2019

BIOLOGICAL SAFETY MANUAL

Prepared by Environmental Health and Safety

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University Emergency Contact Numbers

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St. John's Campus	864 - 4100
Health Sciences Centre	864 - 4100
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Grenfell Campus	637- 2888
Ocean Sciences Centre CEP	9-911* 864-4100

* When utilizing 911, a follow-up call should be made to CEP or Security Services

Environmental Health and Safety

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Website: **http://www.mun.ca/health_safety/**

Acronyms

BSC	Biosafety Cabinet
BSM	Biological Safety Manual
BSO	Biological Safety Officer
BSOP	Biosafety Standard Operating Procedure
CBS	Canadian Biosafety Standards
CBSG	Canadian Biosafety Standards and Guidelines
CDC	Centre for Disease Control
CEP	Campus Enforcement and Patrol
CFIA	Canadian Food Inspection Agency
CL	Containment Level
CZ	Containment Zone
DGR	Dangerous Goods Regulations
EHS	Environmental Health and Safety
GMLP	Good Microbial Laboratory Practices
HAA	Health of Animals Act
HAR	Health of Animals Regulations
HEPA	High Efficiency Particulate Air
HPIR	Human Pathogen Importation Regulations
HPTA	Human Pathogens and Toxins Act
HPTR	Human Pathogens and Toxins Regulations
HSMS	Health and Safety Management System
IATA	International Air Transport Association
IBC	Institutional Biosafety Committee
ICAO	International Civil Aviation Organization
LAI	Laboratory Acquired Infection
LFH	Laminar Flow Hood
LRA	Local Risk Assessment
MUN	Memorial University of Newfoundland
NSF	National Sanitation Foundation
PHAC	Public Health Agency of Canada
PI	Principal Investigator
PPE	Personal Protective Equipment
PRD	Pathogen Regulation Directorate
RG	Risk Group
RNC	Royal Newfoundland Constabulary
TDGA	Transportation of Dangerous Goods Act
TDGR	Transportation of Dangerous Goods Regulations
TOR	Terms of Reference
UHSC	University Health and Safety Committee
WHMIS	Workplace Hazardous Materials Information System

1.0 Introduction

This biological safety manual (BSM) has been developed by Environmental Health and Safety (EHS), Memorial University of Newfoundland (MUN), with the approval of the Institutional Biosafety Committee (IBC). This manual is intended to provide information to minimize the risk to students and employees, as well as the surrounding environment, of exposure to biohazardous agents. This, indirectly, serves to protect experimental research by controlling the unwanted spread of contamination. This manual also provides information to promote compliance with all biosafety-related legislation.

It is the responsibility of the Principal Investigator (PI) to implement and adhere to the procedures outlined in this manual, as well as the applicable legislation. No experiment should be considered so important that it jeopardizes the health and safety of students and employees or contaminates the environment.

A biohazardous agent is a biologically-derived material that poses a health risk to humans, animals or plants. Research, teaching and other work-related activities that involve the handling or storage of biohazardous agents may have adverse impacts on faculty, staff, students, community, or environment. MUN has developed and implemented a program to manage these potentially harmful impacts. The main objectives of MUN's Biosafety Program are to:

i. Provide a formal risk assessment process to identify the level of risk associated with each biological material/agent and experimental procedure used.
ii. Advise on the mitigation of identified risks by assigning an appropriate level of containment with relevant hazard control measures.
iii. Ensure compliance with all biosafety-related legislation and guidelines, and funding agency requirements.

All work conducted by University members with potentially hazardous biological materials on University premises or under the control of the University is to be performed in accordance with the requirements of this manual.

2.0 Health and Safety Policy Statement

MUN strives to provide an incident and accident free environment. The University believes that health and safety is a shared responsibility but recognizes that the employer is ultimately responsible for the health and safety of all members of the University community.

The President ensures that a Health and Safety Management System (HSMS) is documented, implemented and maintained.

All members of the University community have an individual responsibility to integrate health and safety practices into their daily activities. Members of the University community are also required

to take reasonable care to protect their own health and safety and that of other persons at or near the workplace.

Every supervisor is responsible for fulfilling the requirements of the University's HSMS. They are also responsible for taking every reasonable precaution to protect and promote the health and safety of those workers under their supervision.

MUN cooperates with established health and safety committees, contractors, and members of the University community to ensure that the requirements of the Occupational Health and Safety (OHS) Act and the University's HSMS are fully implemented and integrated into all University work, study, and research activities.

3.0 Organization and Administration of Biosafety

3.1 Purpose and Scope

This BSM has been prepared for use by MUN personnel who work with biohazardous agents as defined in this manual. This manual is intended to provide guidance on biological safety (operational and containment requirements), legislative obligations and emergency protocols for activities involving the use of biohazardous agents at MUN.

MUN is licensed with the governing bodies, Public Health Agency of Canada (PHAC) under the Human Pathogens and Toxins Act (HPTA), and Canadian Food Inspection Agency (CFIA) under the Health of Animals Act (HAA) and must comply with all applicable biosafety-related legislation.

This manual applies to all members of the University community (including, but not limited to: faculty, staff and students) that receive, possess, use, store, transfer or dispose of biohazardous materials on University premises, or in a building or location administered by or under the control of the University.

3.2 Public Health Agency of Canada (PHAC)

The PHAC is the national authority on biosafety and biosecurity for human and most terrestrial animal pathogens and toxins (see exceptions under section 3.3). In 2009, the Human Pathogens and Toxins Act (HPTA) was passed to promote biosafety and biosecurity in Canada. The HPTA expands the PHAC's ability to reduce the risks posed by human pathogens and toxins by standardizing controls over activities involving these agents, whether they are imported or domestically acquired. Under the HPTA, the Human Pathogens and Toxins Regulations (HPTR) and Canadian Biosafety Standards (CBS), 2nd edition provide the framework for biosafety in Canada.

3.2.1 Laboratory Certification and Import/Export of Human/Terrestrial Animal Pathogens

Researchers who work with Risk Group (RG) 2 and above **human** and **most terrestrial animal pathogens** must demonstrate compliance with appropriate containment level (CL) physical containment requirements, as outlined in the CBS, prior to commencement of work. Importation of most terrestrial animal pathogen cultures (RG2 and above) falls within the scope of Memorial's Pathogen and Toxin License, issued by the PHAC. A separate import permit is not required for importation of human and most terrestrial animal pathogens under this license. However, the Biological Safety Officer (BSO) must approve requests for import/transfer prior to acquisition (by way of a completed Biohazardous Materials Transfer Request Form). In addition, all laboratories that work with the above mentioned biohazardous materials must be listed on a current Biosafety Certificate after successful inspection by MUN's BSO.

3.3 Canadian Food Inspection Agency (CFIA)

The Health of Animals Act (HAA), 1990, and the Health of Animal Regulations (HAR) give the CFIA the legislative authority to control the use of imported animal pathogens and pathogens associated with reportable animal diseases. These included materials of animal origin that contain potential pathogens. As of April 1, 2013, the PHAC became the sole Canadian agency involved with regulating most terrestrial animal pathogens. The CFIA, however, continues to issue import permits for **non-indigenous animal pathogens** (pathogens causing foreign and emerging animal diseases), **aquatic animal/invertebrate pathogens**, **animals** (including animal by-products, tissue, sera and blood that are infected with animal pathogens) and **plant pathogens**. The CFIA has produced a number of standards that must be followed by facilities that work with the biohazards identified above:

1. Containment Standards for Facilities Handling Aquatic Animal Pathogens – applies to facilities that handle aquatic animal pathogens, aquatic animal products and by-products or other substances that may carry an aquatic animal pathogen or part thereof. This document sets the minimum mandatory physical and operational requirements for facilities importing and/or working with aquatic animal pathogens or infectious materials.

2. Containment Standards for Facilities Handling Plant Pests - applies to facilities that work with plant pests other than weeds, soil, genetically modified plants and arthropod biological control agents. This document sets the minimum mandatory physical and operational requirements for facilities importing and/or working with plant pests.

3.3.1 Import/Export of CFIA-regulated Pathogens

Researchers requiring importation of RG2 and above materials regulated by the CFIA must have a valid import permit prior to importation. Import permit applications can be obtained from the CFIA by completing the application found at:

http://www.inspection.gc.ca/animals/biohazard-containment-and-safety/pathogen-imports/eng/1300215299626/1320599995275

All requests for importation of CFIA-regulated animal pathogens must be pre-approved (reviewed/signed) by MUN's BSO. All laboratories that work with the above mentioned biohazardous materials must be listed on a current Biosafety Certificate.

3.4 Canadian Biosafety Standards (CBS)

The PHAC in conjunction with the CFIA released the 1st edition of the Canadian Biosafety Standards and Guidelines (CBSG) in 2013. The CBSG provided a harmonized national standard for the handling and storing of **human and terrestrial animal pathogens and toxins** by Canadian laboratory researchers and workers. In addition to imported pathogens and toxins, the CBSG applied to any facility where human and/or terrestrial animal pathogens or toxins have been acquired domestically in accordance with the reasonable precautions provision of the HPTA. At the time, these standards and guidelines combined and updated (and replaced) the following documents:

- Laboratory Biosafety Guidelines 3rd Edition, 2004 (PHAC).
- Containment Standards for Veterinary Facilities 1st Edition, 1996 (CFIA).
- Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents, 2005 (CFIA).

The 2nd edition, Canadian Biosafety Standards was released in 2015 and updated the biosafety standards originally published in the CBSG. The Canadian Biosafety Handbook (CBH) is a companion document to the CBS in which the physical containment, operational practice, and performance and verification testing requirements are set out to ensure the safe handling and storing of human and terrestrial animal pathogens and toxins.

All research at MUN involving human and/or terrestrial animal pathogens/toxins must comply with all aspects of the CBS.

3.5 Institutional Biosafety Committee (IBC)

The University has established and shall maintain an IBC composed of members of the University community whose experience and training enable them to work with the biohazardous agents defined in this manual. The IBC shall report to the University Health and Safety Committee (UHSC) and has the following mandate:

1. Formulate and implement policies and procedures governing the use of biohazardous agents/materials.
2. Provide advice on the safe use and disposal of biohazardous materials/agents in all areas administered by or under the control of the University.
3. Review reports of inspections, audits, incidents and other relevant materials presented by the BSO. Make any recommendations deemed appropriate based on the information supplied in these reports.
4. Respond to biosafety issues that require immediate consultation.
5. Report periodically to the UHSC.
6. Approve and revoke internal biosafety certificates, as necessary.

7. Monitor and approve revisions to the BSM.
8. Act in accordance with the committees Terms of Reference (TOR).

3.6 Roles and Responsibilities for Biosafety

PHAC Pathogen and Toxin License Holder

The PHAC Pathogen and Toxin License Holder is a corporate officer for the University, and has the highest level of legal signing authority on behalf of the University. This person is ultimately responsible for all licensed activities at the University. The Vice President (Administration and Finance) is the License Holder for MUN.

Executive and Senior Management

The senior management of the University will ensure that adequate funds and resources are provided to run the biosafety program effectively. Furthermore, the senior management will provide support for biosafety in operations.

Although the ultimate responsibility for biosafety within the University and affiliated institutions lies with the President, information and concerns regarding biosafety are communicated through the UHSC.

The Vice President (Finance and Administration) appoints members to the IBC following recommendation by the IBC Chair, as outlined in the IBC TOR.

IBC

The IBC is responsible for development of all policy related to biosafety at MUN including, but not limited to:

1. Biosafety certificate approvals.
2. Import/export of biohazardous materials
3. Biosafety training.
4. Biohazardous waste disposal.
5. Environmental protection from biohazardous materials.

The IBC approves the use of all biohazardous materials at the University through the review/approval of internal biosafety certificates. The IBC is also responsible for monitoring the implementation of its policy as per the committee's TOR.

Department Chair

The department chair holds administrative responsibility for an individual academic/administrative department at MUN. The department chair shall:

1. Ensure the department's compliance with health and safety standards.
2. Ensure that biosafety-related issues are dealt with in a timely fashion.

Managers, Supervisors and Biosafety Certificate Holders

A supervisor is defined as any person who directs the work of others. These responsibilities extend to all corporations, contractors, onsite personnel, or research laboratories. Managers, supervisors, and biosafety certificate holders shall:

1. Ensure compliance with all biosafety legislation, policies and procedures as they are outlined in this BSM.
2. Report all incidents or concerns to the BSO.
3. Respond to inspection reports and ensure that any corrective actions required are implemented.
4. Ensure workers complete prescribed biosafety training prior to commencing work with biohazards.
5. Report any unresolved issue(s) to their Department Chair and the BSO.
6. Receive suggestions on changes and improvements to biosafety procedures and practices.
7. Ensure the availability of an appropriate biohazard spill kit and personal protective equipment (PPE) for personnel at all times.
8. Ensure that all hazards are adequately mitigated to ensure the safety of workers.

Laboratory workers (includes students)

All individuals that conduct their work within MUN-authorized biohazard laboratories (staff or students) are classified as “authorized workers”. Prior to authorization, workers must complete approved biosafety training and register as a biohazard worker with the BSO. Authorized workers shall:

1. Ensure that all applicable and prescribed safety training is completed prior to commencement of work, and that continual training is completed as necessary.
2. Comply with all safety-related directives given by their immediate supervisor and/or the BSO.
3. Register as an authorized worker by completing the Biohazard Worker Registration form and file it with the BSO. A copy, signed by the BSO, must be maintained with laboratory training records.
4. Follow all safety procedures and guidelines when working with biohazardous materials.
5. Read MUN’s BSM and Biosafety Standard Operating Procedures (BSOP) and follow the instructions contained within.
6. Notify their immediate supervisor of all incidents or concerns related to working with biohazardous materials.

BSO

The BSO is delegated the authority to apply for a specific biosafety license on behalf of the University (PHAC Pathogen and Toxin license). The BSO is the PHAC’s and CFIA’s contact and correspondent for all matters associated with the license and, unless otherwise specified, is the only person who can request changes to a license on behalf of the University. The BSO may exercise the powers and shall carry out the functions set out in the HPTR.

The BSO has the authority to suspend operations in cases where he or she perceives an immediate threat to health, safety, or the environment.

The BSO shall:

1. Act as contact and liaison with Governments, PHAC and CFIA regarding MUN's BSP.
2. Discharge all obligations of the position as set out in the laws and regulations of Canada.
3. Act as a point of contact for the IBC with respect to applications and approval of biosafety certificates.
4. Act as a point of contact for documentation from the IBC to biosafety certificate holders and other parties who may have requested information from the committee.
5. Develop and put in place a system to receive, record, evaluate and provide resolution to health and safety issues that arise from the use of biohazardous agents.
6. Take any other actions as directed by the IBC to ensure the integrity of the BSP.

Dangerous Situations

- Where an IBC member and/or the BSO becomes aware of imminent danger to life as a result of a biohazardous agent the IBC member and/or the BSO will:
  - Immediately take any actions necessary to ameliorate the imminent danger.
  - As soon as practical, inform the IBC of the situation and the action(s) taken. The IBC will review the situation and decide whether further action is required to nullify any remaining danger.
- Where an IBC member and/or the BSO becomes aware of a situation that contravenes MUN's biosafety program, policies and/or procedures, but does not present an imminent danger to life, the IBC member and/or the BSO will:
  - Review the situation and provide the details to the IBC. The IBC will review the situation and provide recommendations to the BSO. The BSO will ensure the recommendations are presented to the individual with authority for the situation, and:
    - ensure the corrections are carried out in a timely manner.
    - report to the IBC regarding the resolution of the situation.

4.0 Biosafety at MUN

For the purposes of MUN's BSP, a biologically hazardous material or agent ("biohazard") is defined as an organism or the component of an organism that poses a health risk to humans, animals or plants. The definition applies to, but is not limited by, the following list of biologically hazardous materials and agents. The list is obtained, in part, from Workplace Hazardous Materials Information System (WHMIS) Class D, Division 3, the Human Pathogens and Toxins Act and the Transportation of Dangerous Goods Regulations and includes:

- Viruses, fungi, parasites, bacteria.
- Toxic metabolite products of virus, fungi, parasites & bacteria (microbial toxins).
- Cell lines and other tissue culture.
- Unfixed tissues and tissue specimens from non-human primates and humans.
- Cells, blood and body fluids from non-human primates and humans.
- Nucleic acids derived from pathogens, human oncogenes, and transformed cell lines.
- Zoonotic agents.
- Genetically Modified Organisms (GMO), which includes genetically altered plants.

- Plant pathogens and pests (i.e. viruses, bacteria, nematodes, etc.).
- Prions.
- Wild animals, including cells, tissues and body fluids.

Where questions arise as to whether an organism or biological agent is defined as a biohazard, please consult the PHAC's CBS or Laboratory Biosafety and Biosecurity's web site or forward the questions to the BSO (mailto:bso@mun.ca).

4.1 Local Risk Assessment

Prior to commencing work with any biohazardous material, a robust Local Risk Assessment (LRA) must be documented in order to determine the appropriate CL and work procedures to be used (it should be noted that the CL is often, but not always the same as the RG of the biological hazards utilized). This LRA is documented as a part of the Biosafety Certificate application process (please refer to Section 5). A biohazardous LRA must incorporate the following:

1. **Biohazardous agent**: the **RG** of the biohazardous agent to be utilized must be determined. The RG for many biohazards has been determined (Pathogen Safety Data Sheets; PHAC ePathogen Risk Group Database or contact the BSO for more information). For agents where no documented RG is available, PHAC's Pathogen Classification System shall be used (see procedure below).

2. **Host**: The health/medical status of all individual(s) manipulating the biohazardous agent (i.e. workers) and the use of appropriate PPE play a role in the likelihood of exposure, that an exposure would cause illness, as well as the consequence of the illness to an individual. For biohazard work involving animals, this shall include personnel responsible for all aspects of animal handling.

3. **Environment**: the procedures utilizing biohazardous agents (experimental design) as well as the facility (engineering controls) affect the overall risk.

PHAC Pathogen Classification System

PHAC has based the classification of biohazardous agents on the impact that a pathogen has on the individual(s) manipulating the pathogen and on the general population. This risk classification ranges from RG1, including biohazardous agents with little or no risk to healthy individuals, to RG4, including biohazardous agents that pose a high risk to individuals and communities. **If the RG for your specific pathogen/toxin is unknown**, a Risk Assessment Matrix is available to aid in the risk classification of your biohazardous agent of interest, and **must be submitted with the biosafety certificate application**.

Health Canada bases the risk groupings on several risk factors including the following:

Pathogenicity/Virulence

- Pathogenicity is defined as the ability of a biohazardous agent to cause disease/illness. Virulence is the relative power and degree of pathogenicity possessed by organisms to produce disease. When examining the severity of the disease, biological agents that will cause death are considered to be the most pathogenic. The duration of the disease is also a factor. Microorganisms causing chronic illness often have a greater pathogenicity to those causing acute symptoms.

Route(s) of infection

- Route of infection is defined as the way the biological agent gains entry into a host. Typically, biological agents can infect a host through the following routes: airborne, ingestion, direct inoculation, mucous membrane and skin contact. This risk factor is a very important to consider as it helps determine the precautions that must be taken when the agent is being manipulated in the laboratory.

Mode of transmission

- The mode of transmission is the way that the pathogen travels to the host. This can include direct contact, indirect contact, aerosolized droplets, vectors, zoonosis, etc.

Ability to Spread/Communicability

- Communicability is the ease with which the pathogen can spread from one individual to another. Pathogens with limited ability to spread carry a lower risk than those that easily spread.

Stability/survival in the environment

- Stability/survival is the ability of the biological agent to remain biologically active when outside a host. Certain agents are able to remain infectious for days or weeks when left on the open bench, while other agents degrade and become inactive within minutes.

Infectious dose

- The infectious dose is the amount of a pathogen required to cause an infection in the host. Pathogens with low infectious dose therefore carry a higher risk as a few individual organisms can potentially cause infection.

Availability of effective preventative and therapeutic treatments (prophylaxis)

- The availability of vaccines, antibiotics, antivirals, etc., reduces the overall risk of working with specific biological agents as the likelihood of infection or the severity of infection can be minimized.

Host range

- The larger the range of potential hosts for a pathogen, the higher the risk involved.

Natural distribution (endemicity)

- The natural distribution of a pathogen affects its risk as pathogens with a natural local distribution would have a lower associated risk compared with non-indigenous pathogens.

Impact of introduction/release into the environment

- Environmental impact examines how the biological agent may affect the general environment if it is released. It is important to not only look at the agents that affect humans, but also those that affect plants and animals. The release of plant or animal pathogens could have both environment and economic detrimental consequences.

The complete set of criteria for classification is set out in PHAC's CBS.

Risk Group l (low individual and community risk)
A biological agent that is unlikely to cause disease in healthy workers or animals.

Risk Group 2 (moderate individual risk, limited community risk).
A pathogen that can cause human or animal disease, but under normal circumstances is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock or the environment. Laboratory exposures rarely cause infection leading to serious disease. Effective treatment and preventive measures are available and the risk of spread is limited.

Risk Group 3 (high individual risk, low community risk)
A pathogen that usually causes serious human or animal disease, or which can result in serious economic consequences but does not ordinarily spread by casual contact, from one individual to another, or that can be treated by antimicrobial or anti-parasitic agents.

Risk Group 4 (high individual risk, high community risk)
A pathogen that usually produces very serious human or animal disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact.

Risk Group (RG)	Containment Level (CL)	Laboratory Type	Laboratory Practices	Safety Equipment
1	Basic – CL1	Basic teaching, research	GMLP*	Project specific; open bench work
2	Basic – CL2	Primary health services; diagnostic, research	GMLP* plus protective clothing, biohazard sign, BSOP's	open bench plus BSC# for work with potential aerosols, large volumes, high concentrations
3%	CL3 (or CL2+&)	Special diagnostic, research	As Level 2 plus special clothing, controlled access, directional air flow	BSC and/or other primary devices for **all** activities
4^	CL4 (maximum containment)	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSC's, double-ended autoclave, filtered air

* GMLP – Good microbiological laboratory practices (see CBS for definition).
# BSC – Biosafety Cabinet
% RG 3 work requires PHAC/CFIA certification prior to work commencement.
& CL2+ - CL2 physical and operational requirements with additional operational requirements.
^ RG 4 work is prohibited at MUN.

4.2 Biosecurity

A biosecurity plan must be implemented to prevent theft, misuse or intentional release of pathogens and/or toxins, as well as unauthorized access to containment zones. The type of biosecurity plan that is created and implemented will depend on the nature of the containment zone, the type of research or diagnostics conducted (including locations for *in vivo* work) and the local environment. Personnel from varying levels of administration can be involved in the creation of the biosecurity plan. Key features of a biosecurity plan should include facility security, inventory of pathogens and emergency protocols for security incidents.

Facility security: In this part of the plan, strategies used to prevent the entry of unauthorized personnel and the theft of pathogens must be examined. For instance, access to pathogens must be restricted somehow (eg., kept under lock and key) and the containment zone must have specific security protocols in place to prevent the entry of unauthorized personnel (eg., key card access, identity badges, protocols for locking doors, etc.). Biosafety certificate holders are responsible for ensuring facility security measures are in place (as identified on their biosafety certificate application) and strictly followed at all times.

Inventory of Pathogens: A current (up to date) inventory of all biohazardous materials on hand and in long-term storage (more than 30 days) must be maintained by biosafety certificate holders. Depending on the risk associated with the pathogen or toxin, varying levels of information are necessary for the inventory (see section 5.1.3). Access to pathogens and/or toxins must be restricted to authorized laboratory personnel and a tracking system must be established in order to ensure accounting for materials and waste. Personnel who have access to pathogens/toxins must be documented and kept on file within the lab (**"authorized biohazard worker list"**).

Emergency Protocols for security incidents: In those cases where there have been unauthorized personnel entering the containment zone (including unauthorized MUN personnel and external contractors/vendors) or pathogen/toxin samples stolen, misused or intentionally released, the immediate supervisor (biosafety certificate holder) must be notified **first**. It is the responsibility of the biosafety certificate holder to report the incident via Memorial's Incident Management System (MIMS) or via the MUNSafe app as well as to the BSO directly. Depending on the nature of the security incident, the BSO may coordinate efforts with the CEP, RNC or representatives for PHAC/CFIA.

4.3 Laboratory Acquired Infections (LAI's)

Biohazardous materials can enter the body through various routes, including: inhalation, breaks in the skin, needle stick incidents, through mucus membranes, and ingestion. Exposure can happen during handling of tissues/cell cultures, specimens, and laboratory animals (including animal fluids/tissues and excrement).

Exposure to biohazardous materials can occur through the following: generation of aerosols during manipulations of organisms, spills and splashes, accidental injections, animal or arthropod bites, cuts from broken glassware or equipment, and centrifuge accidents.

Documentation of LAI's by the PHAC and the Centers for Disease Control (CDC) clearly demonstrates that the generation of aerosols during manipulation or through accidental generation poses the greatest threat to laboratory personnel. Therefore any procedure or manipulation that has the potential to create an aerosol or to impart energy into an aerosol causing it to spread shall be carried out in proper confinement (i.e., certified BSC).

The most successful means of reducing exposure to biohazard materials is through proper laboratory techniques.

As part of the exposure control process, upon completion of the manipulation of the biohazardous material an effective decontamination/disinfection program shall be carried out. The program will use a method or material proven effective in destroying the biohazardous material (see section 6).

Medical Surveillance Program

A medical surveillance program has been developed primarily to prevent potential LAI's, but also to provide a mechanism to detect and treat potential LAI's before serious injury or disease occurs. Prior to commencement of work with infectious materials and/or toxins, the biosafety certificate holder is responsible for informing the student/staff of the specific hazards associated with their work, including the symptoms of illness and any preventative measures available against the specific infectious materials and/or toxins to be used (i.e. vaccinations) including any risks/benefits associated with these treatment options. This is verified and documented in the declaration section of the **Biosafety Worker Registration form,** a copy of which must be forwarded to the BSO prior to the commencement of work (original is retained by the biosafety certificate holder).

Workers with either a known immunodeficiency disease, are taking immunosuppressive medications, are pregnant or who have open wounds that cannot be adequately covered (such as large burns or open stitches) may not be permitted to work in some laboratory environments depending on the condition and the infectious agent/toxin involved. This decision is made by the individuals supervisor after a thorough local risk assessment (LRA) has been completed.

Pregnant laboratory workers must self-identify themselves to their supervisors as early as possible. The biosafety certificate holder must conduct a LRA to determine whether changes to the scope of work are necessary to ensure the safety of the employee and developing foetus. This LRA must be relayed to the BSO.

Refer to the Canadian immunization guide for information on available vaccinations.

Post-exposure response

Following a definitive exposure to infectious materials or toxins (i.e. personal contamination, exposure to aerosols, needle-stick, etc.), three basic steps must be followed in order:

1. **Emergency first aid/Reporting** – If emergency first aid is required, it should take precedence over everything else. Contaminated clothing should be removed and both the exposed person and responding person should thoroughly wash and disinfect hands prior to first response.

If emergency first aid is not required, immediately inform your supervisor of the details of the exposure. The supervisor must complete an investigation and submit an accident/incident report outlining the details of the exposure (see Incident Reporting below).

2. **Medical testing/treatment** – As soon as possible, report to the emergency department of the closest local hospital for prescribed testing/treatment.

3. **Follow-up** – The BSO will follow up with the individual exposed and his/her supervisor to review the accident/incident report. During this follow-up, the root cause(s) of the exposure will be identified, and preventative measures put in place to minimize the likelihood of reoccurrence.

Incident Reporting

All work-related incidents, injuries or occupational diseases (including exposures to potentially infectious or intoxicating biohazards and potential or known LAI's) must be reported.

The initial report should go to your direct supervisor who, with your assistance, enters the information into Memorial's Incident Management System (MIMS) within 24 hours by following the link below:

http://www.mun.ca/MIMS/

MUN's BSO must be informed as soon as possible, as a condition of MUN's Human Pathogen and Toxin license.

Incidents can also be reported using the MUNSafe app. Please note that incidents requiring immediate response should be reported to Campus Enforcement and Patrol (864-4100).

5.0 Biohazardous Risk Management

Risk management as it relates to biosafety involves the use of administrative controls, engineering controls and PPE to safely manage risks pertaining to the use of biohazardous materials.

5.1 Administrative controls

Administrative controls are controls that dictate how work is performed, and includes policies and standard operating procedures.

5.1.1 Biosafety Certificate

A MUN biosafety certificate is required for all activities (research and teaching) that involve the use or manipulation of biohazardous agents, and materials containing such agents which are:

- **Conducted on University premises, or in a building or location administered by or under the control of the University,**
- **Undertaken by University personnel (staff or students), or**

- **Funded through University-administered funding.**

If the proposed work will involve the use of biohazardous materials in conjunction with animals, IBC approval must be obtained **prior** to IACC approval.

All laboratories where work involving biohazardous materials is proposed must be inspected by the BSO to ensure compliance with CBS requirements (and/or CFIA standards) prior to commencing work with biohazards.

Biosafety Certificate Application

The IBC must approve all activities involving biohazardous materials at MUN. Approval must be obtained from the IBC for all levels of biohazardous materials – including biohazardous materials classified as RG1. The IBC will determine whether the research program falls within the scope of MUN's BSP, the CBS or CFIA standards and approve the appropriate CL required for safe work. The BSO will inspect research facilities, confirm that safety equipment, including BSC's are functioning properly, and advise on the training required by the staff and students conducting the research. A biosafety certificate will be issued when all of the prescribed requirements have been met.

For new applicants, completed application forms, including the Biohazard Procedures Risk Assessment and Matrix for Assessment of Risk Group (the matrix is required only if the RG is unknown) must be forwarded to the BSO **AT LEAST SIXTY (60) DAYS PRIOR TO THE DATE APPROVAL IS REQUESTED**. The BSO will review applications for completeness and forward them to the IBC for approval. Non-MUN personnel wishing to work with biohazardous materials in MUN facilities must secure a MUN-affiliated collaborator or suitable insurance coverage (as determined through MUN's Enterprise Risk Management) before applications will be reviewed. All biosafety certificates are valid for a period of two (2) years. A valid biosafety certificate is required before the University will release funds for any grant that involves biohazards. A single biosafety certificate will be issued per researcher, and will include all projects/locations that utilize biological hazards. A current biosafety certificate must be available in each containment zone listed on the certificate. The biosafety certificate application form and Biohazard Procedures Risk Assessment template are available on the EHS - Biosafety website at:

http://www.mun.ca/health_safety/OHSMS/BSMS/BiosafetyCertificateApplicationp.php

Biosafety Certificate Amendment

If a principal investigator will make changes to their protocols, biohazardous materials and/or locations where biohazards will be used, an amendment to their biosafety certificate explaining the proposed changes must be approved by the IBC prior to commencement of work. The BSO may approve amendment requests involving personnel or authorized locations only. All other amendment applications will be reviewed by the IBC for approval.

Applications must be approved **before** changing experimental protocols, starting new research projects and before the expiration of the certificate. Biosafety certificate amendment application forms are available at:

http://www.mun.ca/health_safety/OHSMS/BSMS/BiosafetyCertificateApplicationp.php

Biosafety Certificate Renewal

Biosafety certificates renewals can be requested by completing a biosafety certificate application form (check the "renewal" box), including the Biohazard Procedures Risk Assessment and Matrix for Assessment of Risk Group (the matrix is required only if the RG is unknown) and forwarding to the BSO. **COMPLETE RENEWAL APPLICATIONS MUST BE RECEIVED BY THE BSO NO LATER THAN NINTY (90) DAYS PRIOR TO THE CURRENT CERTIFICATE'S EXPIRATION DATE.** MUN's Research Grants and Contract Services will suspend the release of biosafety-related funds once a certificate has expired.

5.1.2 Operational Practice Requirements

The operational requirements for handling biohazardous materials *in vitro* include those outlined in chapter 4 of the CBS (see Section 3.4) (or appropriate CFIA standard – see Section 3.3) as well as this BSM. These operational practices include training, PPE, work practices and emergency response planning.

In addition to the requirements of the CBS and CFIA standards, BSOP have been developed for a variety a biosafety issues at MUN, and are present as standalone documents that complement this manual. A list of current BSOP is available on the EHS>Biosafety website. Verification of compliance to the CBS operational practice requirements (and/or CFIA standards) and MUN BSOP will be verified during laboratory compliance inspections (see Section 5.1.6).

5.1.3 Biohazardous Materials Inventories

An up to date inventory of all biohazardous materials must be maintained and available for inspection at all times. For CL1 and CL2 facilities, the species and storage location [room number and location within the room (e.g. "freezer #1)] is required (for cell lines, also include the name of the cell line, and the RG of any viral, fungal or bacterial agents present). For CL2+ or CL3 facilities, additional inventory information, such as number of vials/samples and preparation date, is required (contact the BSO for more details).

Example of a basic biohazard inventory required for a CL1 or CL2 zone.

Infectious material/Toxin	Risk Group	Storage Location	Notes/Comments
Clostridium difficile	2	Rm. 217, Freezer #3	
Salmonella sp.	2	Rm. 229, Freezer #1	
Human cell line Raji (ATCC CCL-86)	2	Rm. 229, Freezer #1	Contains EBV
Botulinum neurotoxin	2	Rm. 217, Fridge #1	100 µg

Example of a basic biohazard inventory required for a CL2+/CL3 Zone

Infectious material/Toxin	Risk Group	Storage Location	Quantity	Notes/Comments
Bacillus anthracis	3	Room 303, Freezer #4, Shelf #1, Box #6	12 vials Prepared May 6, 2015	
Rabies virus	3	Room 303, LN2 storage #1, Cane #4, Box #6	23 vials Prepared Feb 23, 2013	
HIV-1	3	Room 217, LN2 storage #3, Cane #5, Box #2	15 vials Prepared Sep 28, 2014	Common storage area; freezer is locked (bring key)

5.1.4 Biosafety Training

All authorized personnel (faculty, staff and students) in laboratories where biohazardous materials are handled (CL 1-3) must have both **general** and **laboratory-specific** biosafety training. In addition, any work involving animals at MUN must have prior Animal Care Services approval:

http://www.mun.ca/research/about/acs/

General Biosafety Training – **All authorized personnel** in laboratories utilizing biohazardous materials must complete general biosafety training prior to commencement of work. This training covers introductory biosafety topics such as biosafety regulation in Canada, MUN's BSP and BSOP's, PPE, biosafety laboratory equipment and other relevant biosafety material. MUN's biosafety course is available online via Brightspace (D2L). General biosafety training must be refreshed every **five (5) years**. Proof of training, acknowledging successful completion of MUN's biosafety training course must be retained with in-lab biosafety records and documented on the individuals Biosafety Training Log.

Laboratory Specific Biosafety Training – Authorized workers in biohazard laboratories must receive laboratory-specific training on various aspects of the laboratory. This training must be provided by the **biosafety certificate holder** (or designated individual) and must include, at a minimum:

- identification of the hazards associated with mechanical (equipment) and operational (laboratory protocols) features of the work undertaken (including symptoms of disease caused by the infectious materials and the necessary precautions to prevent exposure),
- the correct operation of laboratory equipment,
- the design and operation of the containment zone and associated containment systems.

In additional, an annual review of emergency response procedures is required for all authorized workers (see below). Trainees must be accompanied by authorized workers until they complete all training requirements. All in-house biosafety training, whether mechanical or operational, must be documented in the Biosafety Training Log.

Annual Emergency Response Refresher – Annually, biosafety certificate holders (or designate) must provide refresher training on the applicable emergency response procedures at MUN to each authorized biohazard worker under their supervision. This should include (but is not limited to):

- a review of biohazard spill response;
- incident reporting requirements/procedures;
- location of safety showers/eyewash facilities and spill kits;
- emergency contact numbers, etc.

An ERP template is available and must be completed for each CZ authorized on a biosafety certificate.

Refresher training must be documented in the Biosafety Training Log and be available within the primary lab for inspection.

All training must be documented and made available for inspection. Proof of D2L biosafety training (e.g. grades or BSO-signed biohazard worker registration form) and Biosafety Training Logs (one per authorized biosafety worker) must be maintained in a laboratory biosafety records binder and made available for inspection at all times.

5.1.5 Biohazard Signage

The universal biohazard symbol is used to identify the presence of biohazardous materials. As such, all laboratories authorized to work with pathogens and/or toxins must display an EHS approved biosafety sign at **all entrances** to the containment zone (CZ). The biosafety sign must contain the **room number**, **biosafety certificate number**, **universal biohazard symbol**, **emergency contact information** and **requirements for entry**. A fillable Containment Zone (CZ) signage template is available. This must be filled with the relevant information and printed **IN COLOR**. It is the responsibility of the biosafety certificate holder to ensure that all locations authorized on the biosafety certificate are properly signed.

5.1.6 Compliance Enforcement

As a licensed institution under the HPTA and HAA, MUN is responsible for compliance to all applicable Federal biosafety legislation. The HPTR and HAR outlines the regulatory responsibilities under the HPTA and HAA as well as the authorities of the BSO, while the CBS, as well as the CFIA's "Containment Standards," describe the specific biosafety standards that must be in place. Internal biosafety certificate holders must ensure compliance with all biosafety-related legislation (see sections 3.2 – 3.4 of this manual).

Biosafety Enforcement

All authorized biohazard laboratories will be inspected by the BSO periodically. Additional inspections for higher risk locations may be required by the BSO. A compliance checklist provided by the BSO will be used. All items in non-compliance with the CBS, CFIA standard, license conditions or MUN biosafety procedural requirements will be categorized as incidents through

Memorial's Incident Management System (MIMS) according to Memorial's Hazard Identification and Risk Mitigation Health and Safety element. The university's Hazard Identification and Risk Management element includes a risk severity and scoring matrix that is used to determine the potential severity, very low to very high, of the non-compliances identified and the action required including timeframe to implement controls. It is the responsibility of the biosafety certificate holder to ensure that all incidents are satisfactorily addressed within the timeline given. The outcome of internal compliance inspections can impact the status of biosafety certificates, and as a result, funding release. Unresolved incidents shall be escalated to the University Health and Safety Committee (UHSC) and reported to the PHAC Pathogen and Toxin License Holder (Vice President Administration and Finance), if necessary, for final resolution.

While all individuals working in a laboratory associated with biohazardous materials are expected to carry out their work in a manner that is compliant with the terms of the biosafety certificate, oversight of compliance is a shared responsibility between biosafety certificate holder and Administrative Head of the unit where the biosafety certificate is held.

5.2 Engineering Controls

Engineering controls are built into the design of a containment zone to minimize the risk as they provide a line of defense when working with biohazardous materials. Engineering controls can include specific ways that the containment zone is designed, as well as specialized equipment used within the containment zone.

5.2.1 Physical Containment Requirements

The physical containment requirements for laboratories handling human and/or terrestrial animal pathogens/toxins are outlined in chapter 3 of the CBS. The containment level requirements include: structure and location, containment barrier, access, surface finishes and casework, air handling, facility services, and essential biosafety equipment.

Laboratories that handle aquatic animal pathogens or plant pests must satisfy the physical containment requirements outlined in the CFIA's Containment Standards for Facilities Handling Aquatic Animal Pathogens and Containment Standards for Facilities Handling Plant Pests, respectively (see Section 3.3).

MUN biosafety certificate holders are responsible for ensuring that their laboratories are in compliance with **all** relevant physical containment requirements prior to commencing work with biohazardous materials. Inspections will be conducted regularly to ensure that compliance is maintained (see Section 5.1.6).

5.2.2 Essential Laboratory Biosafety Equipment

Biological Safety Cabinet (BSC)

A BSC is a ventilated cabinet that uses a combination of high efficiency particulate air (HEPA) filtration, laminar air flow and containment to provide primary protection while working with

biohazardous material. When properly maintained and used in conjunction with good laboratory and/or animal facility handling techniques, BSC's are valuable tools used to minimize risk. BSC's are distinguished from a chemical fume hoods by the presence of HEPA filtration and the laminar nature of the air flow. BSC's are designed to provide primary containment during procedures that have the potential for aerosol production and/or use large volumes and/or high concentrations of pathogens/toxins. HEPA filters trap 99.97% of particles of 0.3 μm in diameter and 99.99% of particles of greater size. This enables the HEPA filter to effectively trap most known infectious microbes and ensure that only safe air is discharged from the cabinet. HEPA filtered air is directed over the work surface providing protection of work surface materials from contamination. Various classes of BSC, each with their own benefits and limitations are available (for detailed descriptions, see Ch. 11 of the CBS).

BSC Purchase, Installation, Testing and Certification

Only BSC's that meet the criteria of the National Sanitation Foundation (NSF) standard [NSF 49 Class II (laminar flow) Biosafety Cabinetry] and are NSF certified may be purchased. A listing of NSF Certified BSC's is accessible at the NSF website located at:

http://www.nsf.org/Certified/Biosafety

NSF/ANSI Standard 49 Class II (laminar flow) biosafety cabinetry applies to Class II BSC's, and is designed to minimize the hazards inherent in working with biohazardous materials assigned to biosafety CL's 1, 2, or 3. The standard defines the tests for which a cabinet must comply to become NSF Certified.

BSC's must be field tested and certified upon initial installation, annually and after any repairs/movement by an NSF accredited BSC certifier. Testing for Class II BSC's must be in accordance with NSF/ANSI 49. Requests for certification should be forwarded to the Department of Technical Services. An up to date certification sticker must be present on the BSC prior to use with biohazardous materials.

BSC's must be used for any work that has the potential to generate aerosols containing biohazardous materials, large volumes of biohazardous materials or highly concentrated solutions of biohazardous materials. Specific instructions will be determined during the biosafety certificate holders LRA. Please refer to **BSOP-04: Working with Biosafety Cabinets** for the complete protocol for working in a BSC.

Chemical Fume Hoods

Chemical fume hoods are containment devices similar in appearance to BSC's. Fume hoods are used to collect potentially harmful chemical gases, vapours, mists, aerosols and particulates generated during the manipulation of chemical substances. Fume hoods are **NOT** to be confused with BSC's and are **NOT** permitted for use with biohazardous materials as they provide no protection for the environment from potentially infectious aerosols. Additionally, some organic vapours can compromise the integrity of HEPA filters (refer to manufacturer's SDS). Therefore, if

such an event is known or suspected to have taken place, the HEPA filter should be tested and/or replaced before subsequent use.

Laminar Flow Hoods ("clean air" benches)

Laminar flow hoods (LFH's) are benches that provide a supply of clean (HEPA filtered) air to provide protection from contamination to the product/sample only. The LFH cannot be thought of as an engineering control as it does not provide protection for the environment or worker. As a result, any potentially infectious aerosols produced will lead to exposure of the operator and the environment. The discussion of the LFH is included here as it is a piece of equipment that works to maintain a sterile work environment and is often confused with a BSC. As with fume hoods, LFH's are **NOT** permitted for use with biohazardous materials.

Centrifuges

Centrifugation of materials creates the potential for aerosol generation (i.e. due to tube breakage, improper use of safety cups/rotors). When using a centrifuge with biohazardous materials, ensure to:

- Decontaminate the outside surface of cups/rotors.
- Use equipment according to manufacturer's specifications (i.e. balancing the rotor).
- Use thick-walled plastic centrifuge tubes (with exterior thread screw tops, if possible).
- Check the integrity of cup/rotor seals should be verified prior to use (if an LRA identifies the need to use sealed safety cups/rotors).
    - Sealed safety cups/rotors must be unloaded in a certified BSC.
- Allow time for potential aerosols to settle prior to opening cups/rotors.

Autoclaves

Autoclaves operate at high temperatures and high pressure to sterilize waste, equipment and products. The use of autoclaves is strictly limited to personnel trained in their operation and maintenance. Please refer to **BSOP-02: Autoclave Safe Use** for a detailed procedure for autoclave use.

Vacuum and aspirator apparatus

Aspirators connected to vacuum devices are often used during cell culture as media is routinely changed during cell growth. The primary concern with vacuum pumps is that the process of aspiration can cause the aerosolization of infectious material or toxins, and subsequent contamination of the vacuum line and pump. A device (e.g., in-line HEPA filters with an upstream hydrophobic filter and/or disinfectant traps) must be used to protect the vacuum from internal contamination.

Cryogenics and Liquid Nitrogen

Liquid nitrogen and other cryogens are liquefied gases that are cooled below room temperature. These are often used to store biological samples to prevent or slow down degradation. Liquid nitrogen poses two main dangers: freezing and suffocation.

With a boiling point of -196ºC, liquid nitrogen can instantaneously freeze exposed skin. Similarly, items in contact with liquid nitrogen can become extremely cold and thus become freezing hazards. Finally, some items become brittle after contact with liquid nitrogen and may shatter, creating a laceration hazard.

Because liquid nitrogen is heavier than air, it will displace air at ground level creating an asphyxiation hazard if ventilation is insufficient. Handling of liquid nitrogen should only be done in well ventilated areas.

Anyone working with liquid nitrogen or other cryogens must receive appropriate training prior to the commencement of work. Please refer to the ***cryogenic handling precautions*** outlined in MUN's Laboratory Safety Manual.

Mixing apparatuses/shakers/blenders

The operation of equipment capable of agitating, mixing, blending, etc. can generate biohazardous aerosols. If using this type of equipment with potentially infectious materials:

- Use laboratory or accessory equipment specifically designed to contain aerosols.
- If possible to do without disrupting the laminar airflow, use equipment within a certified BSC.
- Allow time for aerosols to settle before opening vessels or removing covers.

A Laboratory equipment and furniture release form must accompany all requests for equipment servicing.

5.3 Personal Protective Equipment

Personal Protective Equipment (PPE) is designed to protect the laboratory worker from exposure to biohazardous substances, as well as toxic and corrosive agents, excessive heat and other physical hazards. It must be emphasized, however, that PPE represents the last line of defence against exposure, with engineering and administrative controls being the primary and secondary lines of defense. Appropriate PPE is required whenever working with biohazardous materials or when otherwise instructed to according to conditions of the internal biosafety certificate, and must be supplied by the employer. Selection of appropriate PPE is based on the hazard(s) involved. Please refer to MUN's Laboratory Safety Manual and Radiation Safety Manual for specific instructions regarding the selection and use of PPE when working with chemical and radiation hazards, respectively.

Hand Protection

Appropriate gloves must be worn for all procedures that may involve direct or accidental contact with biohazardous materials. Gloves should wrap the cuff of your lab coat. Open wounds must be covered with waterproof dressings prior to applying gloves. Prior to exiting a BSC after procedures involving biohazards, gloves must be removed **inside** the BSC.

Hazard-specific hand protection must be utilized when necessary (i.e. puncture-resistant, heat/cold resistant, etc.).

General tips for use of hand protection:

- Verify that gloves are intact; inspect for rips/tears before use.
- Change gloves often if wearing for long periods of time.
- Never reuse disposable gloves. Dispose of used gloves in an appropriate waste receptacle prior to decontamination.
- Remove gloves and wash hands prior to exit from the containment zone.

Foot Protection

Only closed-toed, closed-heel shoes are allowed in laboratories authorized for work with biohazardous materials. Shoes should have no or low heels and be made from materials that are easily cleaned and decontaminated.

In areas where speciality footwear is required it must be of design, construction and material appropriate to the protection needed.

Safety footwear is designed to protect feet against a wide variety of injuries. Impact, compression, and puncture are the most common types of foot injury. Choose CSA approved footwear according to the hazard.

Eye/face Protection

CSA approved safety glasses/goggles/face shields are required for any work involving biological agents where there is a risk of eye injury (i.e. flying objects, splash, and aerosol generation). The choice of eye protection will depend on the risks from work being conducted and will be determined during the LRA. Face shields should be used to protect the nose, mouth and skin against splashes and spills.

Body Protection

Laboratory coats are used to protect street clothing against biological or chemical spills. Laboratory coats are mandatory when working with biohazardous materials in a laboratory. Lab coats are to be fastened closed while working and removed prior to exit from the containment zone.

Instructions for selection and use of protective laboratory clothing are as follows:

- Select knee-length laboratory coats with button or snap closures.
- Select laboratory coats that are composed of non-flammable materials, and fit snugly.
- Laboratory clothing should be kept clean and replaced when necessary. Lab coats must be effectively decontaminated (i.e. autoclaved) PRIOR to laundering.
- They type of laboratory coat (i.e. coat, smock, gown, full body suit, etc.) should be selected only after careful consideration of the specific hazard(s) and degree of protection required.
    - High-containment zones may require additional layers of protection based on the LRA.
- Lab coats are not to be worn in non-laboratory areas (i.e. outside of the containment zone).
- Lab coats must be stored separately from outside clothing within the laboratory.

Open legged clothing (i.e. shorts) is not permitted in labs where work with biohazardous materials is authorized.

Respiratory Protection

Respiratory protection may be required if there is a risk of exposure through inhalation of infectious aerosols, aerosolized toxins and/or allergens. The requirement for respiratory protection will be identified during the LRA and written as a condition of the biosafety certificate. Individuals requiring respiratory protection must complete respiratory protection training and fit testing prior to obtaining the appropriate respirator. For more information, contact the Technical Services.

Donning/Doffing

Donning and doffing of PPE should always be done in a manner that facilitates safe work within the containment zone. For containment zones where only lab coats and gloves are required, the following donning/doffing procedure shall be followed:

	Single Gloves and Lab Coat	Double Gloves and Lab Coat	
Donning Order (Descending)	▪ Lab coat (properly fastened) ▪ Gloves (fitted over cuffs of lab coat)	▪ Inner gloves ▪ Lab coat (properly fastened) ▪ Outer gloves (fitted over cuffs of lab coat)	**Doffing Order (Ascending)**

Canadian Biosafety Standards and Guidelines 1st Ed.

For containment zones requiring multiple layers of PPE, the donning/doffing procedure must be documented and strictly followed.

Considerations when doffing gloves are as follows:

- Gloves should be carefully removed by grasping the outside of the glove near the wrist with the opposite gloved hand and carefully peeling the glove off, turning it inside out.

- The removed glove should be held in the opposite gloved hand. A finger from the ungloved hand should slide under the wrist of the glove to peel it off from the inside, creating a bag for both gloves that is carefully discarded in a designated biohazardous waste container.
- Hands are then to be washed before leaving the containment zone.

Other considerations when doffing PPE:

- Gloves are removed after working in the BSC and should be discarded as biohazardous waste within the BSC. When a double layer of gloves is worn, it is the outermost layer of gloves that is removed prior to exiting the BSC.
- Gown should then be removed, remembering that the gown front and sleeves may be contaminated. The gown should be removed by unfastening the ties and peeling the gown away from the neck and shoulders, keeping the contaminated side away from the body and folding or rolling it into a bundle before discarding it in the designated waste container for decontamination.
- Protective footwear and/or shoe covers should be removed next and decontaminated, stored or discarded.
- Face shield and/or protective eyewear should then be removed, remembering that the outside of the eyepiece may be contaminated. These should be handled by the head band or ear pieces and pulled away from the face, then placed in a designated receptacle for decontamination.
- Mask or respirator can then be removed, remembering that the front of the mask may be contaminated. Masks are removed as per the manufacturer directions and precautions should be taken to avoid transfer of contamination from the outside of the mask. The mask is then discarded.
- Hair covers and protective headgear can be removed and discarded or decontaminated.
- Finally, the inner pair of gloves can be removed and discarded.

Always wash your hands following doffing of PPE.

6.0 Decontamination, Disinfection and Sterilization

It is a basic biosafety principle that all contaminated materials be decontaminated prior to disposal. Decontamination is the process by which materials and surfaces are rendered safe to handle and includes both sterilization (the complete destruction of all microorganisms, including bacterial spores) and disinfection (the destruction and removal of specific types of microorganisms). It is the responsibility of all laboratory workers to ensure the effective use of products for decontamination of materials, equipment, and samples from containment zones; of surfaces and rooms; and of spills of infectious materials. These procedures represent a critical containment barrier whereby failure in the decontamination procedure can result in occupational exposure to infectious agents and/or the unintentional release of agents from a containment facility.

All contaminated materials must be decontaminated before disposal or cleaning for reuse. The choice of method is determined by the nature of the material to be treated. This may include, but is not limited to, laboratory cultures, stocks and clinical specimens; laboratory equipment, sharps and protective clothing; and other items that have come into contact with infectious materials. Laboratory bench tops and surfaces are to be decontaminated after any spill of potentially infectious materials and at the end of the working day.

6.1 Disinfection Agents

6.1.1 Chemical Disinfectants

Chemical disinfectants are used for the decontamination of surfaces and equipment that cannot be autoclaved, such as specimen containers and other items removed from containment, and for clean-up of spills of infectious materials, rooms and animal cubicles, and a variety of other items for which heat treatment is not feasible. The initial choice of a chemical disinfectant depends upon the resistance of the microorganisms of concern. The most susceptible are vegetative bacteria, fungi and enveloped viruses. Mycobacteria and non-enveloped viruses are less susceptible; bacterial spores, protozoan cysts and prions are generally the most resistant. Consideration should also be given to practicability, stability, compatibility with materials and health hazards. Refer to **BSOP-03: Biohazard Decontamination and Spill Response**.

6.1.2 Thermal Decontamination

Autoclaves use high pressure and heat to effectively decontaminate most biological materials, provided that the autoclave conditions are appropriate for the loads treated. Autoclaves are generally used to sterilize laboratory equipment and experimental solutions, in addition to the decontamination of some types of biohazardous wastes prior to disposal. At MUN, use of autoclaves is strictly controlled and users must be sufficiently trained prior to operation. **BSOP-02: Autoclave Safe Use** has been developed and must be followed by anyone authorized to use autoclaves at MUN. All autoclaves must be certified biennially as per NL Regulations.

6.1.3 Incineration

Some materials are not sufficiently decontaminated with chemical or thermal methods and therefore must be incinerated. For a list of materials requiring incineration, see **BSOP-01: Management of Biohazardous Waste**. If you will require incineration of biohazardous materials, please contact the BSO as early as possible in the experimental design to arrange for this service. Biohazardous materials destined for incineration must be sealed in a leak-proof, impact-resistant container and the external surface must be chemically decontaminated prior to pick-up.

6.2 Biohazardous Waste Disposal

All contaminated materials must be effectively decontaminated prior to disposal. The method(s) of decontamination must be described during the LRA and approved by the IBC prior to implementation. **BSOP-01: Management of Biohazardous Waste** outlines the types of treatment

methods acceptable for various biohazardous materials and must be followed by anyone disposing of biohazardous waste at MUN.

6.3 Spill Response

All authorized workers in labs using biohazardous materials must be trained to adequately respond to biohazardous spills. In addition, a fully stocked biohazard spill kit must be present in all locations authorized for biohazard use. This spill kit should be regularly checked to verify that all contents are present, in good condition and not expired. **BSOP-03: Biohazard Decontamination and Spill Response** has been developed and outlines the steps involved in addressing a variety of spill scenarios. In addition, a generic spill kit contents list is provided. Individual laboratories should assess whether additional items are required in their kit(s) based on the types of biohazardous materials used in the laboratory. A copy of BSOP-03 should be posted in a prominent location within the laboratory for quick reference and/or within the spill kit(s).

7.0 Transport of Biohazardous Material

The **movement** and **transportation** of infectious material and toxins (or biological material suspected of containing them) is an essential part of routine laboratory procedures in both research and diagnostic settings. For the purpose of this biosafety manual, movement refers to the action of moving biohazardous materials within a containment zone or between containment zones within the same building (or adjacent buildings as long as public roads are not used), while transportation refers to the action of moving biohazardous materials between buildings or locations along public roadways or through airplane/ship transport (domestic or internationally). This distinction is required because the transportation of infectious substances falls under the Transportation of Dangerous Goods Act (TDGA), the Transportation of Dangerous Goods Regulations (TDGR), and the Dangerous Goods Regulations (DGR) issued by the International Air Transport Association (IATA). Please refer to **BSOP-04: Movement and Transport of Biohazardous Materials** for more information.

7.1 Movement of Biohazardous Materials

Whenever biohazardous materials are **moved** within or between containment zones (including the movement of biohazardous waste), good laboratory practices shall be implemented to prevent contamination and inadvertent spills. Procedures must be in place to prevent a leak, drop, spill, or similar event during the movement of infectious material or toxins within the containment zone, or between containment zones within the same building. Generally, the movement of samples containing biohazardous agents in labelled impact-resistant, leak-proof containers, in conjunction with a cart when necessary (i.e. multiple items) will help reduce the likelihood and severity of a spill. For movement between containment zones, a biohazard spill kit must be available at all times during transit.

7.2 Transportation of Biohazardous Materials

Biohazardous materials being transported, or being offered to a commercial carrier for transport, must be packaged and labelled in accordance with national and international regulations. These regulations provide details on the packaging, documentation and certification requirements that are designed to ensure the safe shipment of such materials in order to protect the public, shipping and receiving personnel, transportation workers, commercial carriers, and emergency responders.

7.2.1 Domestic Transport

The transport of biohazardous materials within Canada is governed by the TDGA and TDGR, which are administered by Transport Canada. Individuals who are required to transport biohazardous materials within Canada must have up to date TDG certification, which demonstrates proficiency in the labelling, packaging and documentation requirements outlined in the TDGR. All items transported by MUN personnel must be pre-approved (signed) by the BSO (see Section 7.3).

7.2.2 International Transport

The transport of biohazards internationally is governed by international regulations developed from the Recommendations on the Transport of Dangerous Goods (Model Regulations) by the United Nations (UN) Committee of Experts on the Transport of Dangerous Goods. Based on the UN Model Regulations, the International Civil Aviation Organization (ICAO) outlines the standards and requirements for the safe air transport of dangerous goods, including infectious substances, in the Technical Instructions for the Safe Transport of Dangerous Goods by Air. The ICAO Technical Instructions have been adopted by and apply in most countries worldwide, including Canada. The IATA, an international association representing 230 commercial airlines, issues the DGR annually. These regulations set forth the ICAO requirements for the safe packaging and transport of dangerous goods, including infectious substances, as they apply to the airline industry. As the majority of carriers (both passenger and courier/cargo) around the world are members of this organization, anyone shipping infectious substances internationally is subject to the IATA DGR and the ICAO requirements. Additionally, any shipment of biological material or infectious substances travelling within another country/territory may be subject to transportation regulations specific to the local jurisdiction.

7.2.3 Importation

Prior to importing any biohazardous materials, MUN's BSO must be informed, regardless of the risk group, the nature of the material, or its origin (condition of licensing). Anyone wishing to import RG2 or higher CFIA-regulated biohazardous agents may be required to obtain an import permit from the CFIA, which must accompany the materials during importation into Canada. Prior to obtaining an import permit, the biosafety certificate holder must demonstrate that their facility meets the physical containment requirements outlined in the applicable CFIA standard(s). The BSO will ensure that the facility meets these requirements through a biosafety inspection (see section 5.1.6) prior to approval. Applications for importation permits must be signed by the BSO.

Importation permits will only be issued in the name of the applicant (i.e. biosafety certificate holder), who remains legally responsible for the imported material.

7.3 Transfer Between Researchers

Movement and/or transport of biohazardous materials between researchers (either within MUN, domestically or internationally) requires assurance that the recipient's facility is compliant with the relevant physical containment requirements. To facilitate this, the transfer must be accompanied by a Biohazardous Agent Transfer Request form signed by the sender and recipient as well as both institutions BSO's.

Version History:

Version	Date	Author(s)	Notes
1.0	2009-06-01	EHS	First writing.
2.0	2015-10-01	Rod Hobbs	Revision of manual to include HPTR and CBS requirements.
2.1	2015-11-17	Rod Hobbs	Addition of IBC edits. Final approval.
2.2	2019-12-12	Rod Hobbs/IBC	Removal of links to repealed regulations and processes. Content update.