect against any aerosols that may be generated is a BSC, other pieces of equipment built with safety features to contain aerosols should also be used in the lab. These include specially constructed centrifuges, sonicators, lyophilizers, etc. Examples of laboratory equipment that may create aerosols include:

- **Centrifuges:**

  - Do not overfill centrifuge tubes. Wipe the outside of the tubes with disinfectant after they are filled and sealed;
  - Use sealed safety cups and/or sealed rotors when working with BHM
  - Open cups inside a BSC following centrifugation;
  - If a BSC is not available, allow cups to sit for 10 minutes following centrifugation before opening to allow aerosols to settle;
  - A BSC should not be used as an enclosure for a centrifuge.

- **Cell Sorters;**
- **Lyophilizers;**
- **Blenders, Vortexers, Shakers, Sonicators, and Homogenizers:**

  - Use a laboratory blender with a tight-fitting gasket lid and leak proof bearings. Do not use domestic kitchen blenders, as they leak and release aerosols;
  - Allow aerosols to settle before opening.

Safety equipment may not always be sufficient to contain aerosols and other means of protection may be required. This could include the use of respiratory protection. If a respirator is required, it must be fit tested before use and at least annually. It is also very important to have the proper Emergency Response Plan in place, including an approved spill clean-up protocol and fully stocked spill kit. If aerosols could have been accidentally generated in the lab as a result of an

incident, the lab must be vacated for at least 30 minutes to allow these to settle before clean-up can commence.

The above operational procedures are a requirement for CL2 labs handling pathogens on the open bench at UPEI and are also recommended for CL2 labs with a BSC. The most significant piece of equipment to protect one from aerosols is a Class I or Class II BSC. It is recommended that a BSC be used for all procedures that could generate infectious aerosols.

4.3 Biological Safety Cabinets (BSCs)

A BSC is the most commonly used piece of equipment to contain aerosols in the laboratory. Through the use of HEPA filters and a continuous stream of inward air, aerosols can be contained within the cabinet. Exhaust air is directed through the HEPA filter and released into the atmosphere through ductwork, or back into the laboratory. Depending on the type of BSC, the product can also be protected as it is only exposed to filtered air.

- **There are three classes of BSCs:**

  - **Class I** BSCs provide personal and environmental protection but do not protect the product. Cage changing stations also operate in this way. The user is protected from the litter or materials in the BSC and only filtered air is returned to the lab. Class I BSCs may also be hard ducted to release filtered air to the atmosphere;
  - **Class II** BSCs provide protection to the product, as well as to the operator and the environment, and are the type most commonly found at UPEI. This class is further subdivided into types, A1 and A2, B1 and B2, and C1. The amount of air exhausted compared to that recirculated is the main difference between these units. They may be hard ducted or return air to the room;
  - **Class III** BSCs are completely enclosed and provide the maximum protection to the operator and to the environment. They are used with RG4 pathogens in high containment labs.

BSCs must be installed in the proper location. It is important that there is sufficient clearance around the unit to allow for proper functioning and access for servicing. It should not be located directly across from a door, another BSC, fume hood, or workstation. They must be connected to an emergency power source. Certification by a qualified individual must be done after installation and on an annual basis thereafter. They must also be certified after any servicing has been done. Once the BSC has been used, it must be decontaminated by a qualified individual before it can be moved to a new location. After arriving in its new space, it cannot be used until it has been recertified by a qualified technician.

To provide the anticipated protection, the BSC must be operated correctly. Some BSCs are intended to run continuously; others are shut off when not in use. If the unit is turned off, it must be allowed to run for at least five minutes when restarted. Only one person is to work in a BSC at a time. They are not designed for multiple users. Open flames must not be used in a BSC. The heat from the flame will disrupt the air currents and/or damage the HEPA filter and jeopardise safety. The use of micro incinerators is recommended.

Start-up procedures are established to ensure that there is proper air flow, and that the workstation operates efficiently. Sash height is integral to safe operation. When seated at the BSC, the sash should be at arm pit level. Adjust seat height to achieve this. Check airflow with a small strip of paper or tissue and note the reading on the magnehelic gauge. It is good practice to note the gauge reading after the unit has been serviced, perhaps indicating the needle position with a bit of tape and referring to this each time the BSC is used. If the reading varies from this position, it could indicate that the cabinet is not functioning properly. Before starting any work, all internal surfaces are to be wiped down with an appropriate disinfectant. All materials that will be required are to be gathered and placed in the BSC in advance of beginning the work, being sure that the front and back grills are not obstructed. A container of appropriate disinfectant is required to be present in the BSC when any work is being done therein. While all items needed should be placed in the unit before working, do not overcrowd the cabinet by including items that may not be necessary. A well organised workstation will have clean items on one side and contaminated items on the other.

Work in the BSC should be done as far to the rear of the cabinet as possible. Take care not to block the grills while performing the procedures. Work cautiously and without excessive arm movements. When entering and exiting the cabinet, move arms straight in and out, not sideways, and avoid sweeping movements. Work from clean to dirty and have a biohazardous waste receptacle on the dirty side of the work area. No contaminated items are to be removed from the cabinet without first being decontaminated. In the event of a spill, follow the SOP for spill clean-up in a BSC, which is required.

When finishing work, close all containers and decontaminate their surfaces before removing them from the BSC. Once this has been done, disinfect all interior surfaces of the BSC with the appropriate disinfectant. Then allow the unit to run for at least five minutes if it is to be turned off. Develop a schedule for routinely cleaning the drip tray beneath the work surface.

Some BSCs have ultraviolet lights that are used to aid in the disinfection of the interior of the BSC. Their use is discouraged, as the efficacy of this method is limited by many factors. It should never be used as the sole method of disinfection. It should be noted that the bulbs are not tested during the annual BSC inspection, so there is no assurance that the proper UV irradiation intensity and wavelength is being delivered.

For a detailed description of the types of BSCs and their operation, please refer to the Canadian Biosafety Handbook, chapter 11.

Fume hoods and laminar flow benches are not BSCs. They have specific indications for use, which do not include handling BHM. Please refer to the UPEI Laboratory Safety Manual for further information on fume hoods.

4.4 Vacuum Pumps

Vacuum pumps are frequently used in labs, often together with BSCs. They may be self-contained units, or part of the building infrastructure. To prevent contamination of the mechanical system during the aspiration process, an in-line HEPA filter (0.20 microns) must be installed between the

vacuum valve connection and the collection flask. The filter must be changed on a regular basis. Checking the filter should be on the monthly laboratory safety checklist if a vacuum pump is used. Vacuum lines must also be checked regularly for integrity. Place collection flasks in secondary containment to prevent spills in case of flask tipping or breaking. Do not leave aspirate in the collection container; deal with this waste in a timely fashion. If the waste is to be autoclaved, transfer it to the appropriate lab (i.e., Central Services) as soon as possible. If it is to be disposed of via the sanitary sewer, carefully pour it down the drain after appropriate chemical decontamination is completed, followed by three minutes of running water.

4.5 Water Baths

To prevent contamination, regular cleaning is required. A disinfectant may be added to the water, or the water temperature may be raised to a high temperature for a short period of time on a regular basis. If relevant, this activity should be added to a lab's monthly safety checklist to ensure that it is done on a routine basis.

4.6 Personal Protective Equipment (PPE)

There are a variety of PPE choices for those working in a CL1 or CL2 laboratory, depending on the activities that are to be performed. It is important to remember that PPE is the final line of defense against the agents of concern. Other mitigation controls, such as engineering controls and equipment as well as administrative controls are integral to one's safety. Minimum PPE requirements for CL2 *in vitro* labs are:

- **Safety eyewear** appropriate to the area and the task must be worn in all CL1 and CL2 laboratories. Minimum eye protection consists of CSA approved safety glasses. Even with permanent side shields, they do not provide significant splash protection and therefore should not be worn when large volumes of liquid are manipulated. Goggles and face shields may be necessary for certain tasks, based on your local risk assessment.
- **A lab coat that fits properly** and is fully fastened. Lab coats with cuffed sleeves and snap closures (rather than button) are recommended. It must not be worn outside of the lab;
- **Disposable gloves**, appropriate for the work to be done. Remember, jewellery worn under gloves may puncture the protective barrier and is therefore not recommended to be worn. Gloves may protect, but if items such as doorknobs, computer keyboards, or a cell phone are touched with gloved hands, contamination of the environment can occur, placing people at risk. Gloves should be inspected for any damage before use and changed frequently. One pair should not be worn for a long period of time. They should be pulled over the cuff of the lab coat so no skin is exposed. They are to be changed after any known contamination, and after handling infected material. When removed, this must be done in a fashion that does not contaminate the hands. Once removed, hands must be washed. Tiny, undetectable holes may be present in any glove, so hand washing is essential to protecting the wearer and others from contamination;

- **Shoes**, which must have closed toe and heel, have a low heel, and cover the entire foot;
- **Long pants** or similar clothing items that cover the legs to the ankle;
- **Safety glasses**, goggles, and/or a face shield, as determined by the local risk assessment for the laboratory.

Other PPE items may be required, depending on the work activity or the location of the lab. For example, entering our rodent facility will require that additional PPE be worn. This includes a gown and hair and foot coverings. Working with certain rodent strains may require you to change into scrubs and additional PPE before entering the animal room. When a risk of splashing exists, such as when working with pathogens in the aquatic facility, waterproof aprons may be required as well. If work with liquid nitrogen is involved, face protection and insulated gloves are required.

When the PPE required for your laboratory is more extensive than lab coats, gloves, and safety glasses, a written description of the step-by-step process by which PPE is put on (donned) and taken off (doffed) must be developed. This should be posted where the PPE is stored for easy reference. For examples of simple and more complex donning and doffing procedures, please refer to the Canadian Biosafety Handbook, chapter 9 (Use of Personal Protective Equipment; http://canadianbiosafetystandards.collaboration.gc.ca/cbh-gcb/index-eng.php)

Wearing contact lenses is not recommended in the lab, but if they are worn, secondary eye protection is required when there is a known or potential risk of exposure by splashes or flying objects.

Respiratory protection may be required for various reasons. This may be a protective measure to mitigate the development of allergic reactions, or to protect the wearer from potential aerosolized agents. Please remember that all respirators, even N-95 respirators, must be fit tested before they are to be worn and fit testing must be repeated annually. Fit testing is also required after any facial changes have occurred that might alter the effective fit of the respirator. Surgical masks are not interchangeable with respirators and are not to be worn in their place.

4.7 Personal Items in the Lab

Items sometimes taken into a CL2 lab that can become fomites and aid in the transmission of the pathogen to people outside the lab include ear buds, cell phones, keys, and personal computer tablets. This was illustrated in a CDC 2011 report (http://www.cdc.gov/Salmonella/typhimurium-laboratory/042711/index.html) and again in a 2017 CDC report (https://www.cdc.gov/salmonella/typhimurium-07-17/index.html).

Using personal electronic devices in a CL2 lab without a governing SOP to protect the phone, etc. from contamination is prohibited. Taking these items into a lab and later returning these items to the home where they may be handled by others is unsafe.

Also consider that computer keyboards, telephones, cellphones, etc. are not easily decontaminated. It is required that these items and paperwork stations are kept well away from

areas where BHM are manipulated. Gloves must be removed, and hands washed before handling these items.

4.8 Sharps

Sharps include needles, scalpel blades, razor blades, and other similar items with edges sharp enough to cause injury. Even broken glass can be considered a sharp. Their use must be minimized in the lab. The use of engineered safety sharps is encouraged. Recapping needles is not permitted in most situations. Needles and syringes are not to be separated, and needles are not to be recapped, sheared, or bent. If needles must on occasion be recapped or separated from the syringe, this must be justified, and a dedicated SOP describing when and how this procedure is to be done to prevent needle stick incidents provided for review by the IBC as part of the biosafety permit application. If approved by the IBC, the SOP must be available and used in the lab. Otherwise, uncapped needles with an attached syringe are to be immediately disposed of after use in an approved sharps container. When this container is ¾ full, it is to be taken to Central Services where it will be autoclaved before disposal. Never over fill this container.

4.9 Transporting BHM on Campus

When transporting BHM between laboratories within a building, or between buildings on campus, it is important to take steps to prevent potential exposure and/or environmental contamination from spills or leaks associated with this transport. Arrangements should be made to limit the number of moves (with travel through public areas minimized), to reduce any possibilities of container breakage, and, if breakage should occur, to contain the material within the transport container. The precautions taken should reflect the risk associated with the properties of the biological/biohazardous material to be transported.

4.9.1 Between laboratories within a building:

The BHM should be in a breakage resistant primary container whenever possible (e.g., plastic test tube rather than glass).

After surface decontamination has been completed, place the primary container in a leak proof, breakage resistant, sealed (has a tight-fitting cover) secondary container with secure hand grips. If the primary container is glass containing a liquid, place sufficient absorbent material in the secondary container to absorb all liquid in the event of a leak. A biohazard symbol is required on the outside of the secondary container as well as information on the laboratory of origin. This is to include the laboratory room number, contact name, and phone number. Surface decontaminate the secondary container before removal from the lab with a disinfectant appropriate for the contained BHM. After being transported to the new location, the BHM is removed from the secondary container and the secondary container is returned to the lab of origin and again decontaminated.

If a spill should occur in the secondary container during transport, the spill is to be handled according to the spill cleanup protocol for that BHM.

A laboratory cart must be used if the load is heavy or consists of multiple items. The use of a cart is recommended whenever possible, especially if the load is to be transported between floors. The cart must have a lip around the edge to prevent the contents of the cart from falling off if the cart should get bumped.

Ensure the material is supervised continuously between origin and destination.

4.9.2 Between Buildings on Campus:

Transportation of Dangerous Goods regulations apply, depending on the distance between buildings.

Follow the above directions, using a leak proof, sealed primary container within a sealed, leak proof, breakage resistant secondary container which is appropriately identified.

The use of a coolant may be required if the material must be kept frozen.

The use of a cart for transport is recommended even if the material is not heavy.

4.10 Decontamination and Waste Management

All potentially contaminated materials must be decontaminated prior to disposal or reuse. For biohazardous contamination, a few different processes are frequently used to make the material safe for disposal or reuse. The following definitions are from the Canadian Biosafety Handbook:

Sterilization: Process that completely eliminates all living microorganisms, including bacterial spores.

Disinfection: Process that eliminates most forms of living microorganisms; disinfection is much less lethal to infectious material than sterilization.

Decontamination: The process of removing and/or inactivating infectious material or toxins; this may be accomplished through disinfection or sterilization.

Decontamination leaves the surfaces and materials safe to handle and thus protects those in the lab and in the wider community. Each lab needs to have a daily workspace and equipment decontamination procedure in place.

When large pieces of equipment that may have been contaminated with BHM must be removed from the lab as waste, for repair, or for transfer to another lab, they must first be decontaminated. Decontamination is recorded by completing an equipment decommissioning form and attaching it to the item. This lets Facility Management or Biomedical Engineering know that the item is safe to handle. A supply of these forms should be kept in each lab. For additional copies, please contact the BSO or AVC Biomedical Engineering.

All contaminated or potentially contaminated materials from CL2 labs must be decontaminated before disposal or reuse. At UPEI, the most frequent methods for this are chemical disinfectants, autoclaves, and incineration.

4.10.1 Chemical Disinfectants

Chemical disinfectants are most frequently used for surface decontamination and to treat material or objects that cannot be autoclaved. Selection of the correct chemical disinfectant for the task is crucial. If the pathogen of concern is not susceptible to the disinfectant, or if the chemical is used incorrectly, not only can pathogen or toxin decontamination be incomplete, but personal injury could result.

Use of disinfectants requires not only an effective product be used, but also that a proper concentration of that product is in contact with the pathogen or toxin for the required amount of time. Some disinfectants are inactivated by organic matter, so this may have to be taken into consideration when choosing a product. Some of the most commonly used disinfectants at UPEI include bleach solutions, isopropyl alcohol (IPA), Virkon, T36, accelerated hydrogen peroxide, and Cavacide. Each product has advantages and disadvantages. While IPA may be effective after only a two-minute contact time, this may be hard to achieve as it evaporates quickly. If large volumes are used, it could pose a fire hazard. A bleach solution has a broad spectrum of activity and reasonable contact times. However, metal surfaces can be damaged by this so they must be rinsed with water or IPA. Also, materials saturated with bleach must not be autoclaved. Once bleach has been diluted, the product degrades quickly; to ensure efficacy, solutions must be made fresh daily.

The MSDS for the disinfectant product used must be available in the lab and all lab personnel must be familiar with these documents.

Disinfectant stored in workplace containers require labels that comply with WHMIS. The name and concentration of the disinfectant and the expiry date of the product must be on the label to meet biosafety requirements.

For information on choosing a chemical disinfectant, please see Chapter 15 of the Canadian Biosafety Handbook.

4.10.2 Autoclave

Autoclave decontamination of waste is carried out at central locations on campus, rather than in individual autoclaves in individual labs. Autoclave operation must follow specific rules on loading and unloading for safety and efficacy. Efficacy must also be routinely monitored to ensure proper operation. Chemical monitors are used in each load, and biological indicators are used frequently to ensure correct operation. SOPs for autoclave operation at the AVC are created and maintained by Central Services for the decontamination of biohazardous lab waste. Autoclaves are also present in the Veterinary Teaching Hospital to meet their needs and in the Duffy Science Centre.

Please discuss in advance the best practice to use when mixed waste (such as biohazardous waste containing radioisotopes or hazardous chemicals) may be generated in the lab, or when chlorine may be present in the waste collected with Central Services or Duffy Science Centre staff as relevant. These materials may be hazardous when autoclaved and endanger staff.

4.10.3 Incineration

The incinerator at AVC is used to treat waste that cannot be autoclaved, such as animal anatomic waste and other organic matter. It does not have the ability to safely burn plastic, so it is important that material to be incinerated is enclosed in paper or cellulose compost bags that do not contain plastic. Please contact Diagnostic Services for details on acceptable products. Material to be incinerated is transported to Morphologic Pathology in appropriate primary and secondary containers (please refer to section 4.9). To find out when the next run will occur, please contact Morphologic Pathology staff. Material may need to be stored for several days in a secure refrigerator or freezer while awaiting the next run.

4.10.4 Gaseous disinfectants

Specific areas or items, such as BSCs, may be decontaminated with gaseous disinfectants. Contact the BSO for more information.

4.10.5 Outside Service Provider

A company specialized in the decontamination of biohazardous or mixed biohazardous and chemical waste may be hired from time to time for specific research projects. When applicable please contact the Health, Safety and Environment Office for more information.

4.10.6 Waste Management in CL2 Laboratories

Waste management in the lab is extremely important when dealing with BHM. No contaminated waste can be disposed of before it is decontaminated. There are four general waste containers found in most labs, each with specific containers.

Biohazard Bags – these are red bags with the biohazard symbol clearly visible. All biohazardous waste, with the exception of contaminated glass and metal sharps, is put into these bags. This might include items such as gloves, petri plates, paper towels used to clean up a spill, swabs, etc. They are autoclaved before disposal.

There are clear autoclavable biohazard bags available for special circumstances, such as when a contaminated lab coat or other clothing item is sent to be decontaminated. As it is clear, staff will be aware of the contents and will have it returned to the lab of origin.

Glass Sharps Container – these are plastic containers, provided by Central Services for UPEI laboratories, that are labeled with both a biohazard symbol and a “Glass Sharps” label. This container is used for broken test tubes, slides, and glass pipettes. Once filled with contaminated glass, containers are returned to Central Services to be autoclaved prior to disposal.

Metal Sharps Container – all metal sharps are placed in these containers, whether contaminated or not. Materials to be disposed of in these containers include needle and syringe units, scalpel blades, and razor blades. Please ensure that they are not overfilled; there is a line on the container to indicate the maximum fill level, approximately ¾ full. All sharps containers are returned to the Central Services autoclave facility to be treated before disposal. Do not recap needles or separate needles and syringes.

General Waste Bags – these are orange garbage bags, found in the large waste containers in each lab that are used for non-contaminated waste only. This might include paper towels used when hand washing, packaging material, and any other non-sharp, non-contaminated waste. These bags are the only waste containers removed from the laboratory by Custodial Services.

4.10.7 Disposal of contaminated liquids

Contaminated liquids, such as cell culture or broth culture liquids, may be decontaminated in the laboratory by adding a suitable disinfectant to the liquid. This may be a disinfectant like bleach, added to create a 0.5-1% NaOCl solution and left for a minimum of 30 minutes. After the contact time has elapsed, the liquid may be poured down the sink drain, followed by a large volume of water. If the liquid has a high organic content, this method of decontamination is not acceptable. This material must be taken to Central Services to be autoclaved. Please contact Central Services staff for details.

4.10.8 Mixed Hazardous Waste

When biohazardous waste is combined with chemical or radiological hazards, the mixed waste may require special consideration. Depending on the particular chemical waste combined with biohazards, it might be autoclavable or it may require special handling by an external service provider. Chemicals that cannot be autoclaved are those that are flammable or that could be very reactive or highly toxic. Please discuss this with the autoclave facility staff in advance of beginning your work.

When radioactive material is included in the biohazardous waste, it may need to be treated as radioactive waste first, and then, when safe, treated as biohazardous waste. All projects involving radioisotopes must be approved through the Radiation Safety Officer.

Please refer to the waste management section of the UPEI Laboratory Safety Manual for additional information.

4.11 Medical Surveillance

The primary purpose of medical surveillance is to identify conditions that could prevent an increased risk of adverse health effects due to the work being performed. The UPEI Medical Surveillance Policy (http://www.upei.ca/policy/adm/ord/gnl/0012) focuses on the prevention of illness related to the laboratory exposure of personnel to infectious materials, biotoxins, or animal allergens in the course of their research, aiding in the detection of illness due to exposure to these materials, and to provide to personnel the appropriate exposure response procedures.

Other areas, including respiratory protection, hearing protection, radiation safety, and asbestos abatement, are covered by other Policies and guidance documents. Questions on these or other areas may be directed to the Health, Safety and Environment Manager.

Preventive measures related to medical surveillance for research involving BHM include:

- Review and approval by the IBC of medical surveillance measures to be associated with work at the University involving BHM.

These could include planning for vaccinations (such as Hepatitis A or B or rabies), additional personal protective equipment (PPE), and/or the implementation of special procedures, depending on the project.

- The identification and use of required personal protective equipment (PPE).
- Ensuring the education of personnel on potential routes of exposure, response procedures if exposed, and symptoms of infection to aid in early detection of potential disease.

It is essential that all lab personnel understand how they should respond to an exposure. First aid measures are to be taken immediately in the lab, such as washing the wound or flushing mucus membranes for 15 minutes. For exposures to human blood or bodily fluids, immediately after the area has been washed or flushed for 15 minutes, medical help is to be sought by going directly to the emergency room at the Queen Elizabeth Hospital, where the individual will be triaged. **Do not delay this consultation**. If antiviral medications are to be started, there is a window of opportunity within which this is most effective. For those exposed to other human/zoonotic/animal pathogens or potentially infectious material, the decision to seek medical help may depend on the pathogen and the nature of the exposure. If medical help is accessed at the time of exposure or at a later date, informing the physician of the nature of your work is critical.

The individual is to take their vaccination history and titre records, as this information will be sought by the attending physician. Take the source blood or fluid sample with you if possible.

Enough medication for a couple of days and a prescription for the remaining course of treatment may be provided, depending on medical opinion. For further information on the procedure and possible decisions that may follow medical consultation, please refer to the PEI Department of Health and Wellness document on percutaneous exposure to blood borne pathogens.

Those projects involving RG2 human/zoonotic pathogens must include a Plan For Post-Exposure Prophylaxis (PPEP) to Bloodborne Pathogens and/or Human Pathogens, which is an attachment on the biosafety permit application form housed in the UPEI Researcher Portal.

The PPEP is an essential document that will outline the required response to exposure. All personnel that could be exposed must understand the information and abide by it. A Pathogen Safety Data Sheet (PSDS) contains vital information, such as potential routes of infection and symptoms of related illness and is to be attached to the application. All personnel working with these agents must be aware of the information in the PSDS and the PPEP.

- The required reporting of all potential exposure, incidents, near misses, and laboratory acquired infections.

Report any illness that may be associated with agents manipulated in the lab. Many times, there is no known incident during which exposure occurred. Personnel should also discuss any illness or immunocompromised condition that could make them more susceptible to the agent they work with with their supervisor. Personnel who become pregnant should inform their supervisor as soon

as possible and discuss any potential risks to the pregnancy from biological and/or chemical hazards in the lab. Additional PPE or a temporary work reassignment may be indicated, depending on the situation and medical advice.

- Immunization and/or protective titre verification as required.

Vaccines may exist for some infectious pathogens with which personnel plan to work. This is to be investigated by the PI and will be reviewed by the IBC. For those directly working with human blood, serum, plasma, and tissue, hepatitis B vaccination and proof of immunity will be required before work can start. Titres are preferably drawn four to six weeks after the final vaccination. If vaccinated years ago, a titre is to be run. In these cases, the titres sometimes appear to be very low. A booster vaccination may be required, after which the titre must be rechecked. The UPEI Health and Wellness Centre can assist in obtaining many medical surveillance requirements.

- The development of mitigation strategies for personnel working with animals in research which pose an allergen risk.

For staff working with animals, particularly rodents, dogs, and cats, allergic reactions may develop over time. Minimizing one's exposure to the allergens is advisable. This can be aided by the manipulation of potential allergen sources in ventilated cage change stations and biological safety cabinets. Ventilated cage racks are also important housing features to mitigate the risk. One can decrease exposure by wearing dedicated clothing in the animal rooms and following a regimented hand washing policy. Respirators are highly recommended when working with rodents. These must be fit tested each year. A surgical mask is not designed to protect the wearer so should not be used for allergen mitigation. If you are concerned about allergy development, please talk to your supervisor and your medical provider. For further information on respirators and fit testing, please review the Respirator Protection Program in the UPEI Laboratory Safety Manual or contact the Health, Safety and Environment Manager.

4.12 Biosecurity

While biosafety strives to protect people, animals, and the environment from infectious pathogens, the role of biosecurity is to protect this same BHM from misuse, loss, or theft. In protecting these materials, one also safeguards other contents of the lab, which can include chemicals, computers and laboratory equipment, animals, and research data. The University has a Biosecurity Plan that can be found on MyUPEI. The Biosecurity Plan reflects the nature of the BHM used and stored at UPEI. The plan is based on physical security, operational practices, inventory maintenance, and information security.

Those working in CL2 labs must keep these labs locked when unoccupied. Strict adherence to the UPEI key control policy is necessary. Keys must not be duplicated or loaned to others. Lost keys must be reported immediately. Only authorized personnel can work in the lab. Visitors must be escorted at all times by an authorized user. BHM is preferentially stored within the lab. If they are stored outside of containment, they must be kept in locked refrigerators, freezers, and walk in coolers. All BHM must be inventoried, and this inventory must be kept up to date.

Any actual or suspected breach of security is to be reported immediately. Campus Security will respond to reports of break in, damage to property, etc., and will determine whether the incident requires the involvement of city police. Even suspicious activity should be reported as this may lead to the prevention of a more serious event. Biosecurity incidents are to be reported using the UPEI Incident Reporting Form located at: http://www.upei.ca/vpaf/health-and-safety/incident-reporting.

Biosecurity training is required for all persons working in CL2 laboratories and must be renewed **every 3 years.** This is offered in tandem with biosafety training.

5. Guidelines for Working with Specific Materials

5.1 Working with Human Blood, Tissue, and/or Bodily Fluids

These guidelines cover the use of human blood, tissue (including primary cell cultures and established cell cultures known to be infected), and/or other bodily fluids in the course of teaching, research, health screening, or service at UPEI. These guidelines apply to faculty, staff, students, and participating visitors working with these materials. This does not include those activities conducted by the UPEI Health and Wellness Centre or those activities run by other health professionals that may occur on campus. The requirements for biocontainment and safe work practices are outlined in general terms, but may be altered by the IBC, based on the local risk assessment (LRA).

5.1.1 Blood Borne Pathogens (BBP)

Blood borne pathogens are micro-organisms that may be present in human blood, tissue, or certain bodily fluids and are capable of causing disease in people. There are many BBPs, but those of greatest concern are hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). Even when samples are screened for certain pathogens, they should not be considered safe, but should be handled as if infected, as there is the potential for pathogens other than those screened for to be present.

Incidents in the laboratory that involve breaks in the skin may allow entry of these and/or other BBPs. This could arise due to a needle stick injury, or absorption through broken skin due to eczema, acne, cuts, etc. Mucous membrane exposure via aerosols generated in the lab or by splashes or sprays of contaminated material is another significant potential route of exposure.

5.1.2 Containment

While human clinical samples from members of the general population are exempt from the licensing requirements of the HPTA, any further processing of these samples that could isolate or propagate pathogens potentially present in them would require HPTA licensing. At UPEI, the IBC considers all human blood, tissue, and most bodily fluids to be RG2 BHM. Hence, all work with human blood, tissue, and/or most bodily fluids should be conducted in CL2 facilities and using related operational practices, based on a LRA. However, it is possible that the LRA could determine that a higher or lower containment level would be required for a given research project. The UPEI Biosafety Policy and UPEI Medical Surveillance Policy requirements must be met before any work can begin.

5.1.3 Immunization

Hepatitis B immunization is indicated for research personnel working with human clinical samples, primary human cell lines (unscreened), hepatitis B virus cultures, and anyone handling waste generated from these sources. Before beginning work with human samples, proof of immunity must be provided. This includes both a fully documented vaccination series and a test for immunity (serum titre) one or more months after completion of the vaccination series.

As the vaccine schedule includes three vaccines administered over six months, for those who have not previously been vaccinated, preplanning is required to allow desired start dates to coincide with proof of immunity. If for any reason vaccination is refused or cannot be implemented, then the individual may seek medical exemption. In such exceptional cases, the individual must provide proper documentation from a licensed medical professional for review and approval by the IBC, in consultation with UPEI Health and Wellness Centre. Additional information or modifications may be requested as part of the review process. It is possible that without appropriate vaccination a person's program of study or work may be impacted.

A copy of an individual's HBV vaccination record and verification of immune status or fully approved HBV vaccine exemption will be required and will be kept in confidence in a secure location. The Research Compliance Coordinator should be contacted at the time of a biosafety permit application to request a Vaccination and Titre Confirmation form be sent to the UPEI Health and Wellness Centre to be completed for all project team members concerned.

If an individual has no proof of vaccination and does not believe it was received, the individual is considered susceptible to infection. A full vaccination series must be completed, followed by a serum titre check one month after the final vaccination is given. If an individual is not able to provide proof of previous vaccination, but believes a HBV vaccination series was done in the past, every attempt should be made to locate the missing records. If not available, serology should first be completed to determine if a titre exists. If the titre is reported to be present but nonprotective, a booster should be given, and the titre rechecked a month later. However, if the test indicates that previous vaccination has never taken place, a complete HBV vaccine protocol is to be completed, including a second titre check approximately one month after the final vaccination in the series is given.

Please contact the UPEI Health and Wellness Centre to arrange to speak with a health professional regarding vaccination requirements and the determination of protective titres as required for specific research activities. The cost of vaccination is to be covered by the Principal Investigator of the specific research project and will not be covered by the University. Before appointments for vaccination are booked, the PI must contact the UPEI Health and Wellness Centre to provide invoicing details. Additionally, personnel should have been added to the relevant biosafety permit prior to requesting that the Vaccination and Titre Confirmation form be sent to the UPEI Health and Wellness Centre.

In addition to HBV vaccination, it is recommended that everyone receive the generic immunizations, as endorsed by the PHAC and outlined in the UPEI Infectious Disease Policy (http://policy.upei.ca/adm/hrd/ohs/0006).

The above requirements were developed with the help of the medical staff at the UPEI Health and Wellness Centre and in consultation with provincial authorities in the vaccine preventable disease program. Their expertise is greatly appreciated.

5.1.4 Prior to Work Beginning

Although there is no oversight of pathogens in their natural environment under the HPTA, due to the potential risks involved in working with this material, a UPEI biosafety permit, including site-

specific protocols and an exposure control plan, must be approved prior to any work commencing. For those activities involving human subjects as defined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, 2022), UPEI Research Ethics Board approval, and any other relevant ethics approvals, must be in place before samples are acquired or work begins. Training for every worker handling BHM must be completed before this work starts, including BBP training, basic biosafety training, and laboratory or site-specific training. Training must be documented, signed by the trainer and the trainee, and maintained by the PI.

All required immunizations and/or proofs of immunity must be completed before working with this material.

The lab should be CL2 compliant. Based on the LRA, the IBC may determine that a higher containment level is required. UPEI does not have a CL3 facility, so work at this level is not permitted on campus. It is also possible that the IBC may, based on the LRA, determine that some activities could occur at a lower level of containment, although CL2 operational practices will be mandatory.

Appropriate PPE must be available and used. At a minimum, this must include a lab coat and gloves, as well as closed toe shoes which fully cover the foot, and full-length pants. If the potential for splashes has been identified in the LRA, safety glasses, goggles, or face shields are to be used to prevent exposure of the mucous membranes of the eyes, nose, and mouth.

5.1.5 Source of Human Material

As much information as possible should be obtained about the study's source population to help determine the health status of the individual(s) and to determine if BBPs are, or are likely to be, present in the study group. Screened samples might be used, or the individuals may be asked to self-identify if they have a known communicable disease. Individuals with specific symptoms may sometimes be excluded from the trial to minimize certain risk(s). If a BBP is known to be present in the samples, this information must be included in the local risk assessment, as this may lead to the requirement for a higher containment level.

Self-experimentation is not permitted as per the Canadian Biosafety Standard. Blood from project workers or personnel with access to the lab cannot be propagated, stored, or manipulated for the purpose of research.

5.1.6 Collecting Human Samples

The collection of blood samples from human participants via venipuncture must be done by a trained phlebotomist or registered medical professional. For small blood samples taken by capillary rupture, training must be provided to the personnel collecting the sample by a trained phlebotomist or medical doctor, and the procedure may be performed either by or under the direct supervision of either of these. Training must be documented. A description of the device(s) to be used must be included in the biosafety permit application.

5.1.7 Universal Precautions

When working with human blood and bodily fluids, it is prudent to assume that all materials may harbour BBPs and should be handled accordingly. It is impossible to test all samples against all

potential BBPs. Universal Precautions is a set of steps taken to protect oneself from contact with blood and bodily fluids through the assumption that the material is infected with BBP. Universal Precautions include proper handwashing techniques employed whenever gloves are removed, the use of appropriate PPE to aid in the prevention of contact with the BHM, the use of engineering controls, such as BSCs and sealed centrifuge cups, disinfection and spill clean-up protocols, limitation on sharps use as much as possible, and proper waste disposal. Universal precautions must be employed in the laboratory.

5.1.8 Containment Equipment

It is recommended that human blood/tissues/fluids be manipulated in a BSC. Equipment that might generate aerosols must be equipped with aerosol containment features. Under certain circumstances, dependent on the review of the LRA, certain procedures may be safely carried out on the open bench with the use of other safety devices such as bench top splash shields and plastic backed absorbent paper. Centrifugation employing sealed rotors or safety cups is recommended.

5.1.9 Sharps

The use of sharps must be strictly limited and is only to take place when there is no alternative available. Engineered safety sharps must be used if possible. Needles are not to be recapped, bent, sheared, or removed from the syringe. If recapping is unavoidable, then a procedure must be developed, documented, and approved by the IBC. Needle locking syringes should be used. Biohazard sharps containers must be utilized and are to be located as close to the area of use as possible. Single use lancets are required for skin capillary samples. Spring loaded safety lancets are recommended.

5.1.10 CL2 Operational Practices

All work must be done using CL2 operational practices, even if the LRA determines that activity can take place in a lower containment space. A laboratory biosafety manual must be created and contain the SOPs for safe work practices. Please refer to the Canadian Biosafety Standard and the Canadian Biosafety Handbook for further information.

5.1.11 Waste Disposal

All biohazardous waste must be decontaminated before disposal according to UPEI protocol. Contaminated sharps must be placed in approved sharps containers and autoclaved before disposal.

5.1.12 Spill Clean Up

Spill clean-up protocols are to be part of the biosafety permit application. An appropriate biological spill kit must be in the vicinity of the work being done. Any spill must be reported to the supervisor and a UPEI Incident Report Form must be submitted as soon as possible and no later than 24 hours after the incident.

5.1.13 Post Exposure Prophylaxis

A plan for post exposure prophylaxis (PEP) for workers who are exposed to human blood, tissues, and/or bodily fluids must be available. The plan must include immediate first aid procedures,

which must be detailed in the biosafety permit application. If possible, the sample involved in the exposure should be saved and provided to attending medical personnel. The PEP must also indicate the need for timely medical consultation and the necessary UPEI incident reporting procedures. Vaccination history and record of vaccine response to hepatitis B virus immunization should be provided at the time of the medical consultation.

The incident must be reported to the PI or other supervisor and a UPEI Incident Report Form (http://www.upei.ca/vpaf/health-and-safety/incident-reporting) must be submitted no later than 24 hours post exposure.

5.2 Working with Viral Vectors at UPEI

Before any *in vitro* or *in vivo* work with viral vectors can begin at UPEI, a LRA must be completed by the PI, through completion of the biosafety permit application, and reviewed by the IBC. The LRA is to include detailed information on risk factors, such as the viral vector to be used, and the nature of the insert, generation, and replication competency. Work can only proceed once a biosafety permit for the project has been approved. In most applications, only vector systems that are replication incompetent may be used at UPEI. It is recommended that all vectors be obtained from commercial suppliers and that only the latest generation system is used, as this provides better biosafety features and is less likely to lead to the production of replication competent virus.

To see the SOP for working with Lentiviral vectors at UPEI, please contact the BSO. Before planning work with other vector systems, contact the BSO.

5.3 Working with Research Animals

Working with animals can pose health and safety concerns due to a number of different issues. If large animals are involved, one must be very conscious of the potential for serious injury. Special handling and restraint procedures are required. Regardless of the size of the animal to be handled, one must be aware of the behavior of the species, the proper handling techniques, and any other innate risks.

Zoonotic disease transmission is a potential risk to personnel. Aerosol transmission is a possibility for some diseases, however, as UPEI does not allow work with RG3 pathogens, this mode of transmission is less likely here. Transmission can also occur through animal contact, bites or scratches, or indirectly, through contact with contaminated equipment in the environment. Proper use of PPE can be very effective in disease prevention.

Individuals who are or who become immunocompromised or who become or are planning to become pregnant should discuss this with their health care professional in light of their work and any possible risk factors.

Another significant risk of working with research animals is the development of a work-related allergy, usually manifested as well-recognised symptoms such as a runny nose, itchy eyes, sneezing, skin rash, and possibly asthma. Those individuals with a history of allergic reactions are more likely to develop an allergy to the research animals than those with no such medical

background. The chances of developing such an allergy are influenced not only by one's medical history but also by the degree to which one is exposed to the potential allergen. As stated in the CCAC training module on occupational health and safety, laboratory animal allergy may be the most prevalent occupational hazard facing people working in experimental animal facilities.

Education programs for staff, health monitoring of at-risk persons, improved engineering standards for ventilation and relative humidity, and provision of appropriate PPE are all ways to minimize the development of allergies. All personnel handling research animals must be informed of the risk and of potential mitigating procedures. The University Veterinarian and/or Animal Care Committee can be consulted for further information and training.

Prevention measures are very simple. The proper use of PPE is essential. A suitable fit-tested respirator is recommended when working with rodents. If an individual has a history of allergy, this is a valuable means by which their health can be protected. Do not wear a surgical mask for allergen protection. These masks are meant to protect the patient, not the wearer. Minimizing contact with allergens is helpful in preventing reactions. Work clothes and street clothes could be kept separate, and showers after work can help reduce allergen contact. Always wash hands after handling the animals. The use of ventilated cages and BSCs are examples of engineering methods to minimise contact.

6. Templates and Attachments

The following templates are available for download in the attachments section of the “Application for Biosafety Permit” on ROMEO and as appendices to this Standard. These should be completed and adapted for your lab and study and attached as part of the application as relevant.

- Appendix A. Biosafety spill template for spills in a centrifuge
- Appendix B. Biosafety spill template for biological materials
- Appendix C. Biosafety spill template for spills in a BSC
- Appendix D. Biosafety spill kit minimum requirements
- Appendix E. Plan for Post Exposure Prophylaxis template
- Appendix F. Biosafety Resume template

Several additional Standard Operating Procedure templates for CL2 laboratory biosafety manuals are also available. For copies, please contact the UPEI BSO.

BIOSAFETY SPILL TEMPLATE: CENTRIFUGE

Please note that PIs must complete the information at the end of this form and store one copy of the protocol in the spill kit for easy reference in the event of a spill.

• Staff must be aware of the procedures to be followed in the event of exposure or spill;
• Centrifuge spill procedures are dependent on the type of biological agent involved;
• Ensure all procedures are specific for the type of agent that you are working with;
• Be prepared to handle a spill for the type and for the amount of biological agent used in your space;
• Refer to the appropriate SDS and/or PSDS when developing your procedures.

Immediate response to spill within a centrifuge:

• Shut centrifuge off, leave lid closed for 30 minutes to allow aerosols to settle. Notify others not to use the centrifuge during this time. Attach signage to indicate that a biological spill has occurred. The time that the spill occurred should be included on the sign;
• Wear appropriate PPE. If possible, remove the centrifuge or safety rotor and/or centrifuge buckets to a BSC for clean-up. If the centrifuge does not have this removable safety features, then clean in situ with extreme caution, after letting the aerosols to settle for 30 minutes;
• With forceps, place any broken glass in a glass (or metal) sharps container;
• Wipe down all working surfaces and items within the BSC with specified concentration of identified disinfectant for the indicated time. If bleach is used, then rinse with alcohol;
• All clean-up materials should be placed in a biohazard bag and autoclaved. However, if bleach was used as a disinfectant the cleanup materials cannot be immediately autoclaved. Please consult with Central Services about this issue;
• Immediately report the spill to the supervisor/lab manager. If the BHM is a human/zoonotic pathogen then the Biosafety Officer is to be contacted immediately;
• If eyes and/or mucous membranes have been exposed, then wash or flush the exposed areas for 15 minutes at an eye wash/emergency shower station. If skin has been exposed then wash with soap and water for 15 minutes. If skin has been punctured then gently encourage bleeding through the washing procedure. Do not apply bleach or any other caustic disinfectant to the area;
• If the exposure involved human blood, tissues, or other bodily fluids then follow the post exposure protocol;
If warranted, medical help should be sought. A copy of the SDS/PSDS should be provided to the medical personnel;
Complete and submit a UPEI Incident Report and Investigation Form. Complete a WCB form if the spill could lead to potential consequences to health.

For a spill that can be contained and decontaminated by lab personnel:

• Notify others in the lab;
• If an aerosol was generated, or that risk exists, hold your breath while immediately leaving the lab.

Close the door and post a sign informing others not to enter due to a biological spill. Do not re-enter the lab for at least 30 minutes to give the aerosolized particles time to settle;
• Remove any contaminated PPE/clothing and put it in a biohazard bag to be decontaminated;
• If eyes and/or mucous membranes have been exposed, then wash or flush the exposed areas for 15 minutes at an eye wash/emergency shower station. If skin has been exposed then wash with soap and water for 15 minutes. If skin has been punctured, gently encourage bleeding through the washing procedure. Do not apply bleach or any other caustic disinfectant to the area;
• If the exposure involved human blood, tissues, or other bodily fluids then follow the post exposure protocol;
• If warranted, medical help should be sought. A copy of the MSDS/PSDS should be provided to the medical personnel;
• Retrieve the biological spill kit containing all necessary cleaning supplies;
• If the spill involves organic matter that could interfere with disinfectant activity, the organic material should be removed and placed in a biohazard bag;
• Cover the area with paper towels or other absorbent material. Apply the appropriate disinfectant to the paper towels, starting at the perimeter and working towards the centre, saturating the area;
• Pick up any broken glass with forceps and place in a glass (or metal) sharps container. Place other waste in an appropriate biohazard autoclave bag; all adjacent areas must be wiped down with disinfectant to decontaminate the area;
• All clean-up materials should be placed in a biohazard bag and autoclaved. However, if bleach was used as a disinfectant in the clean up, materials cannot be immediately autoclaved. Please consult with Central Services about this issue;
• Immediately report the spill to the supervisor/lab manager. If the BHM is a human/zoonotic pathogen then the Biosafety Officer is to be contacted immediately;
• Complete and submit a UPEI Incident Report and Investigation Form. Complete a WCB form if the spill could lead to potential consequences to health.

All of the following questions must be completed:

1. Size of spill that laboratory staff can safely clean up is:
2. Location of biological spill kit/s in work area. Note: if the work is to be conducted in more than one location then specify each lab number and the location of the spill kit within that lab:
3. Name of disinfectant to be used:
4. Concentration of active ingredient in the disinfectant:
5. Contact time:

BIOSAFETY SPILL TEMPLATE: BIOLOGICAL MATERIAL SPILLS

Please note that PIs must complete the information at the end of this form and store one copy of the protocol in the spill kit for easy reference in the event of a spill.

• Staff must be aware of the procedures to be followed in the event of exposure or spill;
• Biological spill procedures are dependent on the type of biological agent involved;
• Ensure all procedures are specific for the type of agent that you are working with;
• Be prepared to handle a spill for the type and for the amount of biological agent used in your space;
• Refer to the appropriate SDS and/or PSDS when developing your procedures.

Immediate response to large spills:

Lab procedures should not generate volumes of biohazardous materials that cannot be easily contained and decontaminated by lab personnel. In the event that a spill involves volumes that cannot be contained and decontaminated by lab personnel then the following steps must be taken:
• Alert everyone in the area that there has been a biological spill and vacate the lab;
• Cordon off area with caution tape from the spill kit and/or use appropriate signage;
• Call UPEI Security at x0384 (902-566-0384); have SDS/PSDS available;
• Call 9-911; have MSDS/PSDS available;
• Immediately report the spill to the lab supervisor and to the UPEI Biosafety Officer at x5071 (902-620-5071);
• If eyes and/or mucous membranes have been exposed, wash or flush the exposed areas for 15 minutes at an eye wash/emergency shower station. If skin has been exposed wash with soap and water for 15 minutes. If skin has been punctured gently encourage bleeding through the washing procedure. Do not apply bleach or any other caustic disinfectant to the area;
• If warranted, medical help should be sought. A copy of the SDS/PSDS should be provided to the medical personnel;
• Within 24 hours of the spill, fill out and submit a UPEI Incident Report and Investigation Form and Workers Compensation Board (WCB) form if indicated.

For a spill that can be contained and decontaminated by lab personnel:

• Notify others in the lab;
• If an aerosol was generated, or that risk exists, hold your breath while immediately leaving the lab. Close the door and post a sign informing others not to enter due to a biological spill. Do not re-enter the lab for at least 30 minutes to give the aerosolized particles time to settle;
• Remove any contaminated PPE/clothing and put it in a biohazard bag to be decontaminated;
• If eyes and/or mucous membranes have been exposed, wash or flush the exposed areas for 15 minutes at an eye wash/emergency shower station. If skin has been exposed wash with soap and water for 15 minutes. If skin has been punctured gently encourage bleeding through the washing procedure. Do not apply bleach or any other caustic disinfectant to the area;

• If the exposure involved human blood, tissues, or other bodily fluids then follow the post exposure protocol;
• If warranted, medical help should be sought. A copy of the MSDS/PSDS should be provided to the medical personnel;
• Retrieve the biological spill kit containing all necessary cleaning supplies;
• If the spill involves organic matter that could interfere with disinfectant activity then the organic material should be removed and placed in a biohazard bag;
• Cover the area with paper towels or other absorbent material. Apply the appropriate disinfectant to the paper towels, starting at the perimeter and working towards the centre, saturating the area;
• Pick up any broken glass with forceps and place in a glass (or metal) sharps container. Place other waste in an appropriate biohazard autoclave bag; all adjacent areas must be wiped down with disinfectant to decontaminate the area;
• All clean-up materials should be placed in a biohazard bag and autoclaved. However, if bleach was used as a disinfectant in the cleanup then materials cannot be immediately autoclaved. Please consult with Central Services about this issue;
• Immediately report the spill to the supervisor/lab manager. If the BHM is a human/zoonotic pathogen then the Biosafety Officer is to be contacted immediately;
• Complete and submit a UPEI Incident Report and Investigation Form. Complete a WCB form if the spill could lead to potential consequences to health.

The following information must be provided:

1. Size of spill that laboratory staff can safely clean up is:
2. Location of biological spill kit/s in work area. Note: if the work is to be conducted in more than one location then specify each lab number and the location of the spill kit within that lab:
3. Name of disinfectant to be used:
4. Concentration of active ingredient in the disinfectant:
5. Contact time:
6. Identification of other PPE that will be worn in addition to regular PPE (if applicable):

BIOSAFETY SPILL TEMPLATE: BIOLOGICAL SAFETY CABINET (BSC)

Please note that PIs must complete the information at the end of this form and store one copy of the protocol in the spill kit for easy reference in the event of a spill.

- Staff must be aware of the procedures to be followed in the event of exposure or spill;
- The procedures to clean up spills in the BSC are dependent on the type of biological agent involved;
- Ensure all procedures are specific for the type of agent that you are working with;
- Be prepared to handle a spill for the type and for the amount of biological agent used in your space;
- Refer to the appropriate SDS and/or PSDS when developing your procedures.

Immediate response to spill within a BSC:

- Leave ventilation on;
- Remove gloves if they have become contaminated and replace them with new ones;
- Contaminated materials should be placed in a biohazard bag;
- Cover the spill with paper towels or other absorbent materials and flood area, starting at the perimeter;
- Use the disinfectant specified above for the appropriate contact time;
- If the spilled materials may have contaminated the drip tray and/or grills, then these areas must be decontaminated;
- Wipe down all working surfaces and items within the BSC with specified concentration of identified disinfectant for the indicated time. If bleach is used, then rinse with alcohol;
- All clean-up materials should be placed in a biohazard bag and autoclaved. However, if bleach was used as a disinfectant the cleanup materials cannot be immediately autoclaved. Please consult with Central Services about this issue;
- Let the BSC run for 15 minutes;
- Immediately report the spill to the supervisor/lab manager. If the BHM is a human/zoonotic pathogen then the Biosafety Officer is to be contacted immediately;
- If eyes and/or mucous membranes have been exposed, then wash or flush the exposed areas for 15 minutes at an eye wash/emergency shower station. If skin has been exposed then wash with soap and water for 15 minutes. If skin has been punctured then gently encourage bleeding through the washing procedure. Do not apply bleach or any other caustic disinfectant to the area;
- If the exposure involved human blood, tissues, or other bodily fluids then follow the post exposure protocol
- If warranted, medical help should be sought. A copy of the SDS/PSDS should be provided to the medical personnel;

Complete and submit a UPEI Incident Report and Investigation Form. Complete a WCB form if the spill could lead to potential consequences to one's health.

For a spill that can be contained and decontaminated by lab personnel:

• Notify others in the lab;
• If an aerosol was generated, or that risk exists, hold your breath while immediately leaving the lab. Close the door and post a sign informing others not to enter due to a biological spill. Do not re-enter the lab for at least 30 minutes to give the aerosolized particles time to settle;
• Remove any contaminated PPE/clothing and put it in a biohazard bag to be decontaminated;
• If eyes and/or mucous membranes have been exposed, then wash or flush the exposed areas for 15 minutes at an eye wash/emergency shower station. If skin has been exposed then wash with soap and water for 15 minutes. If skin has been punctured then gently encourage bleeding through the washing procedure. Do not apply bleach or any other caustic disinfectant to the area;
• If the exposure involved human blood, tissues, or other bodily fluids then follow the post exposure protocol;
• If warranted, medical help should be sought. A copy of the MSDS/PSDS should be provided to the medical personnel;
• Retrieve the biological spill kit containing all necessary cleaning supplies;
• If the spill involves organic matter that could interfere with disinfectant activity then the organic material should be removed and placed in a biohazard bag;
• Cover the area with paper towels or other absorbent material. Apply the appropriate disinfectant to the paper towels, starting at the perimeter and working towards the centre, saturating the area;
• Pick up any broken glass with forceps and place in a glass (or metal) sharps container. Place other waste in an appropriate biohazard autoclave bag; all adjacent areas must be wiped down with disinfectant to decontaminate the area;
• All clean-up materials should be placed in a biohazard bag and autoclaved. However, if bleach was used as a disinfectant in the cleanup then materials cannot be immediately autoclaved. Please consult with Central Services about this issue;
• Immediately report the spill to the supervisor/lab manager. If the BHM is a human/zoonotic pathogen then the Biosafety Officer is to be contacted immediately;
• Complete and submit a UPEI Incident Report and Investigation Form. Complete a WCB form if the spill could lead to potential consequences to health.

All of the following questions must be completed:

1. Size of spill that laboratory staff can safely clean up is:
2. Location of biological spill kit/s in work area. Note: if the work is to be conducted in more than one location then specify each lab number and the location of the spill kit within that lab:
3. Name of disinfectant to be used:
4. Concentration of active ingredient in the disinfectant:
5. Contact time:

BIOSAFETY SPILL KIT MINIMUM REQUIREMENTS

Spill kits should contain at least the following:

- Bucket, with lid can be used to store contents of spill kit (should be round and large enough to hold large biosafety bag for ease of clean up);
- Instructions for spill clean-up (copy from biosafety permit application);
- Gloves (appropriate sizes considering all who work in the lab; monitor expiry date of), goggles, face masks, plastic boot covers;
- Absorbent material (paper towels, absorbent pads, old bath and hand towels, etc.);
- Tongs/forceps for picking up broken glass and sharps, dust pan and brush;
- Caution/biohazard tape, sign to post on laboratory door in case of spill (Do Not Enter, Biological Spill);
- Duct tape, magnetic clips for attaching sign to door;
- Biohazard autoclave bags and clear autoclave bag for contaminated lab coats/clothing;
- Appropriate disinfectant (monitor shelf life).

PLAN FOR POST-EXPOSURE PROPHYLAXIS TO BLOODBORNE PATHOGENS AND/OR HUMAN PATHOGENS

1. In the case of accidental exposure remove all contaminated clothing and place it in a clear autoclavable biohazard bag. The bag of contaminated clothing should be submitted to Central Services for decontamination when you are able to do so.

2. Immediately notify your supervisor and BSO of the accidental exposure.

3. If accidental exposure occurs to:

- intact skin, wash the area thoroughly with soap and water for 15 minutes. Do not apply caustic disinfectants. A skin antiseptic can be applied.
- broken skin or in the event of a needle stick injury, gently encourage the area to bleed, and wash for 15 minutes with soap and water. Do not apply caustic disinfectants. A skin antiseptic can be applied.
- eyes, flush with water for 15 minutes
- mucosal surfaces, flush with water for 15 minutes.

4. If medical assessment is warranted, then proceed to the nearest hospital emergency as soon as possible.

- Inform the health care provider of the nature of your work and the specific pathogens/toxins involved;
- If the exposure involves a human/zoonotic pathogen for which medical help is sought then a copy of the Pathogen Safety Data Sheet should be taken to the health care facility with you;
- If the exposure involves a bloodborne pathogen (BBP) then the following steps should followed:
    - Medical attention must be sought immediately. Post exposure prophylaxis is best started within 2 hours of the exposure;
    - Inform the health care provider of your vaccination history and titre results as this information may be used to determine prophylactic treatment;
    - If possible, the sample involved in the exposure should be saved and safely transported with you to the hospital so that it is available for testing for the presence of the BBP.

5. Complete and submit a UPEI Incident Investigation report as soon as possible after the exposure and no later than 24 hours post exposure. If required, complete and submit a Workers Compensation Board report no later than 24 hours post exposure.

This form must be printed and included in your Lab Biosafety Manual. All lab staff must sign and date this form (below) to confirm that they have read and understood the above and agree to abide by the procedures outlined for post-exposure prophylaxis.

List of Lab Staff:

(The printed name, signature, and date of document review are required for each lab staff member)

BIOSAFETY RESUME TEMPLATE

Personnel Contact Information	
Name	
Department	
Phone Number	
Email address	
PI/Supervisor, if applicable	

Education and Experience	
Degree/s	
Position	
Years experience with biohazards	
List relevant biohazardous materials that you have used within the last five years. Include Risk Group, Containment Level and procedures used	

Training		
List biosafety training courses you attended in the last five years (date, location): (attach an additional document with this information if/as necessary)		
Date	Location	Course title

Please verify the following statements by adding an 'x' in the appropriate cell beside each statement.

YES	NO	NA	
			I have completed the UPEI WHMIS training
			I have attended the UPEI Biosafety/Biosecurity training (must be updated every three years)
			I have attended the UPEI Bloodborne Pathogen training (must be updated every five years)
			I have read the UPEI Biosafety Program Standard (available on the Biosafety website)
			I have read the UPEI Laboratory Safety Manual including the UPEI Waste Disposal Protocol
			I have read the UPEI Biosafety Policy (available on the Biosafety website)
			I have read the UPEI Medical Surveillance Plan for Research Involving Biohazardous Materials (available on the Biosafety website)
			I understand the routes of biological exposure and the methods of infection control
			I have read the Canadian Biosafety Standard (CBS) Second Edition
			I am aware of the Canadian Biosafety Handbook and I have read (or will read) the sections relevant to my work with biohazardous materials
			I am aware of the Human Pathogens and Toxins Act (HPTA)
			I have read the Containment Standards for Facilities Handling Aquatic Animal Pathogens (available on CFIA website)
			I have read the Containment Standards for Facilities Handling Plan Pests (available on CFIA website)
			I have completed interim biosafety training through online PHAC modules, as prescribed by the Biosafety Officer and the Institutional Biosafety Committee

I declare the above information is accurate and complete _____ *(yes)* _____ *(no)*

I have read, understood, and agree to comply with the above noted documents as well as the requirements set out by Federal regulators (PHAC, CFIA, ECCC, etc.)

Name:

Date:

Supervisor name (if applicable):

Date: