University of Lethbridge

UNIVERSITY OF LETHBRIDGE BIOSAFETY CODE OF PRACTICE

April 14, 2018

Contents

Acknowledgements

The University of Lethbridge extends a many thanks to the University of Alberta, the University of Sasatchewan, University of Manitoba and the University of Calgary for assistance with the preparation of this code of practice.

Please visit Safety Services Webpage for forms and other resources.

Ammendments:

December 19, 2019: change “Importation of Biological Material” to “Purchase/Transfer of Regulated Biological Material” page 29.

Section 1. Introduction

The leadership of the University of Lethbridge is committed to providing a safe and healthy workplace for its faculty, staff, and students and to ensure the protection of the community and the environment. This Biosafety Code of Practice (BCP) represents the institutional practices and procedures for the safe use and handling of biological materials, recombinant DNA and synthetic nucleic acids at the University of Lethbridge. This document is based on the latest government regulatory requirements, guidelines and current professional standards. The most up-to-date version of the BCP will be posted on the Campus Safety website.

This BCP is designed to inform the laboratory worker of good work practices and safe procedures. It also emphasizes the regulatory requirements that must be followed and the need for all related research and academic activities to be conducted in a safe and responsible manner.

The Biosafety Officer (BSO) in consultation with the Institutional Biosafety Committee (IBC), is responsible for monitoring individual Principal Investigators (PI) and laboratory facilities for adherence to the practices and procedures described in this Code of Practice. It is the responsibility of each PI to ensure that all research personnel in their research groups (e.g., undergraduate research assistants, graduate students, postdoctoral fellows, research associates, technicians, guest workers) are familiar with the contents of this Code of Practice and are trained to recognize potential risk and hazards prior to initiation of their work. Cooperation with the Institutional Biosafety Committee (IBC) and the BSO is essential for compliance with the regulatory requirements that the University research and teaching community must follow for the continued success of research and academic endeavors.

1.1 Regulatory Authority

On December 1, 2015, the *Human Pathogens and Toxins Regulations* (HPTR) came into force and the *Human Pathogens Importation Regulations* (HPIR) was repealed. Unless an institution is excluded or exempted, they are required to apply for a licence under the *Human Pathogens and Toxins Act* (HPTA) to conduct controlled activities (possessing, handling, using, producing, storing, permitting any person access, transferring, importing, exporting, releasing, abandoning, and disposing of a human pathogen or toxin). This licence requirement replaces the requirement to register under the HPTA. It should be noted that there is no fee for licensing activities under the HPTA (including applying for, amending, renewing, etc.).

The University of Lethbridge BCP has been revised in accordance with the requirements and guidance of the **Canadian Biosafety Standard, 2nd Edition (CBS) and Canadian Biosafety Handbook, 2nd Edition (CBH) (http://canadianbiosafetystandards.collaboration.gc.ca/index-eng.php)**

The Canadian Biosafety Standard (CBS), 2nd Edition, 2015, is a harmonized national standard for the handling or storing of human and terrestrial animal pathogens and toxins in Canada. Activities in Canada involving human and animal pathogens and toxins are regulated by the

Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) in accordance with the Human Pathogens and Toxins Act (HPTA), the Human Pathogens and Toxins Regulations (HPTR), the Health of Animals Act, and the Health of Animals Regulations.

The second edition of the CBS updates the biosafety standard originally published as Part I of the Canadian Biosafety Standards and Guidelines (CBSG), 1st Edition, 2013. The CBSG was developed to update and harmonize three existing Canadian biosafety standards and guidelines for the design, construction, and operation of facilities in which pathogens or toxins are handled or stored:

1. Human pathogens and toxins: Laboratory Biosafety Guidelines, 3rd Edition, 2004 (PHAC),
2. Terrestrial animal pathogens: Containment Standards for Veterinary Facilities, 1st Edition, 1996 (CFIA),
3. Prions: Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents, 1st Edition, 2005 (CFIA).

The CBS sets out the physical containment, operational practice, and performance and verification testing requirements for the safe handling or storing of human and terrestrial animal pathogens and toxins. The CBS updates many requirements to be more risk-, evidence-, and performance-based, as well as incorporating new information in the field of biocontainment engineering. In addition, the CBS includes several new requirements and information to support the full implementation of the HPTA and the HPTR. On December 1st, 2015, the HPTR came into force and the CBS came into effect and superseded the CBSG. The CBS is used by the PHAC and the CFIA to verify the ongoing compliance of regulated facilities with the applicable legislation. CBS will support licence applications, renewals, animal pathogen import permit applications, and, where applicable, the facility certification (and recertification) of containment zones. (Canadian Biosafety Standard, 2nd Edition, 2015)

The Guidelines originally published as Part II of the CBSG have also been updated and are published in the Canadian Biosafety Handbook (CBH), 2nd Edition, 2015, available upon request http://canadianbiosafetystandards.collaboration.gc.ca/index-eng.php. Printed copies will be available the spring of 2016. The CBH is a companion document to the CBS that provides core information and guidance as to how the biosafety and biosecurity requirements outlined in the CBS can be achieved. The CBH systematically addresses the concepts required for the development and maintenance of a comprehensive risk-based biosafety management program. In some instances, however, best practices or risk mitigation strategies other than those described in the CBH may also be acceptable to achieve the requirements of the CBS. (Canadian Biosafety Standard, 2nd Edition, 2015

The following federal regulatory bodies provide guidance and oversight for research and academic programs involving biohazardous agents:

- **Centre for Biosecurity**

Please contact PHAC.pathogens-pathogenes.ASPC@canada.ca for questions related to:

- Canadian Biosafety Standard and Handbook
- Biosafety Advisories, Directives, and Guidelines
- Compliance and Enforcement Policy
- Human Pathogens and Toxins Act and Regulations
- Newsletters and other communications
- Pathogen Safety Data Sheets, Risk Group and Risk Assessment
- Training
- Transportation of Dangerous Goods

Please contact PHAC.licence-permis.ASPC@canada.ca for questions related to:

- Biosecurity Portal
- Changes to Biological Safety Officer or Licence Holder
- Importation and Exportation, including Customs Issues
- Licences and Permits (Applications, Renewals, Variation of licence conditions)
- Please contact PHAC.biosafety-biosecurite.ASPC@canada.ca for questions related to:
- Inspections
- Compliance Documentation (Biosecurity Plans, Plans for Administrative Oversight, Local Risk Assessments, Performance and Verification Testing Reports)
- Biocontainment/Laboratory Design
- Incident Notification & Reporting

Any question not described above should be sent to: PHAC.pathogens-pathogenes.ASPC@canada.ca

- **The Canadian Food Inspection Agency (CFIA) http://www.inspection.gc.ca**
  CFIA issues permits for animal pathogens and toxins that are not indigenous to Canada (pathogens causing foreign animal and emerging animal diseases), aquatic and plant pathogens as well as for animals, animal products and by-products, tissue, sera and blood that are infected with animal pathogens. The CFIA Office of Biohazard Containment and Safety is responsible for issuing importation permits and compliance certification for facilities where these types of pathogens or toxins are handled or stored.

- **Environment Canada** http://www.ec.gc.ca/lcpe-cepa/
  Environment Canada administers the Canadian Environmental Protection Act (CEPA, 1999), which requires environmental and health assessments for substances and products of biotechnology that are not regulated by other Acts. CEPA empowers the Minister of the Environment to regulate the import and export of goods determined to be toxic to the environment, including genetically engineered organisms. The legislation protects both the environment and human health from potential harm by new substances that are the result of biotechnology, or are organisms that are non-indigenous to Canada.

- **Department of Foreign Affairs & International Trade (DFAIT)**
  http://www.international.gc.ca
  Through Trade Controls and Technical Barriers Bureau, DFAIT administers the Export and Import Permits Act (EIPA, 1985), which regulates trade in military and strategic goods, and confirms Canada's obligations under international treaties including those concerning biohazards such as:
  - World Health Organization International Health Regulations (2005) – A set of rules aimed at making the world more secure from threats to global health by governing key elements in the prevention, control and containment of infectious diseases.
  - Biological Toxin Weapons Convention (1972) – International convention banning the development, production, stockpiling, acquisition and retention of biological weapons.
  - United Nations (UN) Security Council Resolution 1540 (2004) – Adopted by UN members to prevent the development of weapons of mass destruction, including biological weapons.

- **Canadian Border Services Agency (CBSA)** http://www.cbsa-asfc.gc.ca

CBSA assists DFAIT with the administration of the EIPA and ensures that imports and exports arriving at Canadian points of entry comply with the provisions of the EIPA. The agency also ensures animal pathogens and toxins arriving at Canadian points of entry comply with the federal regulations.

- **Transport Canada** https://www.tc.gc.ca

Transport Canada administers the Transportation of Dangerous Goods (TDG) Regulations, including definitions for labeling, packaging and documentation requirements necessary for shipping infectious substances (including diagnostic specimens) within Canada, and requires that any individual packaging or transporting an infectious material or toxin be trained and certified. Transport Canada also ensures that international shipments of infectious and toxic

substances leaving Canada comply with the regulations of the International Civil Aviation Organization.

1.2 Roles and Responsibilities for Biosafety

1.2.1 Vice-President of Research

- Designated the *Licence Holder* for the University of Lethbridge in accordance with the requirements under the *Human Pathogens and Toxins Act (HPTA) and Regulations (HPTR)*.
- Responsible for ensuring compliance with biosafety related legislation and regulation.
- Ensures adequate resources are available to support the biosafety program and compliance with legal requirements.
- Takes reasonable precautions to protect public health and safety against the release of infectious material and toxins.
- Designates a BSO.

1.2.2 Biosafety Officer

- Administer, implement, monitor and ensure compliance of the Biosafety Program.
- Acts as point of contact for all University members for Biosafety issues.
- Is required to verify the accuracy and completeness of licence applications, communicate with the Minister on behalf of the University (licence holder) and report any non-compliance.
- The BSO has the authority to suspend any biological procedures which are considered unsafe, or that have the potential to cause harm to a member of the general public, or the environment.
- Investigates and reports to the Biosafety Committee any incidents which would result in contamination or exposure to personnel, or contamination to property.

1.2.3 Institutional Biosafety Committee (IBC)

- To make recommendations on activities and/or resources related to the use of biohazardous materials at the University of Lethbridge.
- Assist in developing and implementing a procedures manual specific to the activities conducted at the University of Lethbridge relating to the biosafety and biosecurity.
- Participate in regular reviews and updates of procedures manual as required.
- To assist in identifying and developing training needs.
- Provide assistance and guidance to all members of the University community, including but not limited to: faculty, staff, clinicians and students with respect to conducting biosafety risk assessments, and make recommendations following the analysis of the risk assessments.
- Review projects/protocols and issue biosafety permits for the use of all biohazardous materials to be used by research and academic personnel.

- Approves protocols involving the use of biohazardous materials.
- To approve applications for greenhouse or field trials requiring the use of biological agents and/or genetically modified organisms.
- To annually review procurement, storage, utilization, and disposal of all biohazardous materials at the University of Lethbridge.
- Assist in investigations and review reports of incidents/accidents related to biosafety and biosecurity and provide recommendations for corrective action.

1.2.4 Authorized Personnel working under the HPTA Licence

- Take reasonable precautions to protect public health and safety against the release of infectious material and toxins.
- Adhere to the requirements of the HPTA and HPTR.
- Comply with all conditions of internal biosafety permits.
- Notify the BSO of incidents that result in any inadvertent production, inadvertent release and exposure to disease, missing human pathogens or toxins, or gain of function.
- Not to obstruct the BSO from performing their duties.
- Notify BSO if any shipments do not arrive or arrive in poor/damaged condition.
- Adhere to transfer (import and export) requirements.

1.2.5 Researcher Code of Conduct

Note: *the* BSO *maintains the right to immediately stop any work practice or behavior that presents an immediate danger to personnel, infrastructure or the environment.*

The ability to conduct research on the University of Lethbridge campuses and with its support is a privilege that the University of Lethbridge extends to all of its research and teaching groups. In return, all staff, students and visitors are required to follow pertinent health and safety requirements in order to protect the community, environment, university's personnel, infrastructure, federal certifications and reputation. All members of U of L groups working with biohazardous agents who are expected to conduct independent research activities (including, but not limited to, the PI, research associates, technical staff, post-doctoral fellows, visiting scientists, graduate students, undergraduate students and summer students) must read and abide by the contents of this Code of Practice. This includes groups conducting clinical research as well as the Instructors and Teaching Assistants (TAs) for laboratory courses utilizing biohazardous agents as part of their curriculum. All personnel must document their reading and understanding of the Code of Practice in their group's training and orientation records.

If a U of L research group or personnel are found to be in noncompliance with Biosafety Code of Practice and its associated guidelines and procedures, a written notification of noncompliance from the IBC with recommended corrective actions will be issued.

The notification will describe the issues, expected remedial actions, and define a completion deadline. If the remedial actions are not complete by the deadline, the BSO will suspend the

Biosafety Permit and freeze the group's research funds. The Biosafety Permit and funding will not be reinstated until it has been demonstrated to the satisfaction of the BSO and the IBC that the non-compliance issues have been resolved.

U of L research group or personnel that repeatedly dismiss the contents of this Code of Practice and are found to be in noncompliance with the BCP and procedures could have their U of L Biosafety Permit suspended indefinitely.

1.3 Biosafety Office

The mandate of the Biosafety Office is to liaise between g the U of L research and academic community in order to facilitate a safe workplace, compliance with biosafety regulations, and to demonstrate the University's ability to meet these expectations in a transparent and concise manner. The BSO and members of the IBC are available to provide advice and consult on biohazardous agents, biosafety regulations, practices and equipment, and more general health and safety inquiries.

- **Biosafety Permits** – The University of Lethbridge requires that all individuals who intend to acquire, use, store, transport or dispose of organisms, biological materials or biohazardous materials obtain a biosafety permit. This includes work involving Risk Group 2 organisms or biological material.
    - *The use of Risk Group 3 and Risk Group 4 biohazardous materials **are not** permitted at the University of Lethbridge.*
- **Biosafety Approval of Research Projects** – The Office of Research and Innovation Services (ORIS) requires confirmation of biosafety approval in order to release funding for projects involving biohazardous agents. Similarly, ORIS requires a biosafety approval for any Human Ethics or Animal Ethics application involving biohazardous agents. The process to obtain a biosafety approval involves the BSO conducting a review of the experimental plan of the new project against the Biosafety Permit issued by the IBC for the research group. The review ensures that the group's resources, facility and operating procedures are suitable for the new work. Biosafety approval is specific to both the project and funding source; those research groups conducting multiple projects or receiving funds from multiple sources must apply for biosafety approval for each funding source and project.
- **Laboratory Safety Inspection** – The CBS requires regular inspection of all facilities handling or storing biohazardous agents. This inspection is conducted by the BSO and will also include chemical and radiation safety requirements, if applicable. The BSO will formally schedule inspections with the PI or lab supervisor. A copy of the inspection checklist can be found on the RSS website. A written summary of the laboratory inspection will be sent to the PI outlining the details of the inspection including any non-

compliance issues. The summary report will state remediation or corrective options and dates for resolution. The PI is responsible for providing written confirmation to BSO that the non-compliance has been corrected by the date and/or if not corrected a written reason why the deadline has not been meet. The IBC will also review all laboratory inspections.

- **Importation Permits** –Note that the Public Health Agency of Canada (PHAC) no longer issues import permits. This has been replaced by a licensing system under the Human Pathogens and Toxins Regulations. The BSO will assist U of L personnel in identifying and preparing the application documents for the acquisition of biohazardous material not regulated by HPTA.

- **Biological Safety Cabinet Certification** – CBS (5.1.5) states that biological safety cabinets (BSCs) must be certified in accordance with NSF International (NSF)/ANSI 49. In addition, cabinets must be gaseously decontaminated prior to being relocated, or before personnel may open the filter housings to conduct maintenance or repair. Cabinets must also be retested following relocation to ensure proper functioning. The annual BSC testing and decontamination services is managed by the BSO. The BSO will also provide guidance for the proper installation of BSCs.

- **Incident Investigation** – The BSO investigates incidents and near-misses involving biohazardous agents, and will make recommendations for remediation and prevention. Procedures for reporting incidents or near-misses to RSS, as well as incident and near-miss definitions, are available on the Campus Safety Services webpage.

- **Institutional Level Biosafety Training** – All U of L personnel must receive training specific to their work activities and the PI or supervisor must retain documentation of this training. Safety Services provides institutional level training courses for laboratory personnel, including Workplace Hazardous Materials Information System (WHMIS) Training, General Laboratory Safety, U of L Biosafety training and sites for online Biosafety Training. The RSS courses do not replace the requirement of site-and activity-specific orientation and training that PIs must provide to their staff and students.

Section 2. Biosecurity

A laboratory biosecurity plan should address the processes and procedures related to physical biosecurity, staff security, accountability and control, transportation and transfer security. It should also include incident and emergency response protocols, including instructions for first responders. Lastly, it is essential to train all personnel on security policies and procedures to help ensure correct implementation.

2.1 Biosecurity Plan

The complexity and level of detail of the biosecurity plan is generally consistent with the level of risk posed by the biological materials in question. The biosecurity plan is based on the outcome of the biosecurity risk assessment. A biosecurity plan addresses:

- Physical Security
- Personnel Management
- Inventory, transfers and transport security
- Incident and accident and emergency response
- Information security
- Training

The development of a biosecurity plan should be a collaborative process involving various staff members, including but not limited to: PIs, laboratory personnel, BSO, security personnel, operational staff.

2.1.1 Physical Security

The physical security element of a biosecurity plan seeks to reduce the risk of unauthorized access to sensitive materials through:

- Establishing boundaries/containment
- Access controls (locks)
- Intrusion detection
- Alarms

2.1.2 Personnel Management

Personnel management procedures must identify the roles and responsibilities of personnel who handle, use, store, possess, produce, transfer, dispose of, and transport pathogens or toxins. These procedures include:

- Establishing procedures for approving and granting visitor or student access to controlled areas,
- Implementing procedures for maintenance and cleaning personnel who have access to controlled areas.

Key to personnel management is the training/retraining of staff on the roles and procedures required to ensure proper implementation of biosecurity plan.

2.1.3 Inventory, Transfers and Transport

Good biosafety and biosecurity practices include adequately protecting and securing infectious materials against loss, theft, misuse, and release. Maintaining an up-to-date inventory of biohazardous material allows the PIs to track when material enters and leaves the laboratory. Inventories cannot account for each and every viable cell/virus particle; instead, they are based

on the number of containers and their location. The biosecurity issues related to inventory, transfers and transport can be addressed by the following activities.

a) Develop a detailed inventory and itemized records. Inventory control systems are common to any quality assurance program and are requirements in quality management system approaches.
    - Update inventory regularly to include new material.
    - Include transfers, inactivation, and disposal.
    - Include materials for a containment zone even if stored in locked storage equipment outside of the containment zone.
    - Include who has access to the materials and the area where the materials are stored/used.
    - Include documentation (e.g. letters of transfer, import permits, Pathogen Safety Data Sheets).
b) Implement controls to ensure that the materials remain where they are intended to be and are used by authorized personnel for the specified purpose.
    - Use physical controls (locks) and restricted areas.
    - Appropriate labelling is important, especially if the materials will be stored for extended periods of time.
    - Containment Level 2 laboratories may store biohazardous materials outside the containment zone provided materials are adequately secured; however, it is strongly recommended to store materials within the appropriate containment area if possible. Containment level materials stored outside of containment, must be in a labelled, leak-proof, and impact resistant container and kept in locked storage (e.g. freezer or refrigerator).
    - The movement and transportation of biological materials is an essential part of routine laboratory procedures. There needs to be accounting for pathogens throughout their shipment/movement to reducing the risk of theft and loss.
c) In the event of an inventory discrepancy, notification procedures need to be in place, as well as associated incident reporting.

2.1.4 Incident and Emergency Response

An incident is an event that could be the result of either an accident or of malicious intent that may or may not result in injury or harm, but has the potential to do so. Incidents include accidents as well as near misses and dangerous occurrences. Many types of incidents can occur in a laboratory or in an animal work environment, including:

- Inhalation
- Percutaneous inoculation (puncture, bites, needle stick)
- Mucous membrane exposure (contact from contaminated hands/surfaces)
- Ingestion

- Environmental release (e.g. improperly treated waste, containment failure)
- Biosecurity breach (e.g. theft, unauthorized individual deliberately or inadvertently accessing a restricted area, intentional misuse of an agent)

All staff, students and guest workers need to be trained to report all incidents to supervisor and complete a Campus Accident and Incident Report (CAIR). CAIR reports are directed to RSS for follow up and investigation. All incident investigations require the laboratory supervisor to participate in determining the cause and developing mitigation strategies to prevent the incident from occurring in the future.

2.1.5 Information Security

Information security policies protect sensitive information from unauthorized access and ensure adherence to the appropriate level of confidentiality. The protection of information should be consistent with the level of risk posed by the biological materials in question. Examples of information that might be considered sensitive:

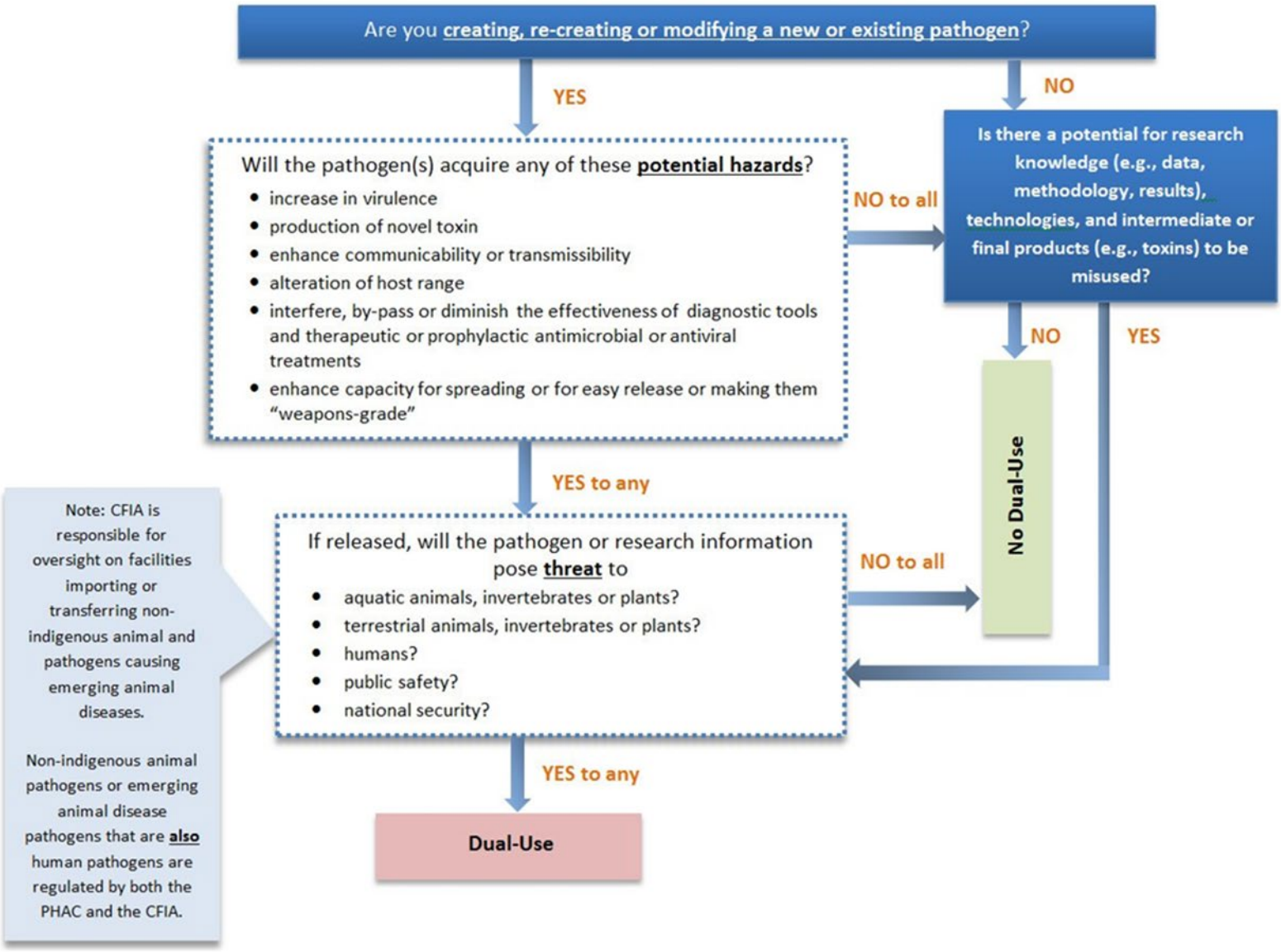
- Risk assessments
- Sensitive experimental protocols and results
- Facility design
- Personnel records and financial records
- Biological material inventories and storage locations

2.1.6 Potential Dual Use in Research

A key component to the hazard assessment is the identification of dual-use potential which all researchers are required to complete. Dual use potential is commonplace in life sciences research because reagents, experimental approaches and derived knowledge often have the potential to be misused and misapplied to obtain nefarious outcomes. A dual-use risk assessment, if done appropriately, should contribute to effective biosecurity oversight.

Faculty/Researchers will use the Public Health Agency of Canada flow chart below to assist with proper identification of dual-use. When research with dual-use potential is identified, it is important to assess the risk associated with the research. The general concepts of a risk assessment take into consideration the hazards identified, the likelihood that the hazard will occur, and the magnitude of the foreseeable consequences. A proper risk assessment should guide the selection of appropriate mitigation strategies to protect the research materials, tools, and information against potential theft, misuse, diversion, or intentional release.

When researchers apply for amendments or renew biosafety permits, they will be required to revisit the chart and indicate if the RG2 material or procedures would pose a potential dual use. This will complement the hazard identification process which is expected to occur when a new material is acquired or a new teaching or research program is initiated.



2.1.7 Training

Training underlies all aspects of the biosecurity plan. It should be provided to all those working in the laboratory, including maintenance and cleaning personnel, first-responders and staff responsible for the security of the facility. It should include:

- Rationale for the biosecurity measures
- Review of relevant national policies i.e. HPTA-(R)
- Institution-specific procedures
- Procedures describing the responsibilities and authority of personnel in the event of emergencies or security breaches

Training should include on-going communication skills development – it should not be a one-time event. Training is a good opportunity to refresh memory and learn new skills and strategies. Training also provides a venue for discussions and team building among staff members.

2.2 Specific Laboratory Biosecurity Plan

To secure their laboratory, research and teaching groups working with biohazardous agents must:

1. Establish procedures and/or SOP to ensure laboratory doors are locked when personnel are not on site. Keep laboratory doors closed. Doors may be temporarily propped open to allow personnel to move a cart or other items through the doorway but should not be left propped open for extended periods of time.
2. Lock fridges and freezers, containing archived biohazardous agents, located outside the common laboratory work areas.
3. Maintain inventory of biohazardous material.
4. Clearly define who has access to the inventory and inventory records.
5. Report missing stocks of biohazardous agents to PI. If investigation with PI fails to locate the missing stocks, a CAIR document must be filed immediately and the BSO contacted.
6. Ensure to account for all biohazardous material transferred or shipped.
7. Report suspicious behavior or unauthorized personnel loitering around laboratory spaces to Campus Security.
8. Report evidence of attempted forced entry to Campus Security.
9. Ensure laboratory keys are returned or access is removed from swipe cards when personnel leave the group or no longer require access to the area.

Section 3. Risk Groups, Containment Levels and Risk Assessments

CBS (4.1.8) requires all research and teaching groups working with biological agents to conduct a risk assessment of their planned activities prior to initiating work in order to determine if any of the material is considered a biohazardous agent.

When conducting a risk assessment for research or academic activities, the PI or supervisor is considered the "employer" of the group and is responsible for ensuring that risk and hazard assessments are conducted. All other personnel (technical staff, post-doctorate fellows, graduate students, summer students, undergraduate students, volunteers, visiting scientists, etc.) are considered workers and must cooperate with the PI/supervisor to ensure that the safety measures identified in the assessments are properly and consistently implemented.

3.1 Risk Groups

Risk group classifications categorize biological material based on inherent characteristics, including pathogenicity, risk of spread and availability of effective prophylactic and therapeutic treatments. Risk group categories identify the ability of the biological material to cause disease in humans and terrestrial animals. Each category is broken down into different levels. As the category levels increase, the danger posed by the biohazardous agents increases; in general, the seriousness of the disease caused by the agent increases as does its transmissibility from individuals to the greater community.

3.1.1 Risk Group 1 (RG1)

Risk Group 1 (RG1) biological material consists microorganism, nucleic acids, or proteins that are either unlikely or unable to cause humans and animal disease (low risk to individual worker, low risk to community).

3.1.2 Risk Group 2 (RG2)

A pathogen that can cause disease in a human and/or animal, but in normal laboratory circumstances is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures can cause disease, but treatments are readily available, and the risk of spread is limited (moderate risk to individual worker, low risk to community).

3.1.3 Risk Group 3 (RG3)

These pathogens usually cause serious human and/or animal disease or can result in serious economic consequences but do not ordinarily spread by casual contact from one individual to another, or cause diseases not readily treatable by antimicrobial or anti-parasitic agents (high risk to individual worker, low risk to community).

3.1.4 Risk Group 4 (RG4)

Any pathogen that produces very serious human and/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 (high risk to individual worker, high risk to community).

3.2 Containment Levels

Containment levels refers to the minimum physical containment and operational practices required for handling biological material, infectious material or toxins safely in laboratory and animal work environments.

3.2.1 Containment Level 1 Facilities

Containment 1 (CL1) is basically a laboratory designed for the safe handling and storing of RG1 biological material. Biosafety is achieved through physical design features and a basic level of operational practices, such as good microbiological laboratory practices. The CL1 zone can include work areas were RG1 biological materials are used: laboratory work areas, large scale production areas and animal work areas.

In Canada the handling and storage and activities involving RG2, RG3, and RG4 human pathogens and toxins are regulated under the HPTA and HPTR. Neither the HPTA nor the HPTR apply to RG1 biological material and do not apply to CL1 facilities.

The following are some basic design features for CL1 laboratories:

- Well designed and functional space
- Cleanable work surfaces
- Use of good microbiological practices*
- Conduct local risk assessment on activities to identify risk and develop safe work practices
- Provide training
- Use PPE appropriate for work being done
- Keep laboratory and animal work areas clean
- Maintain an effective rodent and insect control program
- Employ proper animal work practices
- Decontaminate work surfaces appropriately and in accordance with biological material in use.

(CBSG 1st Edition)

*Good Microbiological Laboratory Practices (GMLP) are the set of safe practices and techniques established in microbiology laboratories (*Please refer to Appendix for Guideline of GMLP*).

3.2.2 Containment Level 2 Facilities

CL2 builds upon the basic laboratory foundation established for CL1. Biosafety and biosecurity at CL2 are achieved through operational practices and a core subset of physical containment requirements that are proportional to the risks associated with the agents handled therein. Operational practices for CL2 include administrative controls (e.g., biosafety program management, training) and procedures (e.g., work practices, PPE use, decontamination) that mitigate the risks associated with the activities conducted within the zone. Physical containment features include facility design (e.g., location, surface finishes, access control) and biosafety equipment, such as primary containment devices (e.g., BSCs) for certain activities (CBSG 1st Edition).

CL2 is used for research involving RG2 biohazardous material affecting humans and terrestrial animals. The IBC has developed a *Biological Safety Checklist for CL2 Laboratory* (Appendix A). The checklist template is intended as a guide for determining if the facility meets the CBS physical and operational requirements for a CL2 laboratory. All personnel working in a CL2 facility must follow all applicable sections of this Code of Practice and CBS. An on-site inspection of CL2 facility will be conducted specifically by the BSO annually.

3.2.3 Containment Level 3 and Level 4 Facilities

At this time, work with organisms requiring Containment Level 3 (CL3) or Level 4 (CL4) facilities is prohibited at the University of Lethbridge; therefore, the IBC will not issue Biosafety Permits for work requiring CL3 and CL4 facilities.

3.3 Laboratory Containment Level and Risk Group

The containment level and risk group of the pathogen are generally the same (e.g., RG2 pathogens are handled at CL2), but there are some exceptions. As part of the local risk assessments (LRA) conducted by PIs/supervisor and IBC, the containment levels may change when the pathogen has been modified or the original conditions of use have changed. These changes reflect the risk mitigation strategies to address the specific modification of the pathogen or conditions of use. The following factors are considered when determining the specific physical and operational requirements for handling a pathogen:

- *Aerosol Generation*: Are equipment or procedures that may generate aerosols being used (e.g., pipetting, centrifugation, homogenization)? Personnel can be exposed to infectious aerosols by direct inhalation of aerosolized droplets or by ingestion of droplets that settle on surfaces or hands.
- *Quantity*: What quantity of pathogen is being manipulated, and in what format (e.g., one large vessel, multiple small vessels)? Large-scale processes (e.g., industrial fermentation, vaccine production) may have different containment requirements (i.e., higher) than laboratory scale work using the same pathogen.

- *Concentration of the Pathogen*: The concentration of the pathogen may vary depending on the work being performed (e.g., diagnostic specimens may contain a lower concentration of pathogen than pure cultures).
- *Type of Proposed Work*: What is the nature of the work (e.g., *in vitro*, *in vivo*, large scale)? For example, for *in vivo* work, the type of animal and the inherent risks associated with that animal need to be considered when determining the appropriate containment level.
- *Shedding* (specific to animals): The shedding of pathogens should be considered when working with infected animals. Pathogens may be present in the saliva, urine or feces, and may also be exhaled by the animal.

3.4 Risk Assessment Process for Biological Materials

3.4.1 Pathogen Risk Assessment

Agencies such as PHAC, CFIA and CDC (Center for Disease Control) have conducted pathogen risk assessments on well-characterized pathogens resulting in the development of Pathogen Safety Data Sheets (PSDSs) that are readily available on their respected websites. However, it is the responsibility of the PIs and/or researchers to conduct pathogen risk assessments on uncharacterized pathogens or pathogens that may have been modified. The BSO will assist individuals PIs in their pathogen risk assessments as necessary. The pathogen risk assessment characterizes the consequences and likelihood of exposure to infectious material, and categorizes the risks associated with a pathogen based on the close examination of the following risk factors:

- **Pathogenicity**: The ability of an organism to cause disease in humans, animals or plants.
- **Virulence**: The degree of pathogenicity determined by the invasiveness and toxicity of the organism.
- **Mode of Transmission**: The mechanism(s) by which an infectious agent is spread.
- **Infectious Dose**: The number of organisms required to initiate an infection.
- **Communicability**: The ease or difficulty with which direct transmission of the agent occurs.
- **Survivability**: The stability of the agent outside of its host.
- **Host Range**: The types of species a pathogen can infect.
- **Endemicity:** Is the pathogen found in or confined to a particular location, region or people. For example, malaria is endemic to tropical regions.
- **Economic/Public Health**: Impact of the agent on economic or public health interests.
- **Prophylaxis & Therapeutics**: Whether or not preventative measures and effective treatments are available against the pathogen.

The IBC will be responsible for the review of the pathogen risk assessment process. Pathogen risk assessments should be reviewed routinely and revised when necessary to take into consideration relevant new data and information from the scientific literature and changes to work intent and procedures.

Pathogen risk assessments are based on three key factors: science, policy, and expert judgment. Given that there is a qualitative component to a pathogen risk assessment, a consistent approach should be used when determining risk group. While most infectious material will clearly fall into one of the four risk groups outlined in section 3.1 above, in some cases, the level of risk associated with the different risk factors can vary dramatically within a risk assessment. As a result, certain risk factors may be considered more important when determining the final risk group. For example, if a pathogen is unlikely to cause disease in humans or animals, it may be irrelevant that it can survive in the environment for a long period of time or that there is no available treatment.

3.4.2 Other Components of Risk Assessment

Important details to consider during the risk assessment include, but are not limited to:

- **Volume of Agent Used**: If growing a microbial agent in single volumes of 10 litres or more, large-scale culture infrastructure and operational requirements are needed beyond the base containment level. The research group must contact the BSO for direct assistance with setting up large-scale culture facilities.
- **Degree of Agent Aerosolization**: Experimental activities, such as lyophilisation, tissue grinding, centrifugation and nebulization of biological material can release large amounts of aerosolized material, which can contaminate surfaces and increase the potential for transmission of the agent. See Section 7 for additional instructions to follow when using these types of equipment.
- **Use of Sharps:** The use of needles, scalpels and other sharps in conjunction with a biological agent can greatly increase the potential for exposure and transmission. See Section 7 for additional instructions to follow when using sharps.
- **Source of Agent:** If an animal, insect, invasive plant or pathogenic microbe is not indigenous to Alberta, escape from an Alberta research laboratory can have a huge negative impact on the province. Examples of agents include avian or swine influenza strains from Asia, pine beetles from British Columbia, and rats (Alberta is considered a rat-free province and any institution wishing to maintain rats must obtain a special license from the province).
- **Genetic Manipulations:** Any research group planning to conduct genetic manipulations of biological agents must review the reasonably expected outcomes of the manipulations and adjust their hazard assessment mitigations accordingly.
- **Use of Attenuated Strains:** Genetic manipulations can also create weakened or attenuated strains of the parent agent. Research groups may work with attenuated strains of infectious agents at a Containment Level below the level designated by the parent agent; however, the group must declare the attenuated strain to the BSO prior to initiating the work.
- **Diagnostic Specimens:** Analyses of diagnostic specimens for several types of Risk Group 3 pathogens may be conducted under CL2 conditions provided the analysis does not

involve amplification of the pathogen (i.e., through culturing). Consult the PSDS for the Risk Group 3 agent on the Public Health Agency of Canada website to see if CL2 diagnostic activities are allowed.

- **Location of Study**: Research groups are often required to obtain biohazardous agents from outside the laboratory. The environments outside the laboratory do not have a containment level and when working under these conditions additional administrative controls must be utilized to make up for the lack of engineering controls.
- **Environmental Release:** The intentional release of biohazardous agents, genetically modified organisms (GMOs) or plants with novel traits (PNTs) from a research facility is beyond the scope of this Code of Practice. Any research group planning an environmental release of such material must provide their hazard assessment to the IBC for review in advance of starting their project.

Where the contents of this Code of Practice do not provide complete instruction for a biohazardous agent identified in a research group's assessment, the group will must identify additional controls to implement in the risk assessment. Example controls applicable to mitigating biohazards are given in Table 3-1. If assistance is required, the group should contact the BSO.

Table 3-1. Mitigation controls that are applicable to working with biohazardous agents.

	Explanation & Examples
Elimination	*Eliminate the use of the biohazardous substance* • Rather than receive a whole biohazardous microbe from a collaborating laboratory, instead receive isolated nucleic acid or antigen preparation • Instead of using tissue specimens from wild caught animals, use tissues from a monitored animal colony • Do not bring live invasive plant, insect or animal species that are non-indigenous to Alberta back to the University campus
Substitution or Replacement	*Use a safer biological substance or a safer form of the biohazardous substance* • Use an a virulent or vaccine strain of a biohazardous microbe • Use a fourth or fifth generation viral-based vector system that can only transform cells if injected with a helper plasmid • Substitute a RG1 eukaryotic cell line for a RG2 cell line from the same species and cell type • Purchase aqueous preparations of microbial toxins rather than lyophilized preparations
Isolation	*Isolate the source of the biohazardous substance* • Transport sealed primary container of biohazardous substance in a secondary container on a cart; do not hand carry • Only handle open containers of biohazardous substance in a BSC or equivalent aerosol containment device • Use centrifuges with safety cups or rotors that can be loaded and emptied inside a BSC
Engineering	*Physical controls (such as infrastructure/equipment) that eliminate or reduce substances being produced; stop or contain substances; separate people or property from the substance by distance or barriers; or limit the area of contamination in the event of spills and leaks, and meet recommended technical and safety standards* • Design laboratories that are compatible with the containment standards necessary for the biohazardous substances to be employed • Set up culture of biohazardous microbes in a smaller side room rather than in the main laboratory (i.e., tissue culture room)

	• Equipment research wing with an autoclave so that biohazardous substances can be treated on site rather than being removed from the building or floor for treatment • Equip laboratory with suitable eyewash station • Use ventilated cage racks with high efficiency particulate air (HEPA) filters to contain animal allergens • Use single-use safety engineered needles when collecting human clinical blood specimens
Administrative	*Work methods employing best practice controls* • Correctly label biohazardous cultures and preparations • Safety Datasheets are available at site of storage and use • Ensure safe and properly organized interim storage of biohazardous waste • Develop effective laboratory work organization layout • Clean up bio-spills immediately • Immediately report all incidents and potential exposures to supervisor • Develop written safe work practices based on hazard assessment • Ensure working-alone processes are in place for after-hour and weekend activities • Control access to rooms where biohazardous substance is used or stored
Personal Protective Equipment (PPE)	***Protective clothing and equipment to be worn by all employees, supervisors, volunteers and visitors*** • Standard laboratory PPE ensemble of fully-fastened laboratory coat or gown, disposable gloves, safety glasses, closed-toe shoes and floor-length pants • Addition of respiratory protective equipment if working with a respiratory pathogen or allergenic biological substances

3.4.3 Clinical Specimens, Animal Tissues & Environmental Specimens

All biological research specimens acquired from the environment and brought into the laboratory for analysis, processing or storage must undergo a risk assessment. The history of the population or location of specimen collection must be reviewed to determine if there is a reasonable probability that a biohazardous agent is associated with the specimens. The following should be reviewed:

- All human clinical and body fluid specimens are considered RG2 agents regardless of their origin. There are numerous human pathogens that could be present in a donor specimen and no way to track in real-time the health status of the patient **(Appendix B: Working with Human Blood and Related Bodily Fluids*).***
- Categorization of animal tissue and body fluid specimens is dependent on the species and location of collection. For example, rodents are common vectors for a large number of human and animal pathogens, yet a blood specimen collected from a captive bred mouse can be considered much safer than a blood sample collected from a feral mouse caught in the wild. The first case could be considered a RG1 material while the second would be considered a RG2 material.
- Categorization of environmental specimens is dependent on the location of collection. If the location has a known history of association with an infectious disease (i.e., a river involved in repeated outbreaks of a waterborne illness) or show signs of contamination with suspect organic material (i.e., water collection immediately downstream of a sewage effluent pipe), the specimens are considered RG2 agents.

- For all epidemiological or ecological studies investigating the presence of a biohazardous agent, all animal, plant, insect, and environmental specimens collected for the study are considered RG2 agents.

3.4.4 Documentation and Monitoring

Keep a copy of the completed risk assessment together with the group's training material. New personnel must review and understand the risk assessment as part of their orientation and training. If sharing a laboratory space, exchange hazard assessments so that each group knows what the other is working with. Copies of a group's risk assessments must also be available upon request by Risk and Safety Services.

Risk assessments must be revisited, reviewed and updated over the course of a project. An assessment should be reviewed when:

- There is a substantial change to work procedures.
- Experimental plans are significantly altered.
- If conducting genetic manipulation experiments and results indicate a significant change in the properties of the GMOs or PNTs.
- New organisms or equipment, or specimens from a new population are introduced into the project.
- The project is expanded or moved to a new location
- With continuing projects, risk assessment should be reviewed annually.

Section 4. Biosafety Approval

4.1 Biosafety Permits

All PIs conducting research or training programs involving biohazardous agents, or storing biohazardous agents in their research facilities must apply for a Biosafety Permit. The Permit identifies the laboratory location, authorized personnel, biohazardous agents and general laboratory safety set-up, and provides the BSO with sufficient information about the PI's research plans to effectively liaise between the PI and federal regulators. To obtain a Biosafety Permit, a PI must complete and submit a New Biosafety Permit Application Form (Appendix C). The Biosafety Permit Application contains the following components:

4.1.1 Biosafety Plan

The PI is required to complete a Biosafety Plan. A Biosafety Plan is required for all and RG2 pathogens and toxins, biological materials, or other biohazardous materials. The biosafety permit holder is required to put into place appropriate safety measures to minimize health and safety risks from the use, storage, and disposal of biohazardous material. A Biosafety Plan template has been designed to assist biosafety permit applicants and permit holders develop a biosafety plan that is in compliance with the HPTA, HPTR, and the Canadian Food Inspection Agency (CFIA) Containment Standards for facilities and Occupational Health and Safety Regulations. The biosafety plan must be available to all authorized workers and should form

part of their health and safety training under the biosafety permit. The Biosafety Plan should be reviewed regularly, and updated accordingly to reflect changes in the work environment, new identified hazards, as well as changes to the biosafety permit. Biosafety Plan Template

4.1.2 Authorized Workers and Training Plans

All members of a research group working with biohazardous agents must be registered as Authorized Workers. Authorized Workers must have documented training plans indicating the training they have received based on the risk assessment. Training plans must be signed by both the PI and the worker. Names of all authorized workers including training documents are to be submitted with Biosafety Permit Application. The BSO needs to be updated of all changes for authorized workers.

4.1.3 Laboratory Containment Assessment

The BSO will complete an inspection of the laboratory to ensure that the containment requirements are meet for the specific work. The inspection will assess both the physical and operational work requirements to mitigate risks associated with the handling of biological material, human pathogens and toxins or other infectious material. The *Biological Safety Checklist for CL2 Laboratories* (Appendix A) will be used for the inspection of CL2 work areas.

4.1.4 Issuing of Biosafety Permit

Biosafety Permits are issued by the IBC for two years. Biosafety Permits will be issued with conditions **(Appendix: D Biosafety Permit Conditions)**. PIs are required to update their Permit as changes occur to their experimental plans, biohazardous agent inventories or group personnel. PIs will be notified by the BSO when it is time for renewal of their Permit and will be asked to complete a permit renewal form. PIs are asked to provide the requested information in a timely fashion in order to remain compliant with the U of L Biosafety Program. Whenever, the BSO updates a PI's permit, they will send a pdf copy of the permit to the PI for their records and to confirm the update was completed.

An up-to-date Biosafety Permit is also required to obtain Biosafety Approval to allow for the release of research funds from ORIS (Section 3.2).

4.1.5 Compliance

The BSO is authorized to conduct inspections and audits of permitted facilities and activities to ensure compliance with the Biosafety Code of Practice, and legislative and granting agency requirements. The permit holder is responsible for correcting any deficiencies identified during inspections and audits.

The University of Lethbridge will take specific and prompt action in order to enforce compliance with the terms and conditions of various licenses issued to the university, and also with the applicable federal and provincial statutes pertaining to the use, handling, storage, and disposal of hazardous agents.

Individuals failing to adhere to the requirements contained within the Biosafety Guidelines, university policies and legislative requirements, are subject to compliance enforcement up to and including suspension of privileges to work with organisms, biological materials, or biohazardous materials at the university.

When, in the opinion of the BSO, there is unacceptable risk to employees, the public, the environment, or university property, the BSO is authorized to take appropriate action which may include the immediate suspension of research activity, prohibited entry to a laboratory, and/or the removal of hazardous material from the premises.

Compliance enforcement related to biosafety permits shall be carried out in consultation with the IBC.

4.2 Biohazardous Agents and Activities Requiring Biosafety Permit

Written application must be made to the BSO and IBC for a Biosafety Permit if a U of L research or teaching group intends to work with or store any of the following biohazardous agents:

- **Pathogenic Microbes** – For the purposes of this Code of Practice, pathogenic microbes are defined as self-replicating organisms that can cause infectious disease in humans, animals or plants. Pathogenic microbes include bacteria, viruses, fungi, prions and eukaryotic parasites. Pathogen Safety Data Sheet (PSDS) available at the PHAC and CFIA websites describe many common pathogenic microbes and assign them to a biohazard risk group. All pathogenic microbes must be recorded in Biological Agent Inventory and the inventory submitted to the BSO annually. If the risk group designation for microbes stored or handled cannot be determined, contact the BSO for assistance.

- **Eukaryotic Cell Lines** – Many commercially-available eukaryotic cell lines of human or animal origin are considered risk group 2 (RG2) material due to presence of pathogenic viruses that infected the original cells prior to their immortalization, or that were used in the process to immortalize the cells. Commercial suppliers of eukaryotic cell lines provide Material Safety Data Sheet (MSDS) indicating the biohazard risk group status of their products. If a commercial supplier cannot provide an MSDS or if obtaining a cell line from a non-commercial source, contact the BSO for assistance. All cell lines must be recorded in Biological Agent Inventory and the inventory submitted to the BSO annually.

- **Biological Toxins & Venoms** –Biological toxins are defined as poisonous substances not capable of self-replication that are produced or derived from a microbe, plant, or animal, and which can cause an adverse health effect in humans and/or animals. This category includes but is not limited to lipopolysaccharides isolated and purified from Gram negative bacteria, as well as insect and animal venoms. All biological toxins must be recorded in Biological Agent Inventory and the inventory submitted to the BSO annually.

- **Human Clinical Specimens & Body Fluids** – There is no all-inclusive, real-time test to determine a person's health status; therefore, all research groups collecting, storing or working with human clinical specimens or body fluids must assume the specimens contain pathogenic microbes and must apply for a Biosafety Permit. This requirement includes tissue preparations used for primary cell cultures and human materials provided by commercial sources even if they have been screened against common human blood-borne pathogens. If stored for more than 30 days, clinical specimens or body fluids must be recorded in the Laboratory Biological Agent Inventory, which is submitted to the BSO annually.

- **Animal Tissue Specimens** – Similar to the situation with human clinical specimens, there is no all-inclusive, real-time test to determine an individual animal's health status. All research groups collecting, storing or working with animal tissue specimens or body fluids from wild animal populations or domestic species with no established health records must assume the specimens contain pathogenic microbes and must apply for a Biosafety Permit. This requirement includes insect and fish species but excludes captive animal colonies and livestock operations with established disease surveillance programs. If stored for more than 30 days, the animal tissue or body fluids must be recorded in the Laboratory Biological Agent Inventory, which is submitted to the BSO annually.

- **Genetically Modified Organisms (GMO)** – Recombinant DNA (rDNA) technologies can be used to modify microbes, insects, animals (i.e., transgenic animals) and plants (i.e., Plant with Novel Traits; PNT) for creation of GMOs. Research groups using rDNA technologies must be aware of the potential of these manipulations to increase the pathogenicity or infectivity of the host organism to humans, animals or plants, and to increase the vigor of the host organism in the environment. As a result, research groups must assess their planned genetic manipulations and determine if there is a reasonable expectation that their manipulations will result in the following:

    - Increase the virulence of pathogenic microbes or introduce virulence factors from pathogenic microbes into non-pathogenic organisms, this includes introducing the ability to produce active biological toxins in novel hosts,

    - Affect the pharmacological properties of the GMO (i.e., cause an increase in resistance to antibiotics, antivirals, insecticides, or herbicides used to control the host organism),

    - Delete genetic material or introduce novel genetic material with potentially adverse effects, such as the over-expression of oncogenes or cytokines, and,

    - Increase the host range, infectivity, or cell tropism of the recombinant organism.

  All GMO that fall under the HPTA must be recorded in Biological Agent Inventory and the inventory submitted to the BSO annually.

- **Viral-based Recombinant Vector Systems** – In addition to the above, research groups must have a Biosafety Permit to work with any recombinant or transformation vector system based on a lentiviral, retroviral, adenoviral, herpesviral or any other pathogenic viral backbone regardless of the generation of the system, or whether or not it is a commercially available product as many of these systems are still considered RG2 materials by PHAC and the CFIA. All vectors must be recorded in the Biological Agent Inventory and the inventory submitted to the BSO annually.

- **Infectious RNA** – Purified positive-sense viral RNA is capable of causing infection and subsequent generation of complete, functional virus particles in host cells. All research groups working with or storing purified genetic material from positive-sense RNA viruses must have a Biosafety Permit for these activities

- **Large-Scale Culture** – Due to the increased possibility of environmental release, all culturing of microbial agents or eukaryotic cell lines if the culture vessel or fermenter has a volume of greater than 10 litres.

- **Non-Indigenous Plant, Insect or Animal Species** – The release of a non-indigenous organism into the environment could have serious human or animal health, environmental and/or economic impacts. Research groups planning to receive and house living specimens of plant, insect or animal species not indigenous to Alberta must be issued a Biosafety Permit for this work.

4.3 Biosafety Approval for Release of Funds

All U of L PIs, students or fellows that are applying for funding for a research project involving a biohazardous agent must have an issued Biosafety Permit from the IBC. Funding for such grants will only be released by Office of Research and Innovation Services (ORIS) upon confirmation of Biosafety Permit. Subsequent renewal or extension of these awards will also require the review of the Biosafety Permit by the BSO and/or IBC. Submissions will not be processed until an up-to-date Permit is issued.

In addition, the Research Ethics Office requires a Biosafety Approval for any Human or Animal Ethics application they receive involving biohazardous agents. When a PI submits an ethics application and declares the presence of a biohazardous agent, the ORIS office will forward the information to the BSO and/or IBC for review. No further action is required by the PI, other than to ensure their Biosafety Permit is up to date.

For more information regarding the biohazards approval process, please contact BSO.

Section 5. Purchase/Transfer of Regulated Biological Material

- As of December 1, 2015, import permits for human pathogen and toxins will not be required from PHAC. To purchase Regulated Biological Material complete the **U of L Regulated Biological Material Request form** (Campus Safety Services webpage). The

BSO will review the form to ensure compliance to the HPTA and HPTR and will need to sign off on the purchase. For importation of Aquatic and Plant Pathogen and Foreign Disease Animal pathogens and/or Animal Tissue contact the BSO for assistance.

- The transfer in/out of Regulated Biological Material between domestic institutions complete and submit to the Biosafety Officer **Regulated biological Material transfer Notification form.**

- The transfer in/out of Regulated Biological Material between international institutions contact the Biosafety Officer.

Section 6. Laboratory Administrative Procedures

All research and teaching groups working with or storing biohazardous agents must adhere to the laboratory administrative procedures described in this chapter in order to remain compliant with the U of L biosafety program. Many of these administrative procedures are not specific to biohazardous agents but are required for groups to demonstrate their due diligence by mitigating all hazards present in their work space, meeting professional and legal standards, and facilitating communication with neighboring research groups and support personnel.

6.1 Laboratory Hazard Signage

The Canadian Biosafety Standard (CBS 4.5.8) requires current entry requirements to be posted at point(s) of entry to the containment zone. Biohazard warning signage must include the international biohazard warning symbol, containment level, name and telephone numbers of a contact person, and entry requirements (Figure 6.1). The sign may be further supplemented with additional requirements for entry, a list of relevant processes and primary containment equipment used in large scale production areas, or information on other hazards (e.g., fire, chemical, radioactive) present in the containment zone.

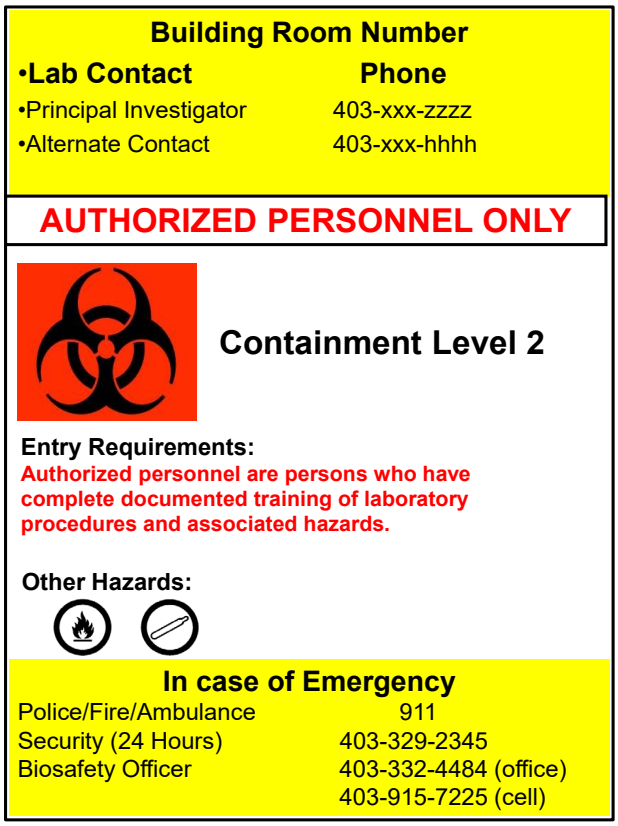


Figure 6-1: Example of biohazard warning signage found at the points of entry to a containment zone (CBSG Part II - Guidelines Appendix A-Supplemental Figures).

6.2 Training Program (CBS 4.3)

Training is a core element of biosafety and biosecurity, and is essential to the success of the biosafety program. It is critical that personnel be knowledgeable about the hazards associated with the pathogens and toxins present in the work environment and the practices and tools that can protect them from these hazards. The training program encompasses both education (i.e., theoretical) and training (i.e., practical). There are several goals for training:

- Safety for the individual taking the training.
- Protection of other personnel sharing the work space with the individual.
- Protection of the work space, equipment housed there and the surrounding environment.

The training and orientation requirements described in this section are considered a minimum for any U of L personnel (including PIs, technical staff, research associates, post-doctoral fellows, graduate students, visiting scientists and volunteers) directly handling biohazardous agents for research or teaching programs. The training and orientation should be completed prior to an individual initiating work with biohazardous agents. Additional

training is required if personnel will also be handling chemical or radiation hazards. The online courses are offered at no cost to U of L employees and students.

Note the online courses detailed below are for personnel who will be conducting independent work with hazardous materials. Summer students and volunteers under the age of 18 are considered minors and may not conduct independent, unsupervised work with hazardous materials in U of L laboratories. Minors must work under the direct supervision of qualified and trained laboratory personnel at all times.

For teaching laboratories utilizing biohazardous agents, Instructors and Teaching Assistants (TAs) must receive the indicated training and orientation. Laboratory instructors and TAs may decide that all students in the laboratory require this training.

- **Workplace Hazardous Materials Information System Training** - The Alberta Occupational Health and Safety Code requires that employers provide Workplace Hazardous Materials Information System (WHMIS) training to all workers who work with or in proximity to hazardous materials. WHMIS training consists of two parts: generic definition training and work-site specific training. RSS has developed an online WHMIS course to cover the generic portion of WHMIS training while the PI is expected to cover the work-site specific training. The online course can be accessed Campus Safety Services webpage.

- **Laboratory Safety Course** – In progress
- **Concepts in Biosafety Course** – In progress
- **Laboratory-Specific Orientation & Training** - Under the HTPA, HPTR, AB OHS Act and WHMIS legislation and each PI is responsible for training all group personnel in the operational procedures and protocols they have developed for their laboratory facilities and research program. Laboratory-Specific Orientation and Training covers such topics as: hazards associated with the work, location and storage procedures for hazardous materials, signs and symptoms of disease, location of safety equipment, evacuation routes, location of laboratory protocols and training materials, waste procedures and the safe operation of laboratory equipment. This information is highly specific to the individual location and research program and can only be provided by the PI; the RSS online courses detailed above are not to be considered an equivalent substitute for this orientation and training. Laboratory-Specific Orientation and Training must be documented with both the PI and individual workers keeping copies of the completed documentation. RSS offers a template, Laboratory Specific Safety Training, which may be used by PIs as a starting point.

- **Working Alone Procedure** - The Government of Alberta has enacted legislation intended to protect individuals who work alone. All U of L research and teaching groups that require personnel to work alone, particularly outside of regular work hours, must have a written Working Alone Procedure. In developing a working alone procedure please refer

to the Working Alone Policy (currently under review) and visit Campus Safety webpage http://www.uleth.ca/security/working-alone to access the Campus Working Alone Login.

6.3 Pathogen Safety Data Sheets & Material Safety Data Sheets

A Pathogen Safety Data Sheet (PSDS) is a technical document that describes the hazardous properties of pathogens and recommendations for their safe handling. A PSDS includes information such as pathogenicity, drug susceptibility, first aid treatment, PPE, and risk group classification. PSDSs for common human and animal pathogens can be found at the http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php. There is also a **PSDS App** including all of the content currently available online in a format that is compatible with your mobile device.

For other types of biohazardous agents, such as biological toxins, eukaryotic cell lines or human clinical products, a PSDS is not applicable but a similar Material Safety Data Sheet (MSDS) can be obtained from a commercial supplier. For each biohazardous agent handled or stored in the laboratory, a research group should have a paper or electronic copy of the applicable PSDS or MSDS available for personnel to read as part of their Laboratory-Specific Orientation and Training (Section 3.3.4). If a PSDS or MSDS cannot be found for a biohazardous agent, one will have to be developed by the research group. Please contact the BSO if assistance is required in finding or developing a PSDS or MSDS.

6.4 Research-Specific Protocols

U of L research and teaching groups must maintain their own research-specific protocols. In order to maintain consistency throughout the laboratory, these protocols should be centrally located within the laboratory and accessible to all personnel. These protocols must include all pertinent safety information, identifying any microbial, chemical and other potential hazards involved in the protocol. All personnel in the laboratory must be familiar with the location of these protocols and must have read and understood all protocols pertinent to their work activities prior to initiating the activity.

6.5 Inventory of Biohazardous Agents

The inventory requirement is established in the Canadian Biosafety Standard. A key element of biohazardous agent accountability is the physical inventory. Developing and reviewing an inventory ensures that all biohazardous material, pathogens and toxins are captured in records and all are accounted for in the inventory. Since it can take a great deal of effort to thoroughly review and accurately update an inventory, one may ask: How often should a laboratory verify pathogen and toxin inventory? In general, it is recommended that an inventory verification is performed at least once every year, similar to inventory verifications of other products often present in laboratories such as chemical reagents or laboratory supplies and stocks. The frequency of inventory verification may vary with the risk associated with the material or the

frequency of additions and deletions from the inventory. For the purposes of this Code of Practice, materials that must be inventoried are biohazardous agents:

- Stored at -70˚C or in a liquid nitrogen dewar.
- Stored at 4˚C for more than one month.
- Stored at room temperature in a non-metabolic state (i.e., spore slant, sealed lyophilized vial, etc.) for more than two weeks.
- Laboratory working cultures or stocks do not need to be inventoried.

The minimum record-keeping requirements for biohazardous agents under the responsibility and ownership of the PI include:

- Genus species, or equivalent designation of each biohazardous agent including strain.
- Location where stored.
- Any restrictions imposed on the use of the biohazardous agents if provided by a commercial or third-party supplier.
- If/when the biohazardous agents are transferred to another group.

Inventories can be kept as paper or electronic documents. Inventories must be kept up-to-date and must be made available on request by the BSO.

6.6 Equipment Maintenance Checklists

It is a legislated requirement to ensure equipment is properly maintained. It is good laboratory practice to use maintenance checklists and schedules for equipment in the laboratory. Some common examples include, but are not limited to:

- Benches: Wiped with appropriate disinfectant daily before and after experimentation.
- Fridges/Freezers: Stored materials should be assessed quarterly and experimental products that are no longer needed should be properly decontaminated and disposed.
- Incubators: Interior surfaces and handle wiped with appropriate disinfectant monthly, or when contamination is suspected.
- Water Baths: Water replaced and disinfectant added monthly.

Certain types of equipment, such as centrifuges and microscopes, also have scheduled maintenance requirements stipulated by the manufacturer. Equipment maintenance minimizes the risk of instrument failure, which could potentially put personnel at risk. Conducting scheduled maintenance also helps to ensure the equipment remains functional, and does not breakdown and disrupt research. Consult the manual provided with the equipment, and follow all required and recommended maintenance procedures.

6.7 Repair or Disposal of Equipment Used with Biohazardous Agents

Any equipment that has been in contact with biohazardous agents must be decontaminated prior to being repaired or removed from the laboratory. Service and support personnel have

the right to refuse to pick up or repair an item if they suspect it has not been properly prepared or fully decontaminated. Failure to properly decontaminate research equipment leaving a laboratory is a violation of federal biosafety regulations. PI must keep record of maintenance and repair of all equipment and include a record of decontamination.

6.8 Laboratory Renovations or Repairs

During the course of laboratory operation, it is sometimes necessary for University maintenance personnel or outside contractors to work within the laboratory. Routine laboratory maintenance or minor renovations requires that laboratory personnel consult the Clearance to Work in Laboratories procedure to ensure that hazards in the facility are properly secured, work surfaces are properly cleaned, and pertinent scheduling and safety information is exchanged between the research group and outside workers before the maintenance or minor renovation is initiated.

6.9 Laboratory Relocations & Close-Outs

Whenever laboratory space is vacated by a research group, either due to the laboratory closing or a relocation of the research group, it is the responsibility of the PI to ensure that the applicable sections of the Campus Safety Services Hazardous Materials Close-out Procedure Checklist are followed and completed by the research group. The Checklist helps ensure that all hazardous materials utilized or stored in the laboratory are safely transferred to a new location, formally turned over to another party, or disposed properly, and that the space is properly cleaned of any contamination.

Section 7. Containment Laboratory Practices

The following are a minimum standard for all research and teaching groups working with biohazardous agents. These procedures align with Federal, provincial and institutional regulations regarding work with biohazardous agents in a laboratory setting. Groups unable to comply with these procedures must identify the issue to the BSO and IBSC for review and discussion. Items discussed in this chapter will be the focus of periodic laboratory inspections and audits conducted by RSS personnel.

Research groups will be required to follow additional safety guidelines if working in their laboratory with chemical, radiation or other hazards in addition to biohazardous agents. In instances where the instructions given in this chapter are at odds with other RSS safety instruction, the research group is to follow the more stringent instruction. If the research group cannot determine the more stringent instruction, they are to contact RSS.

7.1 Laboratory Access

Access to laboratories where biohazardous agents are handled and stored is restricted to authorized personnel. Personnel who have completed the orientation and training outlined in

Section 6.2 may work independently and unsupervised in the laboratory. All other personnel may only enter the laboratory under the escort of someone who has completed this training with the exception of:

- Security Services and RSS personnel may enter a laboratory after hours to investigate potential infrastructure or criminal issues.
- F&O or contractors entering the laboratory under a Clearance to Work Form to complete a repair or minor renovation.

Infants and children are prohibited from entering research and teaching laboratories where biohazardous agents are handled and stored.

7.2 Laboratory Computers, Personal Tablets & Smart Phones

Computer keyboards are difficult items to decontaminate. Computer work stations should be kept well away from work areas where biohazardous materials are handled or stored. Personnel should remove disposable gloves before typing at a computer. If an individual's work activities prevent them from repeatedly donning and doffing gloves to work at a computer, the research group should invest in a liquid-resistant medical keyboard and regularly wipe down the keyboard with a suitable decontaminant throughout the work day. Individuals bringing personal smart phones and tablets into a laboratory environment must be aware that these items can become fomites to carry biohazardous agents out of the laboratory and to their home. If these items are to be used in the laboratory, their screens must be covered with an adhesive screen protector and must be wiped down with an appropriate decontaminant before being taken out of the laboratory at the end of the day. If these items are employed in the laboratory, their use by other members of the individual's household, especially by children, is strongly discouraged.

7.3 Personal Protective Equipment & General Hygiene

Personal Protective Equipment (PPE) refers to a variety of barrier protections that used alone or in combination will protect an individual's skin, clothes, mucous membranes and airways from contact with hazardous materials at the work place. In the case of PPE against biohazardous agents, many also in turn protect research material, such as cell and microbial cultures, from contaminants on the individual's clothes or body.

When entering a research or teaching laboratory for the purpose of performing a task other than working at a computer work station or transiting the laboratory to reach a non-research space, the following minimal PPE (Figure 7.1) must be worn:

1. A properly fitting, fully fastened laboratory coat or gown.
2. Properly fitting safety glasses.
3. Disposable gloves appropriate against the types of biological, chemical and radiation hazards in use in the laboratory.
4. Shoes that fully cover the foot and do not have a high heel.

5. Clothing that does not expose any skin below the waist.
6. Additional PPE may be required as determined by the research group's risk assessment

Figure 7.1: Personal protective equipment required in U of L laboratories

0ther considerations:

- Loose or dangling jewelry must not be worn.
- Sharp jewelry that may damage PPE must be removed.
- Do not insert or remove contact lenses in the laboratory. If an individual wears contact lenses in the laboratory, it is essential that they keep their safety glasses on at all times.
- Open wounds, cuts, scratches and grazes must be covered with waterproof dressings. If a wound cannot be sufficiently covered with dressing, the individual may not enter the laboratory.
- Gloves must never be worn when opening doors, answering a phone, or typing on a keyboard.
- Additional full-face protection must be used during activities where a potential splash hazard exists, for instance when retrieving specimens from a liquid nitrogen Dewar.

- A fit-tested respirator must be used during an activity with the potential to aerosolize a biohazardous agent and cannot be conducted in a biological safety cabinet (BSC).
- Surgical masks are not equivalent to fit-tested respirators to protect against biohazardous agents.
- Place designated waste containers for gloves and other disposable PPE in a convenient location. Laboratory coats and gowns should be hung on individual wall hooks spaced sufficiently apart so that coats and gowns do not brush against each other. A coat stand should not be used with laboratory coats and gowns. Street jackets and coats must be stored separately from laboratory coats and gowns, such as in an individual's locker or office space.
- Always wash hands with soap and water at a designated hand-wash sink as the final step after the removal of PPE and before leaving the laboratory.
- Never wear PPE outside of the laboratory or research support areas.
- Under no circumstances should personnel consume food or drink, or store food, dinnerware, drink containers or utensils in rooms where biohazardous agents are handled or stored. Gum, candy and lozenges are considered food items in this circumstance.

7.4 Aseptic Technique for Bench Work

Working at the bench is one of the most common activities conducted in a research or teaching laboratory. The use of aseptic technique is essential for ensuring both the safety of personnel and contamination-free success of research. Aseptic technique refers to procedures and techniques designed to avoid and prevent cross-contamination of the worker, the work environment and the specimens/material being handled.

Aseptic technique can be summarized with three rules:

1. Maintain a clean, organized work area
   - Keep laboratory benches clear of clutter
   - Avoid reading and writing at the bench
   - Decontaminate bench surfaces before and after experiments
2. Keep sample/media containers closed
   - Open and keep containers at a 45˚ angle while pipetting to minimize production of aerosols.
   - Decontaminate edges of containers prior to transferring liquids
3. Minimize movements
   - Assemble all solutions, samples and equipment before commencing work
   - Avoid rapid movement, or waving of tools or pipettes in the air
   - Establish work flow that moves work materials from "clean" to "dirty" areas.

7.5 Biological Safety Cabinets & Other Aerosol Containment Devices

Experiments involving pathogenic microbes, tissue culture, and human clinical samples require the use of an aerosol containment device. As well, work with invasive plants not native to Alberta and work with allergens associated with laboratory animals may also require aerosol containment. The most commonly used piece of equipment for this is a Biosafety Cabinet (BSC). The purpose of the BSC is both to protect the investigator from potential infection, and to protect the experimental materials from contamination.

7.5.1 Biological Safety Cabinets

Biological Safety Cabinets (BSCs) are the most widely used and accepted primary containment devices. When properly used in research and teaching activities involving the manipulation of hazardous biological agents, the biological safety cabinets are effective in controlling and containing aerosols and particulates.

At the U of L use of a biological safety cabinet (BSC) is required in a CL2 laboratory. Biosafety cabinets are engineering controls to be used in conjunction with good microbiological practices to protect workers from potential infection, and to protect the experimental materials from contamination.

Note: Most biosafety cabinets at the U of L are Class II type A.

These cabinets remove aerosolized biohazardous agents from the air in the cabinet via a highly-efficient particulate air (HEPA) filter and recirculate the filtered air back into the laboratory, therefore they do not require hard-ducting. However, because they return the filtered air back into the laboratory, they are inappropriate for combined projects involving biohazardous agents with chemicals, anesthetics or radioactive isotopes that are volatile in nature.

For additional information on the various classes of BSC and their description please refer to Chapter 11 of the CBSG 1st Edition.

Correct use and maintenance of BSCs

The correct location, installation, testing and certification of biological safety cabinets are critical to its performance in containing aerosols.

- All NSC must be **annually** inspected in accordance to NSF/ANSI 49 standard or when not applicable to the manufactures specifications.
- Certification should be done by trained service personnel who adhere to the standard.
- Laboratory personnel must be trained in the correct use and maintenance of BSC.

- If a BSC needs to be moved or disposed then it needs to be "appropriately decontaminated" to reduce the potential exposure to biohazardous material. Contact the BSO before moving a Biological Safety Cabinet.
- If you require assistance to determine the appropriate biological cabinet to purchase or determine BSC location, please contact the BSO.

Please refer to Appendix E Biosafety Cabinets for more information.

7.6 Needles, Syringes & Sharps

Sharps include needle/syringe assemblies, razor blades, scalpels, and other objects with a jagged or sharp edge that could puncture a plastic bag or potentially cause injury to someone handling them. Alternatives for sharps should be used when available. While working with sharps minimize risk with the following precautions:

- Use sharps with engineered injury protections. For example, a syringe that shields the needle with a plastic cover when it is not in use.
- Keep needles pointed away from yourself and others.
- If needles or scalpels are required with animals, anesthetize or restrain the animal prior to initiating the procedure.
- Never attempt to clip, recap or reuse a needle.
- Discard intact needle and syringe assemblies into an appropriate sharps disposal container (do not attempt to disassemble).
- Laboratories may use plastic containers as sharps containers provided that the plastic is strong enough to not be penetrated by the sharps. Remove the original label and re-label as a sharps container. Dedicated sharps disposal containers are also available from common laboratory supply companies. *Note: Used bleach containers are not puncture resistant and therefore are not to be used as sharps containers.*
- Once sharps disposal containers are 75% full, seal and dispose of following the U of L Disposal of Biohazardous Sharps procedure.
- In the event of a needle stick or puncture from a sharps, follow the Post Exposure Procedure. (**Appendix I: Post Exposure Procedure)**

7.7 Pipetting

The main hazard involved with pipetting is the production of aerosols. Use the following safety measures while pipetting to minimize the risk of exposure to hazardous materials:

- Never pipet by mouth.
- Use a mechanical device such as a Pipet Aid™ or equivalent, equipped with a 0.2 µm filter.
- Use micro-pipettors for the delivery or transfer of small volumes of liquid.

- Where contamination is of particular concern, use aerosol-resistant, filtered pipet tips.
- Avoid using pipettes to mix infectious substances (may generate aerosols).

7.8 Blenders, Grinders, Sonicators & Other Tissue Homogenizing Equipment

The use of blenders, grinders, homogenizers and sonicators with open containers of biohazardous agent will aerosolize the agent. When working with tissue homogenizing equipment with biohazardous agents, adhere to the following:

- Conduct all homogenization with biohazardous agents in a BSC.
- After sonication or blending a sealed preparation, allow aerosols to settle for at least five minutes before opening container.
- Wear appropriate hearing protection when using sonicators.
- Wear double gloves when handling equipment.

7.9 Centrifugation

The two major hazards involved with centrifuging are the production of aerosols and mechanical failure. In order to ensure the safe operation of the centrifuge and to minimize contamination, the following guidelines must be observed:

- Check all rotors, tubes and buckets for cracks or breaks prior to use.
- Ensure the centrifuge speed (relative centrifugal force; rcf) does not exceed the maximum speed allowable for the rotor and/or tubes.
- Wipe up any condensed water present in the centrifuge chamber prior to use.
- Allow sufficient time for temperature-controlled centrifuges to stabilize at the desired temperature before use.
- Use sealed safety centrifuge buckets and rotors when working with ANY biohazardous agents.
- Fill and balance all tubes and rotors in a BSC. After centrifugation is complete, unload the rotor in a BSC. When opening the tubes, the top of the tube should be pointed away from the user.
- Only fill tubes to no more than 75% capacity to prevent spills.
- In the event of a leak, soak the rotor assembly in disinfectant and clean before using again.
- Examine the interior of the centrifuge for cracks, breaks, and spills after every use.

7.10 Vacuum Pumps & Liquid Filtration

Vacuum systems are often used in laboratories for a wide variety of applications and experiments. Most laboratories on campus are equipped with house vacuum lines on laboratory benches. As well, many fume hoods and BSCs contain vacuum lines. When working with vacuum systems and liquid filtration adhere to the following:

- All vacuum lines must contain a 0.2 µm in-line filter between the collection flask and vacuum connection valve, to prevent both contamination of experimental samples and the vacuum line.
- Filtration of fluids containing infectious materials must be done inside a BSC.
- A vacuum flask partially filled with a suitable decontaminant (i.e., a reservoir trap) should be installed between the flask storing the drawn off liquid and the vacuum source.
- Vacuum flasks should be taped on the outside to reduce shattering of glass in the event of a vessel implosion. Tubing connections should be secured with quick disconnects, and the vacuum must be ON and operational before any fluid is filtered. To turn the system OFF, first break the vacuum by disconnecting the tubing at the sample flask, then turn the vacuum pump off. This will prevent a potential back-flow of fluid into the sample flask.
- During filtration, filter pores may become clogged causing the flow rate to slow or stop completely. Visually monitor the flow rate to determine if a filter requires replacement. Filtration of several smaller volumes rather than one large volume is recommended.
- If filtering volatile solutions, a cold trap should be placed in-line between the filtration apparatus and vacuum source.
- Venting of rotary pumps must be to an air exhaust system; not directly into the laboratory.
- Belt driven vacuum pumps must have protective guards, to prevent accidental entanglement.

7.11 Incubators

Incubators must be labelled if they contain biohazardous material. To ensure the optimal use of incubators and to minimize contamination, the following guidelines must be observed:

- All cultures must be well-labeled with the name of the microbe (including strain, if applicable), date started and name(s) of the person running the experiment.
- If equipped with an alarm, incubators must have contact information posted at the equipment to ensure that appropriate action can be taken if equipment fails outside of regular working hours.

7.12 Refrigerators, Cold rooms & Freezers

All refrigerators, cold rooms and freezers holding biohazardous agents must be locked and labeled with a Laboratory Hazard Sign (Section 6.1). Archival stocks of biohazardous agents held in fridges and freezers must be logged in an inventory as per Section 6.5

Refrigerators, cold rooms and freezers are often shared laboratory spaces, and all users should be aware of any biohazardous agents being utilized in the space by other groups.

In order to ensure the optimal use of refrigerators, cold rooms and freezers and to minimize contamination, the following guidelines must be observed:

- Never store food or drink in a laboratory refrigerator, freezer or cold room.
- Adequately seal containers.
- Minimize clutter.
- Do not use cardboard (particularly corrugated cardboard) to store any material in cold rooms as it can harbor fungal spores which can result in mold contamination of the space.
- Defrost and clean freezers regularly in order to minimize accumulation of ice and hazardous vapour inside the unit.
- Walk-in cold rooms should have their floors mopped and shelves wiped down with an appropriate decontaminant at least quarterly (groups sharing a cold room should coordinate this activity amongst their members).
- Post contact names and phones numbers on -80°C freezers to ensure that action can be taken if a unit fails outside of regular working hours.

7.13 Chemicals Used With Biohazardous Agents

There are a wide variety of chemicals used in conjunction with biohazards. Handling and waste disposal can vary dramatically. Personnel must be familiar with the MSDSs and follow the proper handling and waste disposal requirements for each of the chemicals in use. For further information on chemical handling please refer to the Laboratory Chemical Safety Manual (URL or mention RSS website).

Section 8. Transportation of Biohazardous Material

8.1 Perceptions and Expectations

The transfer of biological material requires that special precautions are followed by laboratory personnel. There are two main considerations when transporting biological material:

- Ensuring the safety of personnel, the public and the environment in the event of a spill of the material, and,
- Public perception of the safety of the materials being transported. Biological material may be moved within a University building or between buildings on campus provided the guidelines listed below are followed.
- In all cases, personnel transferring biological materials are to proceed directly from the pick- up location to the delivery location. Personnel transporting biological material are

not to stop along the way to use washroom facilities, or to purchase or consume food or drink.
- Any movement of biohazardous agents off campus falls under the TDG regulations and must have approval from the BSO.

8.2 Transporting Biohazardous Material within Campus

When transporting biological material between labs, floors or buildings the following procedures should be followed:

- Ensure primary containers are in good condition and caps are tightly closed. Damaged containers must not be transported.
- Review the MSDSs/PSDSs for materials being transported to ensure that there are no physical hazards or temperature restrictions associated with the materials.
- Label primary containers to describe the contents accurately.
- Use secondary leak proof containment to transfer material. Ensure secondary container is large enough to hold any liquid if spilled. Include absorbent material in a secondary container.
- Use a cart to transport material.
- If worker leaves designated containment laboratory exit protocols must be followed. Procedure should include removal of all PPE (lab coat, gloves) and hands washed before exiting lab.
- Avoid the use of passenger elevators. Freight elevators should be used whenever possible. Do not use stairs when transporting hazardous materials.

8.3 Transportation and Transfer of Biohazardous Agents Off Campus

Any movement of biohazardous agents off campus falls under TDG regulations and a Biohazardous Agent Transfer Notification (Appendix F) must be completed and signed off by the BSO. The TDG Regulation is federal legislation designed to regulate the movement of dangerous goods via roads, rail, air, and ship and to protect personnel involved in the transport as well as the general public. In case of accident, emergency officials can quickly identify the hazard based on the warning symbols displayed on the package.

Transportation must be arranged with a TDG certified carrier. All individuals who are involved in packaging and transfer of hazardous materials off campus must have valid TDG certification. Contact RSS for information on training available.

Section 9. Decontamination and Waste Management

9.1 Cleaning and Decontamination

All work surfaces and equipment used with biological material (whether or not it is considered a biohazardous agent) must be kept clean and regularly wiped down with an appropriate chemical decontaminant during and at the end of work activities. This helps to prevent odors

and cross-contamination of research and protect individuals' health. If a surface is visibly soiled with organic material, decontaminant should be applied twice, once to remove the organic material and a second time to decontaminate the surface.

Research and teaching groups working with biological materials may use a commercial bench coat to cover their work surfaces but should replace the coat as soon as it becomes visibly soiled or at the completion of the day's work. Bench coat used with biological materials must be autoclaved prior to disposal or disposed of via incineration.

All waste containing biohazardous agents and culture material must be inactivated by sterilization or chemical decontamination. Under no circumstances are personnel to dispose of untreated waste potentially contaminated with biohazardous agents into the regular building waste stream. In addition, personnel are prohibited from pouring untreated, active cultures of any microbe or eukaryotic cell line down a sink or sewer drain.

9.2 Decontamination Methods

9.2.1 Chemical Decontaminants

The selection of an appropriate chemical decontaminant is dependent on a variety of factors, including the resistance of the infectious material or toxin, the application (e.g., liquid or gaseous), and the nature of the material to be disinfected (e.g., hard surface, porous materials). Consideration should also be given to organic load, concentration, contact time, temperature, relative humidity, pH and stability. Table 9-1 describes the susceptibility of microorganisms to chemical disinfectants and those reported to be effective against them.

Table 9-1: Microorganisms ranked according to relative susceptibility to chemical disinfectants. Adapted from: Quinn, P.J., & Markey, B. K. (1991). Disinfection and Disease Prevention in Veterinary Medicine.

Susceptibility	Microorganism	Disinfectants reported to be effective
Extremely resistant	Prions	• Unusually resistant to chemical disinfectants. • High concentrations of sodium hypochlorite (NaOCl) or heated strong solutions of sodium hydroxide (NaOH) •
Highly resistant	Protozoal oocysts	• Ammonium hydroxide, halogens (high concentrations), halogenated phenols.
	Bacterial endospores	• Some acids, aldehydes, halogens (high concentrations), peroxygen compounds.
Resistant	Mycobacteria	• Alcohols, aldehydes, some alkalis, halogens, some peroxygen compounds, some phenols.
	Non-enveloped viruses	• Aldehydes, halogens, peroxygen compounds.
	Fungal spores	• Some alcohols, aldehydes, biguanides, halogens, peroxygen compounds, some phenols.
	Gram-negative bacteria	• Alcohols, aldehydes, alkalis, biguanides, halogens, peroxygen compounds, some phenols, some quaternary ammonium
	Enveloped?	
Highly susceptible	Mycoplasma	• Acids, alcohols, aldehydes, alkalis, biguanides, halogens, peroxygen compounds, phenols, QACs.

The most common chemical decontaminants recommended for use in U of L research and training laboratories are:

- **70% Ethanol** – Used with a minimum contact time of 2 minutes to clean surfaces and equipment used with human clinical specimens, animal specimens, eukaryotic cell lines and non-hydrophilic viruses.
- **2% Virkon**TM – Used with a minimum contact time of 3 minutes to clean

surfaces and equipment used with human clinical specimens, animal specimens, eukaryotic cell lines, viruses and non-sporeforming bacteria.

- **10% bleach** – Is effective against human clinical specimens, animal specimens, eukaryotic cell lines, viruses, bacteria and rDNA technologies. Used at a minimum contact time of 5 minutes, 10% bleach can be used to clean surfaces and equipment. 10% bleach is also used for the remediation of all spills of biological material although the minimum contact time is increased to 25 minutes. Metal surfaces treated with 10% bleach should be rinsed with water (or 70% ethanol in order to prevent corrosion of the metal.

Consult the MSDS for proper disposal of used chemical decontaminants.

For more information on Chemical Decontaminants **(Appendix G: Category of Chemical Decontaminants Information).**

Workers mixing chemical decontaminants must read the MSDS and wear PPE appropriate for the specific decontaminant. Research and teaching groups working with biohazardous agents must declare the chemical decontaminants used in the laboratory (including working concentration and contact time) in their Biosafety Plan submitted with their application for a Biosafety Permit.

9.2.2 Autoclaves and Sterilizers

Autoclaves and sterilizers provide an effective means of sterilizing and decontaminating materials that are biohazardous, or have been exposed to biohazardous agents. Autoclaves are also routinely used to sterilize laboratory supplies, solutions and media. Autoclaving is also the method of choice for the inactivation and disposal of microbial and eukaryotic cell cultures regardless of their risk group designation.

Autoclaves and sterilizers at the U of L may be operated by either an individual research group or as part of a larger Department wash-up facility. Autoclaves operate under high pressure (up to 40 psi) and temperatures (121-134 C°) posing significant risk of injury by such means as:

- Contact burns from the chamber, doors, racks or autoclaved materials,
- Steam burns from autoclaved liquids or residual steam escaping from the chamber,
- Fluid scalds from autoclaved material or residual condensate splashing onto exposed skin, and,
- Bodily injury from a sealed containers or vessels exploding due to the build up of internal pressure during an autoclave cycle.

In order to ensure that autoclaves function properly and to minimize the risk of injury to personnel, the following guidelines are required:

- All personnel must receive training before operating any autoclave unit.

- Before initiating autoclave runs, conduct a daily check according to the manufacturer's operating instructions. If a problem is found or suspected, contact the PI responsible and post "out of service" signage on the autoclave door.
- Material preparation:
    - Use clear autoclave bags with no hazard symbols or be prepared to deface the hazard symbols on bags after autoclaving for disposal.
    - Place materials to be autoclaved (such as loosely closed autoclave bags, covered containers of liquid wastes, secured sharps containers, etc.) in a bin large enough to contain a total spill of the contents.
    - Do not crowd or overstuff items into autoclave bags or bins.
    - When autoclaving liquids:
        - Only autoclavable glassware or plastics should be used to autoclave liquids.
        - Ensure containers of liquids are no more than 2/3 full, in order to prevent liquids from boiling over.
        - Do not exceed 2000ml of liquid per container loaded into an autoclave.
        - Loosen lids or covers on containers of liquid prior to autoclaving to prevent containers from bursting.
    - Open all autoclave bags prior to autoclaving to allow steam to reach the contents of the bags.
    - Affix a piece of autoclave tape to each item or bag in the autoclave.
- When loading the autoclave:
    - Wear appropriate PPE, including heat-insulating gloves.
    - Do not overload the autoclave.
    - Ensure that a proper seal occurs when you close the door.
    - Upon initiation of cycle, wait until the sterilization time has begun before leaving the autoclave.
    - If available, always use a temperature probe. The temperature probes should be placed directly into the densest bag of the load or directly into the vessel of liquid with the largest volume to provide an accurate representation of the temperature achieved.

Table 9-2 describes some basic autoclave cycle parameters, and when they should be used. Many departments have several cycles that are for common use. It is important to note that these are minimum requirements only. If your research group or department has higher standards, defer to those.

Table 9-2. **Common autoclave cycle parameters**

Cycle	Sterilization times at 121°C (min)	Comments
Liquids	15-30	Sterilization time is dependent on use and the type of media/liquids being autoclaved. Refer to laboratory specific SOPs.
Gravity/dry materials	15-30 Followed by 15-30 min dry (exhaust) cycle	This cycle is used for autoclaving lab supplies such as pipette tips, tubes and empty glassware. Refer to lab-specific SOPs for time requirements.
Biological waste	45	Appropriate for most biological materials including microbial and eukaryotic cell cultures.
Biological waste containing endospores	120	A longer sterilization time is required to ensure complete sterilization of all endospores.

9.2.3 Incineration

It is always preferable to treat biohazardous waste on site rather than transporting the waste to an off-campus location for incineration.

The following materials must be incinerated and should not be treated in an autoclave or sterilizer:

- Animal carcasses and body parts
- Human tissue specimens

If biological waste must be stored while awaiting incineration, the waste must be stored as follows:

- No more than 24 hours at ambient or room temperature
- No more than 42 days at 0°C to 4°C
- No more than 90 day below 0°C

9.2.4 Vaporous Decontaminants

Vaporous formaldehyde and hydrogen peroxide are very effective gaseous decontaminants against most biohazardous agents and are ideal for decontamination of heat-sensitive and chemical-sensitive electronic devices. This method is utilized to decontaminate BSC HEPA filters when cabinets need to be moved or repaired. These methods can also be used to

decontaminate small facilities or select pieces of equipment. These methods of decontamination need to be performed by trained specialists using appropriate PPE. Any group considering gaseous decontamination for their area or equipment must contact the BSO for assistance.

Section 10. Biological Waste Management

Caretaking personnel are not authorized to collect laboratory waste from any CL2 laboratory. Laboratory staff will have to decontaminate all waste and dispose of waste either by the domestic sewer (liquids) or garbage (solids) **(Appendix H: Biohazardous Waste Disposal Guide)**.

10.1.1 Transport of Contaminated Waste within Facility

Personnel removing biological waste from a research or teaching laboratory for decontamination in an autoclave room must place the primary containers of waste in a leak-proof, sealable plastic or metal secondary container of sufficient size to contain waste material if the primary container leaks. The waste packaged in this way must be transported to the wash-up or autoclave room on a cart and never hand-carried.

10.1.2 Sharps Waste

Sharps include needle/syringe assemblies, razor blades, scalpels, and other objects with a jagged or sharp edge that could puncture a plastic bag or potentially cause injury to someone handling them. Sharps need to be disposed of in hard sided, puncture proof containers. Each lab will collect the waste sharps until lab container is filled to 2/3 level. Sharps container will be then sealed and placed in GM Pearson Biomedical Waste disposal boxes for incineration. There are a number of disposal boxes located around the University Campus contact BSO for the nearest location. Please contact BSO if the GM Pearson Biomedical Waste disposal boxes are full and need replacing.

10.1.3 Mixed Hazardous Waste

When biohazardous agents are used with chemical and radiological hazards, the resultant waste must be treated as follows:

- Combination biohazard and radiological waste.
- Biohazards with flammable, combustible, volatile or corrosive chemical waste.
- Biohazards with other chemical waste.

Section 11. Medical Surveillance

All new and current laboratory staff and students are advised and encouraged to consult with their personal health care provider to ensure that their general immunization status meets with current Alberta Health, Alberta Immunization Policy 2012-2015.
http://www.health.alberta.ca/documents/AIP-General-Guidelines.pdf

For work with many Risk Group biological agents, immunizations and/or prophylactic or post-exposure anti-microbials are not available. Working at the appropriate containment level and following documented procedures and safe work practices remains critical to protecting the health of workers.

11.1 Project Specific Requirements

PIs must determine if any laboratory staff or students for whom they are responsible and who work with or near animal or human blood/body fluids or other human pathogens have an occupational risk of contracting a vaccine -preventable potentially infectious disease.

Employees and students are encouraged to initiate discussions with supervisors regarding any immunization concerns they may have.

PIs are responsible for documenting any vaccine requirements in their Biosafety Plan. The individual worker training plans must include any known symptoms of illness associated with the microorganism or biohazardous material being handled.

If it is determined that a vaccine is available for potentially infectious diseases and the cost of immunization is not covered by Alberta Health, the research program must cover the expense.

If after being informed a worker or student refuses to safeguard their health through immunization they will not be an “authorized worker” and will NOT be able to work with biohazardous material. No worker or student shall be placed at serious risk of contracting a vaccine preventable potentially infectious disease.

The PI is responsible for determining the level of medical surveillance program that is warranted to detect immunological exposures to any microorganism or biohazardous material used within their laboratory. The PI should seek out the assistance of the Occupational Health Professional, BSO and IBC for guidance in determining the level of medical surveillance required. A medical surveillance program may be as simple as including a statement in the PI’s lab SOP and training that states the symptoms of any illnesses associated with the microorganism(s) (refer to PSDS) and require that if these symptoms appear, the workers must seek medical attention and give their health care provider a list of organisms and PSDSs with which they work. Alternately this may be as extensive as including initial serum banking, or annual or periodic medical evaluations.

11.2 Pre-Placement Medical Surveillance

A pre-placement medical surveillance may be conducted for new workers prior to commencing activities with human pathogens, toxins, or zoonotic pathogens. The primary purpose of such surveillance is to assess the initial health status of the individual and identify if there are any underlying medical conditions that may increase the risk of harm associated with the anticipated job activities. This evaluation may include an interview with the institutional occupational health care provider and/or a personal medical history questionnaire to document the individual’s previous and current medical problems; current medications; known allergies to

medications, animals, or environmental allergens; and prior immunizations. Workers who are immunocompromised (e.g., through radiation therapy or chemotherapy, pregnancy, diabetes, or other conditions) may be particularly susceptible to infections, or experience more severe illness if they contract an infection following exposure to a pathogen. A complete physical examination is rarely necessary as part of this process but may be appropriate.

11.3 Ongoing Medical Surveillance

Workers should be encouraged by the supervisor, without fear of reprisal, to disclose any changes in their health status that could increase their risk of exposure. This could include developing an immunodeficiency or a temporary condition, such as the need to take prescribed antibiotics, pregnancy, impaired vision, or even stress. Routine or periodic medical evaluations are generally not necessary; however, such evaluations may be appropriate in the case of a worker with a substantial risk of exposure to infectious material or toxins, since they may permit early detection of a laboratory acquired illness.

11.4 Post Exposure Procedure

Original studies of laboratory acquired infectious (LAIs) and accidents indicated that up to 80% of LAIs could not be attributed to a known lab accident or exposure. Organisms transmitted through aerosols were considered to be the most plausible cause of these infections. Exposure was presumed to have occurred either by direct inhalation or through touching of surfaces where these aerosols may have landed and subsequent transmission from hand–to-mouth or other mucous membrane.

Where a known incident/exposure occurs (e.g. sharps injury, unforeseen splash to mucous membranes, broken tubes, spill outside of the biosafety cabinet), post-exposure protocol as determined appropriate by the PI shall be initiated immediately and a Campus Accident and Incident Report (CAIR) completed. The Post Exposure Procedure should be posted in the laboratory. **(Appendix I: Post Exposure Procedure)**.

11.5 Allergens

Allergens may be encountered in research when working with biological organisms, isolated tissue specimens from these organisms, or when cleaning up waste materials from biological organisms. Although mammals, particularly rodents, dogs and cats, are most commonly known as sources for allergens, many animal, plant and mold species have the potential to generate allergic reactions in humans; even cricket waste and scales from butterfly wings can illicit human allergies.

Allergy symptoms generally consist of rashes (where the allergen is in direct contact with skin), nasal congestion and sneezing, itchy eyes and asthma-like symptoms (i.e., coughing, wheezing and chest tightness). Personnel may be exposed and sensitized to allergens through direct skin contact, via eyes and mucous membranes or through inhalation. Personnel may also be inoculated with allergens through uncovered wounds or accidental animal bites or needle stick injuries. If personnel suspect they are developing allergies to the biological organisms they are

working with they should inform their PI/supervisor and consult with a physician. Personnel should not ignore signs of allergies; allergies tend to worsen with continued unprotected or improper exposure to the source of allergens. Personnel should also not self-medicate with off the shelf antihistamines without consulting a physician as, while the medication can alleviate symptoms, it may mask an overall worsening of symptoms.

To reduce individual exposure to animal allergens the following should be considered.

- Pre-placement screen personnel for allergies (pollens, molds, animal dander, etc.) before assigning specific jobs handling potential allergen sources.
- Confirm appropriate ventilation rate and humidity in rooms where potential allergen sources are handled or housed.
- Ensure airflow is directed away from workers and back towards the potential allergen source.
- When possible, perform manipulations of potential allergen sources within ventilated hoods or biological safety cabinets; never handle potential allergen sources in a laminar flow hood.
- Avoid wearing street clothes while working with potential allergen sources; change into facility dedicated laboratory scrubs.
- Keep area where potential allergen sources are handled or stored clean and free of dust; regularly mop and wipe down surfaces with wet cleaning towels rather than vacuuming or sweeping (which would generate aerosols).
- When working with live animals, use absorbent pads for bedding and avoid the use of sawdust bedding which can facilitate the aerosolize of urine and fecal material from the cage.
- When working with live animals, if possible, use an animal strain or sex that is known to be less allergenic than others.
- Reduce skin contact with potential allergen sources by using appropriate PPE. In a laboratory setting, required PPE is as described in Section 7.3. For field research or working with livestock, personnel should determine appropriate PPE using Section 7.3 as a reference.
- Use a fit-tested respirator when warranted. Note a surgical mask is not equivalent to a fit-tested respirator; in a hospital setting a surgical mask is meant to protect the patient from the worker and not vice versa.

Section 12. Emergency Response

It is necessary to develop an emergency response plan (ERP) for situations where biosafety and/or biosecurity issues may arise as the result of an emergency. Emergency situations may include incidents or accidents, medical emergencies, fire, chemical or biological spills, power failure, animal escape, failure of primary containment devices (e.g., BSC), loss of containment (e.g., HVAC), and/or natural disasters. The ERP should identify all foreseeable emergency

scenarios and describe response measures proportional to the scale and nature of the emergency.

The permit holder shall immediately report to the BSO all incidents including confirmed or suspected illnesses resulting from exposures to hazardous materials, spills, containment equipment malfunctions, or loss or suspected theft of permitted materials.

Each permit holder/PI shall develop and implement emergency response measures appropriate with the identified risk of the biohazardous materials and activities. The emergency response measures must meet both the biosafety permit and legislative requirements.

All incidents must be **reported** to the Principal Investigator and RSS through the CAIR reporting system. Incidents are to be reported to RSS for follow-up in order to prevent similar or more severe incidents in the future. These reports are treated as confidential documents. Incidents involving biohazardous material will be reported to the BSO. CAIR forms can be found on the RSS website.
All incidents requiring medical assistance or resulting in time off of work must be reported to WCB. It is extremely important that all incidents of this nature be reported to the office of Wellness and Recognition within 24 hours. Wellness staff will complete the appropriate WCB documents.

12.1 Fire or explosion

In the event of an **explosion** or **uncontrollable fire**:

- First, evacuate the immediate area.
- Trip fire alarm on way out of building.
- Call 911 (no prefix necessary)
- Call Security (2345) and give:
    - Identity of the person making the report
    - Nature of the incident
    - Location of the incident (building and room number)
    - Presence of any injuries

If possible, warn others of the situation and seal off the area.

12.2 Medical Incidents

If the injury is severe in that it involves significant loss of blood, loss of consciousness, a broken limb or is potentially life threatening then proceed to the following steps.

- Call **911** immediately
- Call Security (2345) and give:
    - Identity of the person making the report
    - Nature of the incident
    - Location of the incident (building and room number)

- Note that Campus Security will direct ambulance personnel to your location on campus. This is why it is important to call 2345.

If the injury is not severe and but there has been a potential exposure to hazardous material:

- If exposed to a **potentially infectious material** (via cuts, needle sticks, punctures, scratches, spills on chapped or broken skin, animal bites, etc.), the affected area must be immediately disinfected, washed thoroughly but gently with multiple applications of soap and water for at least 5 minutes, and the cut then covered with a sterile bandage (See Appendix I: Post Exposure Procedure).Immediately after first aid and decontamination, report incident to supervisor, seek medical attention if necessary and complete a CAIR document.
- If there has been a chemical exposure, follow the appropriate procedure for the chemical involved. First aid treatment for chemical exposures will depend on the chemical involved. Ensure that you read the MSDS for each hazardous chemical before you begin to work with it and that you are familiar with the appropriate response to an exposure incident.

12.3 Spills

12.3.1 Biological Spills

A. Spills of biohazard material in biological safety cabinets (BSC):

- Leave the BSC in operation.
- Remove contaminated protective clothing, place it in bags and autoclave prior to disposal or laundering.
- Wash hands with disinfectant soap.
- Assemble clean-up materials and don appropriate protective clothing.
- Cover the spill with paper towel. Soak the paper towel with a suitable disinfectant, working from the outside in. Gentle flooding will avoid creating aerosols.
- Allow sufficient contact time for specific disinfectant used (**See Appendix G** Category of Chemical Decontaminants Information)
- Bleach or other disinfectants suitable for the infectious agents in use are acceptable as long as the manufacturer's recommended contact time is used. Ethanol is not recommended because it is difficult to achieve the required contact time due to evaporation.
- If spilled material has gone through the perforated grills then pour disinfectant through grills into the catch tray underneath. Let stand for the appropriate contact time for the disinfectant, drain the tray through drain cock and clean.
- Use forceps to pick up any broken glass or sharps and place in a puncture-resistant container.
- Wipe up spill and place all materials in a plastic bag inside the cabinet.

- If a corrosive disinfectant such as bleach is used it is recommended to rinse surfaces to remove any remaining bleach because it can corrode stainless steel.
- Items in the BSC at the time of the spill must be thoroughly cleaned with a disinfectant prior to removal from the BSC and/or bagged for removal and autoclaved.
- Prior to resuming work in the BSC, wipe the inside of the cabinet with disinfectant and allow BSC to run for 10 minutes.
- Report the incident to your supervisor.

B. Spills of biohazard material in an open area within the laboratory (outside of the BSC):

- Vacate area; warn others to leave
- If the spill came in contact with you or your clothing:
  - Remove contaminated clothing and place in bag for decontamination by autoclaving or chemical disinfection
  - If footwear has been contaminated, take care not to track contamination into clean areas before removing
  - Take a shower if necessary
  - Wash hands thoroughly
- Advise laboratory supervisor and seek assistance from the BSO if necessary
- Mark off area using barricade tape or warning signs to prevent others from entering
- Wait at least 30 minutes to allow aerosols to settle before re-entering area
- Don appropriate protective clothing (respiratory protection, eye protection, long sleeved gown/coveralls with tight fitting wrists, gloves, shoe covers
- Retrieve biological spill kit
- Cover the spill with paper towel
- Soak the paper towel with a suitable disinfectant, working from the outside in. Bleach is often suitable, but ensure that there are not any chemicals in the spill that would result in the release of chlorine gas, gentle flooding will avoid creating aerosols.
- Allow sufficient contact time for disinfection (usually 30 minutes depending on the disinfectant and microorganisms present)
- Use long forceps to pick up broken glass or sharps and place in a puncture-resistant container; remove the soaked paper towels with a double-gloved hand and dispose of them in a suitable receptacle.
- Items in the vicinity of the spill must be thoroughly cleaned with a disinfectant and/or by autoclaving; disinfect protective clothing and equipment
- Report the spill to the BSO and complete a CAIR document.

C. Large spills of biological material not considered biohazardous in an open area within the laboratory (outside of the BSC):

- Some biohazard level 1 material are hazardous to those with compromised immune systems. You should know whether or not the level 1 material that you are working with falls into this category.
- Work to minimize spread of the material to areas outside your laboratory where individuals with compromised immune systems might be present unbeknownst to you.
- Ensure that the laboratory door remains closed and follow the clean-up procedures for biohazardous material above, reducing the precautions where appropriate.

12.3.2 Chemical Release

A chemical release is defined as an uncontrolled release of a hazardous chemical, either in the form of a gas, liquid or solid. In the case of a chemical release, evacuate the area and call Security (2345).

- Stay clear and warn others in the immediate area of the spill. Isolate the area around the spill.
- Assist injured or contaminated persons if you are trained to do so, but do not place yourself at risk of injury or contamination in the process.
- Assess the situation, and determine (a) if it constitutes an emergency situation or (b) whether assistance is required to clean up the spill. In either case contact Security (2345). Give Security the following information:
  - Identity of the person making the report.
  - Nature of the incident and, if possible, the chemicals involved. If the chemical release poses an explosion threat (as in the case of a volatile solvent), then notify security of this fact and evacuate those areas that are affected.
  - Location of the incident (building and room number).
  - Presence of any injuries.
  - If the spill is minor, and trained local personnel, personal protective equipment and spill abatement material are available, then the spill may be cleaned up according to the procedures given in **Appendix J:** Chemical Spill Response Guidelines.
  - All chemical releases should be reported in writing to Risk and Safety Services using the CAIR Form. The report should be submitted within 24 hours of the spill occurring.

12.4 Equipment Associated Emergencies

12.4.1 Centrifuge

- In case of a centrifuge malfunction, rotor failure or centrifuge tube failure, a risk exists of infectious material being released due to the release of aerosols.

- If a centrifuge malfunctions while in operation it must be turned off immediately and unplugged.
- If infectious material is involved, the machine shall not be opened for 30 minutes to allow the aerosols to disperse and settle. **PLACE A NOTE ON THE CENTRIFUGE WARNING OTHERS NOT TO OPEN IT.**
- If using infectious material, leave the room for at least 30 minutes and place a note on the door warning people not to enter.
- The operator, wearing gloves, lab coat and a fit-tested N95 respirator, should remove all debris and disinfect the interior of the centrifuge and the head (or cups).
- It is important to remember that some disinfectants will corrode the interior of centrifuges and rotors so extreme care must be taken to thoroughly rinse following disinfection.
- All debris must be collected, bagged, treated and disposed of appropriately.

12.4.2 Biological Safety Cabinet

- DO NOT use the Biological Safety Cabinet if the ALARM sounds or if there are other indications of cabinet malfunction such as no airflow, reduced pressure on magnehelic gauge (a drop > 0.2), or unusual noises.
- If working with biohazardous material in BSC and there is a malfunction, immediately **stop work** and cover the material; remove gloves and wash hands; don a fit-tested disposable N95 respirator, or half face respirator with HEPA filters, and fresh gloves before proceeding.
- Seal, surface decontaminate and remove any biohazardous material.
- Decontaminate the interior of the BSC.
- Switch off the alarm or the power if the motor is making noise.
- Place a sign on the cabinet to indicate that it is broken and must not be used.
- Contact the BSO to arrange for the repair of the BSC.
- If personnel have potentially been exposed to infectious material due to cabinet failure, take appropriate precautions as outlined above. This type of incident must be reported to the supervisor and the BSO.

12.4.3 Power Failure

- An alternate light source (an emergency light system or large flashlight) must be available.
- If working in a BSC when a power failure occurs, proceed in a manner similar to that for failure of a BSC (above).
- A fit-tested disposable N95 respirator, or half face respirator with HEPA filters, should be available to use in emergencies.
- Stop work with chemical hazards and contain them since the ventilation systems will not be working.

12.4.4 In case of a fire alarm:

- If working with biohazardous materials when the fire alarm rings, cap all flask or bottles of bacteria, virus, cells, etc., so that any infectious material will be contained if the power goes out. Alternatively, if possible to do so quickly and safely, biohazardous material may be dumped into disinfectant solution before evacuating.
- If working with hazardous chemicals or radioactive materials, quickly cover or otherwise contain the material before leaving if it is safe to do so.
- Leave the laboratory closing the door behind you and follow the evacuation map for the area.

Appendix A: Biological Safety Checklist for CL2 Laboratory

Biological Safety Checklist for CL2 Laboratory

This checklist is designed to meet the minimum requirements outlined in the Canadian Biosafety Standard (CBS) 2nd Edition and the safe work practices described in the U of L Biosafety Code of Practice.

Section A: Contact Information

Last Name:	**First Name:**	**Phone:**
Dept:	**Building:**	**Room:**

Section B: Inspection

Date:	**Biosafety Officer (BSO):**

Section C: Laboratory Physical and Design Requirements
(See Chapter 3 CBS)

		Yes	**No**	**Comments**
	Containment zones to be separated from public and administrative areas by a locked door.			
	Dedicated work area for paper/computer work is segregated from the laboratory work areas.			
	Space to be provided for the storage of PPE in use.			
	Aisles and exits are free from obstruction, no tripping or slippery hazard present.			
	If windows are present, they are equipped with screens or sealed shut.			
	Biohazard warning signage (including the international biohazard warning symbol, containment level, name and telephone number[s] of contact person, and entry requirements) to be posted at the containment zone point(s) of entry.			
	Where unique hazards exist, project specific signage to be posted at the point(s) of entry.			
	Surfaces and interior coatings, including, but not limited to floors, ceilings, walls, doors, frames, casework, benchtops, and furniture, to be cleanable, non-absorbent, and resistant to scratches, stains, moisture, chemicals, heat, impact, and repeated decontamination.			
	Floors to be slip-resistant in accordance with function.			

	Sinks to be provided and located to facilitate handwashing upon exit from the containment zone.			
	An emergency eyewash station and shower are available inside, or in the proximity of the laboratory.			
	Certified BSCs and other primary containment devices to be provided, based on work activities.			
	Primary containment devices to be designed to prevent the release of infectious material or toxins. (i.e. centrifuges, BSC, glove boxes)			
	Decontamination technologies for the decontamination of materials to be provided within the containment zone, or standard operating procedures (SOPs) to be in place to safely and securely move or transport waste out of the containment zone to a designated decontamination area.			
	Vacuum systems to be equipped with a mechanism that prevents internal contamination.			
	Laboratory must have a telephone.			
	Effective rodent and insect control program maintained.			
Section D: Operational Practice Requirements (*See Chapter 4 CBS*)				
	Laboratory Work Practices			
	Lab personnel are aware of the location of the BCP and Standard Operating Procedures.			
	Biosafety Permits are posted.			
	All authorized personnel are listed on the Biosafety Permit.			
	No evidence of food or drink being consumed or stored in the lab.			
	Lab personnel are not to apply cosmetics or insert/remove contact lenses in the laboratory.			
	Long hair and loose jewelry are restrained. It is recommended that jewelry be removed before entering lab.			
	All footwear must be closed at heel and toe.			
	Open cuts, scratches and/or wounds are covered with appropriate dressings.			
	Syringes and other sharp objects are disposed in labeled sharps container.			
	No evidence of recapping, bending or removal of needle from the syringe.			
	No oral pipetting of any substance.			

	Are there traffic patterns from areas of low contamination to areas of higher contamination risk?			
	Work surfaces to be cleaned and decontaminated with a disinfectant effective against the pathogen(s) in use, or a neutralizing chemical effective against the toxin(s) in use, at a frequency to minimize the potential of exposure to infectious material or toxins.			
	Verification of the integrity of primary containment devices to be performed routinely, as described in SOPs.			Should have SOP
	Good microbiological laboratory practices to be employed.			See U of L Good Microbiology Practices document
	Containers of pathogens, toxins, or other regulated infectious material stored outside the containment zone are labelled, and leak-proof, impact resistant, and kept either in locked storage equipment.			
	Training and Regulatory Records			
	All personnel have received training relevant to the BCP and laboratory standard operating procedures.			See Training SOP See Personnel Training Plans
	All personnel have received training on the potential hazards associated with the work involved, and on the necessary precautions to prevent potential exposure. (documentation and sign off by employee & lab supervisor)			
	All personnel have received training on the primary equipment used in the lab.			
	All people working in the containment area have been trained in the biosecurity plan.			
	Lab personnel know how to access PSDS and MSDS for their work.			
	Are all new staff and students supervised by authorized personnel when working with infectious material and toxins until they have fulfilled the training requirements?			
	Authorized workers participate in refresher training.			
	Authorized workers review emergency response procedures on an annual basis.			
	Personnel are trained in all decontamination SOP specific laboratory activities.			
	Lab personnel aware of maintaining Inventory Records. Who is assigned to this task?			
	Entry and Exit of Personnel and Material			
	Laboratory doors are to be kept closed.			

	Access is limited to authorized personnel.			
	Caretakers and building maintenance do not enter laboratory unless trained and authorized.			
	Entry requirements must be posted on entry, “Authorized Workers Only”			
	Personal clothing to be stored separated from dedicated PPE.			
	Personal belonging to be kept separate from areas of infectious materials or toxins are handled.			
	Personnel to doff PPE in manner that minimizes contamination of skin and hair			SOP
	All PPE must be removed and hands washed before exiting laboratory.			
	Personal Protective Equipment			
	Personnel (including visitors, trainees and all others) are wearing protective laboratory clothing & foot wear when working in the laboratory.			
	Gloves are worn for all procedures that might involve direct skin contact with biohazardous material.			
	Gloves must be removed and hand washed before exiting laboratory.			
	Lab coats are only worn in the laboratory and are removed before exiting lab.			
	Lab personnel have access to respirators and selected on the basis of hazard present.			
	Face protection is available and used when risk of splashes or flying objects.			
	All users of respirators have received training on use and fit tested.			
	Biological Safety Cabinets			
	Biological Safety Cabinets are certified annually, after repair or relocation. (certification posted)			
	Personnel working in a Biosafety Cabinet are trained in its correct use and have a good understanding of the different types of cabinets and uses.			
	BSCs are located away from high traffic areas, doors and air supplies			
	UV light is not recommended as an effective decontamination process.			
	Follow BCS safe practices and procedures when using.			
	No open flames in BSC.			
	All surfaces are decontaminated after use.			
	Waste is not stored in BSC.			

	Decontamination and Waste Handling			
	All contaminated materials are decontaminated before disposal or removal from the laboratory.			
	All gross contamination to be removed prior to decontamination of surfaces and equipment.			
	Effective products are used for the decontamination of equipment, samples, surfaces and spills of infectious materials.			
	Is there an autoclave in the containment zone? Is there an SOP for transfer of waste from lab to autoclave?			
	Autoclave efficiency is monitored with biological indicators. Monitoring must be documented.			
	An autoclave logbook must be maintained.			
	Sufficient disinfectants effective against infectious materials in use are available at all times within the laboratory.			
	Biohazard autoclave bags are available.			
	All solid biological waste is placed in biohazard autoclave bags and autoclaved.			
	Contaminated liquids to be decontaminated prior to release to sanitary sewers.			
	Sharps to be discarded in containers that are leak-proof, puncture-resistant, and fitted with lids, or specially constructed for the disposal of sharps waste.			
	Primary containment devices to be decontaminated prior to maintenance			
	All clothing and personal protective equipment (PPE) to be decontaminated when a known or suspected exposure has occurred.			
	Emergency Response			
	Emergency procedures for spill cleanup, BSC failure, fire, and other emergencies are written and easily accessible.			
	All spills, accidents or exposures to infectious materials are documented and reported to the laboratory supervisor and the BSO.			
	An Emergency Plan is available to all laboratory personnel. This includes items such as emergency procedures, emergency numbers.			

Section E: Actions Required Resulting from Inspection				
#	Required Action	Priority	Action Taken	Completed

Signatures		
Completed by:	Title:	
Signature:	Phone #:	Date:

Principle Investigators: Please complete the above shaded sections and return to the BSO within 30 days of receiving the inspection report.

Priority A: action required immediately
Priority B: action required within 2 weeks
Priority C: action required within 30 days

Appendix B: Working with Human Blood

This document is being reviewed. Please contact Biosafety Officer.

Appendix C: New Biosafety Permit

New Biosafety Permit Application Form

Applicant Information	
Last Name (Print):	
First Name(Print):	
Department:	
Office Telephone Number:	
Laboratory Telephone Number:	
Email Address:	
Animal Welfare Protocol # (if working with animals)	

Information that is to accompany the Permit Application*	**Check**
Biosafety Plan (see Biosafety Plan Template)	☐
A list of individuals (authorized workers) who will be working under the permit	☐
Authorized Worker Biosafety Training Record for each authorized worker	☐

The information provided in this application and supporting documentation is complete and accurate to the best of my knowledge

Signature of **Applicant**: _____

Date:_____

Signature of the **Department Chair:** _____

Date: _____

The New Biosafety Permit application has been received with required supporting documentation

Signature of the **Biosafety Officer**: _____

Date:_____

*New Biosafety Permit applications will not be approved without the required supporting documentation.

Appendix D: Biosafety Permit Conditions

BIOSAFETY PERMIT CONDITIONS

1. The recipient of this Biosafety Permit shall comply with the Human Pathogen and Toxins Act (HPTA), Human Pathogen and Toxin Regulations (HPTR), Canadian Biosafety Standards, 2nd Edition (CBS), Canadian Biosafety Handbook (CBH) and the responsibilities and requirements outlined in the University of Lethbridge BCP. These documents can be found Campus Safety Services webpage.

TRAINING

2. The Biosafety Permit Holder shall ensure that all authorized personnel receive appropriate biosafety training and be made aware of the hazards involved when working with Risk Group 2 (RG2) pathogens. Supervision and mentorship should be included in the personnel training in order to assess the required skills needed.

3. Copies of training documentation shall be submitted to the Biosafety Safety Officer (BSO).

SIGNAGE

4. Point of entry of the laboratory must have biohazard warning signage. The sign must include the international biohazard warning symbol, containment level, name and telephone number of contact person, and entry requirements. Signage must be displayed on all secured storage units (i.e. freezers) outside the containment laboratory. Contact the BSO for signage details.

RECORDS

5. Copies of U of L Biosafety permit, compliance letters, import permits, training documentation and updated inventories of infectious material shall be maintained in the laboratory.

   Training records should be kept a minimum of 1 year after the individual has left the facility and minimum of 2 years for visitors who receive training.

INVENTORY

6. Up-to-date inventories shall be maintained for all RG2 material purchased under this permit. Annual inventory updates must be submitted to the BSO.

SPILLS, LOSS OR THEFT

7. In case of spill, loss or theft of biohazardous material the permit holder will contact and inform the Biosafety Officer immediately (403-332-4484 or 403-915-7225)

TRANSFER AND TRANSPORT OF BIOHAZARDOUS MATERIAL

8. Transfer or transport of RG2 material is prohibited without prior approval from the BSO.

PURCHASES OF RG2 PATHOGENS

All purchase requisitions for RG2 material shall include:

a) Biosafety Permit holder name or number
b) Authorized Permit holder or designate signature
c) The words “Biohazardous”
d) Authorization from the Biosafety Safety Officer

RECEIPT OF RG2 SHIPMENTS

9. All shipments of RG2 pathogens must be opened in a biosafety cabinet in the CL2 laboratory and then stored in a secure area. A copy of each RG2 shipment packing slip shall be kept with inventory records.

PERMIT AMENDMENTS

10. Request for amendments to this Biosafety Permit must be submitted in writing to the Biosafety Safety Officer.

Appendix E: Biological Safety Cabinets

At the U of L use of a biological safety cabinet (BSC) is required in CL2 laboratory. Biosafety cabinets are engineering controls to be used in conjunction with good microbiological practices. A BSC protects the investigator from potential infection and protects the experimental materials from contamination.

***Note: Most biosafety cabinets at the U of L are Class II type A* (Figure E-1).**

Class II-A BSC - These BSCs remove aerosolized biohazardous agents from the air in the cabinet via a highly-efficient particulate air (HEPA) filter and recirculate the filtered air back into the laboratory, therefore they do not require hard-ducting. However, because they return the filtered air back into the laboratory, they are inappropriate for combined projects involving biohazardous agents with chemicals, anesthetics or radioactive isotopes that are volatile in nature.

Figure E-1: Biological safety cabinet. The picture shows an example of a class II-A cabinet, which does not have a hard-ducted exhaust system. The front sash has an optimal height setting to minimize disruption of the protective air curtain at the front of the work area. Moving the sash higher than this optimum setting will cause the cabinet to alarm.

For additional information on the various classes of BSC and their description please refer to Chapter 11 of the CBSG 1st Edition.

1. **Planning and Organization:**
   - Laboratory personnel must be trained in the correct use and maintenance of BSC.
   - Prepare a written checklist of materials necessary for a particular activity prior to starting work.
   - Have protocols written out and accessible.
   - To minimize the in-and-out motions that could affect the protective barrier of the BSC, determine which materials should be placed in the BSC and which materials should be placed outside.
   - Ensure that the BSC you are working with is appropriate for your protocols. For instance, if you are working with radioisotopes or volatile chemicals, ensure that you have selected the correct BSC type.

2. **Required Personal Protective Equipment**
   - The operator should wear a lab coat and if hazard assessment requires a closed-front over garment (e.g. surgical gown with full-length sleeves)
   - Gloves (latex or vinyl gloves) must be worn when working in a BSC. The use of a bare hands is not advised.
   - Gloves should overlap the cuffs to ensure that aerosols do not contaminate the hands, arms and surfaces.

3. **BSC start up procedure:**

   The following start up procedures must be followed whenever starting to work in a BSC.

   - The use of an open flame within a BSC is prohibited. Flames disrupt the airflow, thereby potentially causing release of biohazardous agents from the cabinet or contamination of research within the cabinet, and may also damage the cabinet's HEPA filter.
   - If a UV light is being employed, turn it off first. These lights have been proven to be an ineffective method of decontamination, and their use is not recommended by the IBC. UV lights may be used to supplement, but not replace, chemical decontamination of the work surfaces and equipment.
   - Turn on the BSC and open the sash to the appropriate sash height
   - Cabinet blowers should be operated at least ten to fifteen minutes before beginning work to allow the cabinet to "purge". This purge will remove any particulates in the cabinet.
   - Ensure that nothing is blocking the front grilles
   - The work surface, the interior walls (not including the supply filter diffuser), and the interior surface of the window should be wiped with one of the following:
     - 70% ethanol (EtOH)
     - 1:10 dilution of common household bleach (i.e., 0.5% sodium hypochlorite)
     - other disinfectant as determined by the investigator to meet the requirements of the particular activity

Note: When bleach is used, a second wiping with sterile water or 70% EtOH is needed to remove the residual chlorine, which may eventually corrode stainless steel surfaces. Wiping with non-sterile water may re-contaminate cabinet surfaces, a critical issue when sterility is essential (e.g., maintenance of cell cultures).

4. **While working in a BSC:**

After the BSC has been sufficiently purged and decontaminated, the following practices should be employed to maintain product, personnel and environment protection.

Arm Movements:

- Avoid disruption of the air curtain at the front of the BSC.
- Once hands/arms are placed inside the cabinet, manipulation of materials should be delayed for approximately one minute. This allows the cabinet to stabilize and to "air sweep" the hands and arms to remove surface microbial contaminants.
- Move arms in and out slowly, perpendicular to the face opening of the cabinet
- Ensure that rapid arm movements in sweeping motions are minimized. This movement will disrupt the air curtain and may compromise the partial barrier containment that is provided by the BSC.

Front Grille:

To ensure that the BSC can provide proper product, personnel and environment protection, it is important that the front grilles are not blocked.

- Raise arms slightly to ensure that arms are not resting on the grille.
- Ensure other items are not blocking the grille (i.e., protocols, pipettes etc.)
- Perform operations as far to the rear of the work area as possible.

Placement of materials inside the BSC:

Materials or equipment placed inside the cabinet may cause disruption to the airflow, resulting in turbulence, possible cross-contamination, and/or breach of containment.

- The surfaces of all materials and containers placed into the cabinet should be wiped with 70% EtOH to reduce the introduction of contaminants to the cabinet environment. This simple step will reduce introduction of mold spores and thereby minimize contamination of cultures.
- Only the materials and equipment required for the immediate work should be placed in the BSC.
- Extra supplies (e.g., additional gloves, culture plates or flasks, culture media) should be stored outside the cabinet.
- Active work should flow from the clean to contaminated area across the work surface.

Microbiological Techniques:

- Good microbiological techniques should always be used when working in a biological safety cabinet. For example, techniques to reduce splatter and aerosol generation will minimize the potential for personnel exposure to infectious materials manipulated within the cabinet.

- Keep clean materials at least one foot away from aerosol-generating activities. This will minimize the potential for cross-contamination.
- The general work flow should be from "clean" to "dirty" (contaminated). Materials and supplies should be placed in such a way as to limit the movement of "dirty" items over "clean" ones.
- Opened tubes or bottles should not be held in a vertical position. Investigators working with Petri dishes and tissue culture plates should hold the lid above the open sterile surface to minimize direct impaction of downward air.
- Bottle or tube caps should not be placed on the toweling.
- Items should be recapped or covered as soon as possible.

Biohazard bags and other waste containers:

The frequent inward/outward movement needed to place objects in biohazardous bags and pipette collection trays is disruptive to the integrity of the cabinet air barrier and can compromise both personnel and product protection. The following describes specific practices to use when working with either of these items:

a) **Biohazard bags:**

- Typically used when contaminated waste is going to be autoclaved.
- If the bag contains material that could leak, it is recommended to double bag
- The bag should be placed to one side of the interior of the cabinet and not taped to the outside of the cabinet.
- Water should be placed within the bag to allow steam to be generated during the autoclave cycle if the bag contains dry waste.
- Materials that are contaminated must be placed into the bag and the bag must be sealed prior to it being removed from the cabinet.
- The bag should be transported and autoclaved in a leak proof tray or pan.

b) **Discard trays or pans:**

- Only horizontal pipette discard trays or pans should be used within the cabinet. Upright pipette collection containers should not be used in BSC‟s nor placed on the floor outside the cabinet.
- Practices to use when discard trays and pans are decontaminated using chemical disinfectants:
    - Discard pipette trays should be placed to one side of the interior of the cabinet.
    - Items should be introduced into the pan with minimum splatter, and allowed appropriate contact time as per manufacturer's instructions.
    - The discard pan should be covered and surface decontaminated in the BSC prior to removal out of the cabinet.

Absorbent Toweling:

- Plastic-backed absorbent toweling can be placed on the work surface (but not on the front or rear openings). This toweling facilitates routine cleanup and reduces splatter and aerosol formation during an overt spill. It can then be folded and placed in an autoclavable biohazard bag when work is completed.

Aerosol generating equipment:

- Aerosol-generating equipment (e.g., vortex mixers, tabletop centrifuges) should be placed toward the rear of the cabinet to take advantage of the air split that occurs in the BSC. The downward moving air "splits" as it approaches the work surface; the blower draws part of the air to the front grille and the remainder to the rear grille.

Open Flames:

- The use of an open flame within a BSC is **prohibited**. Open flames create turbulence that disrupts the pattern of air supplied to the work surface. When deemed absolutely necessary, touch-plate micro-burners equipped with a pilot light to provide a flame on demand may be used. Internal cabinet air disturbance and heat buildup will be minimized. The burner must be turned off when work is completed. Small electric "furnaces" are available for decontaminating bacteriological loops and needles and are preferable to an open flame inside the BSC. Disposable sterile loops can also be used.

Aspirator bottles or suction flasks:

- Aspirator bottles or suction flasks should be connected to an overflow collection flask containing appropriate disinfectant, and to an in-line HEPA or equivalent filter. The flasks and aspirator bottles, if kept in the BSC, must be kept to one side of the cabinet. This combination will provide protection to the central building vacuum system or vacuum pump, as well as to the personnel who service this equipment. Inactivation of aspirated materials can be accomplished by placing sufficient chemical decontamination solution into the flask to kill the microorganisms as they are collected. Once inactivation occurs, liquid materials can be disposed of appropriately as non-infectious waste.

Power Failure while working in the BSC:

When a power failure occurs while you are working in the BSC, the following procedures must be employed:

- Seal all open containers.
- Dispose of gloves within the BSC.
- If the BSC has a movable sash, bring it down to the closed position.

5. BSC shut down procedures:

After work is completed in the cabinet, the following procedures should be followed:

- Allow the cabinet to run for 5 minutes with no activity.
- All containers and equipment should be surface decontaminated prior to removal.
- Remove gloves and dispose of them as appropriate. Wash your hands.
- Put on clean gloves and ensure that all contaminated materials have been appropriately disposed of in the biohazardous bag or discard tray. Seal and surface decontaminate biohazardous bags and waste containers prior to their removal.
- Decontaminate the work surface using an appropriate disinfectant (ie. 70% EtOH)
- At the end of the workday, the final surface decontamination of the cabinet should include a wipe-down of the work surface, the cabinet's sides and back, and the interior of the glass.
- Remove gloves and gowns and wash hands.

6. Installation and Certification of BSCs

The correct location, installation, testing and certification of biological safety cabinets are critical to its performance in containing aerosols.

- BSC must be certified upon initial installation, annually, and after any repairs or relocation. Certification to include verification of correct operation by *in situ* testing in accordance to the NSF/ANSI 49 standard or when not applicable to manufactures specifications. (CBSG Part I 4.6.15)
- Certification should be done by trained service personnel who adhere to the standard.
- If a BSC needs to be moved or disposed of it needs to be “appropriately decontaminated” to reduce the potential exposure to biohazardous material. Contact the BSO before moving a Biological Safety Cabinet.
- If you require assistance to determine the appropriate type or placement of a BSC contact the BSO.

Appendix F: Biohazardous Agent Transfer Notification

Biohazardous Agent Transfer Notification

Supplier Information		**Recipient information**	
Name of Institution or Facility Click here to enter text.		**Name of Institution or Facility** Click here to enter text.	
Street Address Click here to enter text.		**Street Address** Click here to enter text.	
City Click here to enter text.		**City** Click here to enter text.	
Prov. Click here to enter text.	**Postal Code** Click here to enter text.	**Prov.** Click here to enter text.	**Postal Code** Click here to enter text.
Description and Risk Group of Material Transferred Click here to enter text. ☐ **Human Pathogen** ☐ **Human tissues/cells/bodily fluids** ☐ **Animal Pathogen** ☐ **Plant Pathogen** ☐ **Aquatic Animal Pathogen**		**Building(s) and room number(s) where material will be used and/or stored.** Click here to enter text.	
Registration Number Click here to enter text. **Internal Permit Number** Click here to enter text.		**Registration Number** Click here to enter text. **Internal Permit Number** Click here to enter text. Is the recipient lab in compliance with e institutional biosafety program and able to safety handle ansd store the transferred materials ☐ Yes ☐ No	
Supplier Signatures		**Recipient Signature**	
Name of Supplier Click here to enter text.		**Name of Recipient** Click here to enter text.	
Signature of Supplier		**Signature of Recipient**	
Biosafety Officer Name Click here to enter text. **Biosafety Officer Phone #**Click here to enter text.		**Biosafety Officer Name** Click here to enter text. **Biosafety Officer Phone #**Click here to enter text.	
Signature of Biosafety Officer		**Signature of Biosafety Officer**	

Appendix G: Category of Chemical Decontaminants Information

Category of Chemical Decontaminants Information

(Adapted from Concepts in Biosafety; Office of Environmental Health & Safety, University of Alberta)

Category:	Quaternary ammonium detergent
Trade Name:	Roccal™, OstroSan™
Working Concentration:	0.4 - 0.8% (v/v)
Mixing:	4 - 8 ml stock / liter water
Contact Time (min):	30

Notes - quaternary ammonium compounds:

- solution is bacteriocidal, fungicidal and virucidal (on lipophilic viruses only)
- NOT effective against tuberculosis or bacterial spores
- concentrated stocks very injurious to eye; wear eye protection when diluting

Category:	alcohol
Trade Name:	ethanol or isopropanol
Working Concentration:	70% (v/v)
Mixing:	700 ml alcohol + 300 ml of water
Contact Time (min):	30

Notes - 70% alcohol:

- no residue, not corrosive
- is slow acting, may evaporate from surface before disinfection is complete
- is flammable
- effective on vegetative bacteria and lipid viruses; less effective on non-lipid viruses;
- NOT effective on bacterial spores

Category:	Bleach (household)
Trade Name:	Chlorox™, Javex™ (5.25% hypochlorite)
Working Concentration:	0.5% (w/v) hypochlorite for routine use or 3.0 % (v/v) hypochlorite for bacterial spores
Mixing:	100 ml stock + 900 ml water or 600 ml stock + 400 ml water (spores)

Contact Time (min):	30

Notes - bleach

- household bleach is about 5% (w/v) sodium hypochlorite; can get a 12% stock so should adjust your dilution to get the appropriate working concentration.
- a strong oxidizer; avoid mixing with other chemicals
- produces free chlorine in solution, is corrosive on metals. Wash area with soap/water after bleach has been removed
- working solutions must be made fresh (daily); diluted stock quickly loses it's activity
- unopened stock bottle probably good for 6 months. Label date received and expiry date
- very effective disinfectant against many biohazards: bacteria (vegetative and spores), lipid and non-lipid viruses
- need high concentrations to kill tuberculosis bacteria and bacterial spores (use a 60% (v/v) solution of household bleach)
- chlorine binds to proteins so if have a lot of protein in your samples (e.g. blood or cells grown in fetal calf serum), may need to use a higher concentration than 10% (v/v)
- should not autoclave bleach solution as chlorine gas may be released from the autoclave.
- also available in tablet form called Presept™, dissolve in water and use. Presept is manufactured by Johnson&Johnson and may be available from a medical, dental or veterinary supply dealer.

Category:	Iodine
Trade Name:	Wescodyne™
Working Concentration:	0.45% iodine in solution *or* 2.5% (w/v) for bacterial spores
Mixing:	4.5 ml / liter water *or* 25 ml stock + 975 ml of 50% (v/v) ethanol in water (for spores)
Contact Time (min):	30

Notes - iodine

- similar biocidal activity as chlorine
- not as corrosive as chlorine

Category:	phenolics
Trade Name:	Dettol ™ , Lysol™ (5-7% phenols)

Working Concentration:	0.1-0.3% (w/v) of active ingredient
Mixing:	10 - 50 ml stock / liter water
Contact Time (min):	30

Notes - phenolics

- compounds are derivatives of phenol
- effective against some lipid viruses, ricekettsia, fungi, vegetative bacteria **and** tuberculosis
- **NOT** effective against bacterial spores and non-lipid viruses
- unpleasant odor, leaves sticky residue
- concentrated stocks very injurious to eye; wear eye protection when diluting

Category:	chemical cocktail
Trade Name:	Super-Phen Plus™
Working Concentration:	0.63% (v/v)
Mixing:	check manufacturer's recommendation
Contact Time (min):	30

Notes - Super-Phen Plus™

- broad spectrum chemical mixture
- effective on most biohazards including tuberculosis and bacterial spores
- could be a good choice for a spill cleanup disinfectant because it is broadly effective

Category:	glutaraldehyde
Trade Name:	Cidex™
Working Concentration:	2% (w/v) glutaraldehyde in water
Mixing:	check manufacturer's recommendation
Contact Time (min):	30

Notes - glutaraldehyde :

- kills bacteria (vegetative and spores) and viruses (lipid and non-lipid)
- solution is irritating to nose, eyes and skin
- can cause skin sensitization, liver damage and has a low exposure limit to people
- less toxic than formaldehyde
- a glutaraldehyde solution is stable for a long time but is not microcidal until the solution is 'activated' by adjusting the pH to ~7.7 with sodium bicarbonate.

- after activated, the solution is useful for 7 – 18 days depending on the formulation

Category:	formaldehyde
Trade Name:	formalin (37% formaldehyde (w/v) in water)
Working Concentration:	0.2 - 8% formaldehyde in water
Mixing:	5 - 220 ml of 37% stock / liter of water
Contact Time (min):	30

Notes - formaldehyde :

- effective biocidal agent but difficult to handle
- very toxic, a carcinogen, a respiratory irritant
- formaldehyde is a gas; usually used as a solution called formalin (37% w/w formaldehyde + 12% methanol)
- also available as a solid (paraformaldehyde) which releases formaldehyde gas when heated. This is how biohazard cabinets are decontaminated by a trained technician.
- formalin is unlikely to be a good choice for cleaning up a spill in an open lab but it might be used to treat material in a sealed container

Appendix H: Biohazardous Waste Disposal Guide

Biohazardous Waste Disposal Guidelines

- All biohazardous waste must be appropriately decontaminated before disposal.
- Material with radioactive or chemical residues should not be autoclaved.
- Contact Risk and Safety Services http://www.uleth.ca/risk-and-safety-services before generating mixed waste (i.e. *contaminated with biological and radioactive or chemical residues*).

Items to be Disposed		Collection Method	Decontamination	Disposal
Solids e.g. Petri Dishes, Plastic culture flasks, bench coat, gloves 	Place items with biological contamination only	Place in plain clear autoclave bags, close with biohazard logo tape	Autoclave minimum 1 Hr @ 121 C Add autoclave tape to bag as indication of decontamination status	Remove Biohazard Logo Tape after autoclaving. After autoclaving place biohazard bags in dark garbage gags and dispose in domestic garbage.*.
Biomedical Sharps, e.g. All needles, syringes, scalpel, razor blades 	Radioactive Contamination Only	Dispose of into a rigid, puncture resistant, container with a secure lid. Label the hazard appropriately.	None	Radioactive contaminated sharps need to be disposed as radioactive waste.
	Chemical Contamination Only		None	Dispose of as Hazardous Waste http://www.uleth.ca/risk-and-safety-services
	Biological Contamination Only	Dispose of into an approved, autoclavable appropriately labeled sharps container	Add autoclave tape to container as indication of decontamination status. Autoclave Minimum 1 Hr @ 121 C	Remove autoclave tape and dispose of in Sharps disposal box. (GM Pearson Biomedical Waste box)
Glass and other sharps e.g. pipettes, test tubes, flasks	Biological contamination	Dispose of into an approved, autoclavable appropriately labeled sharps container	Add autoclave Tape to container as indication of decontamination status. Autoclave minimum 1 Hr @ 121 C	Dispose of in designated cardboard glass disposal boxes.
Liquids	Biological Contamination Only - **No chemical or radioactive hazards**	Collect in a reusable autoclavable container. Label with Biohazard LogoTape / Autoclave tape.	Autoclave 1Hr @-121 C or decontaminate with a proven chemical method.	Dispose to sewer with copious amounts of water

Appendix I: Post Exposure Procedure

University of Lethbridge

Safety Services

POST EXPOSURE PROCEDURE

Exposure protocol applies to puncture wounds due to contaminated needles or sharp instrument, a splash of blood/body fluids, hazardous chemicals or biological agents into the eyes, mouth or non-intact skin, bites and/or scratches

1. Get immediate **First Aid**

2. **For needle stick injuries or sharps:**
   - Encourage bleeding of injury.
   - Cleanse the site by washing with soap and water.
   - Cover injury with sterile dressing or bandage.
   - Consult PSDS/MSDS if required.

3. **For eye/mouth/nose splash:**
   - Flush with water for 15 minutes.
   - Consult PSDS/MSDS if required.

4. Contact Supervisor and report incident.

5. Seek medical attention immediately for evaluation care. Information which will be useful to the health care professional:
   - Copy of the PSDS/MSDS
   - the description of employee's job duties,
   - route of exposure
   - circumstances of exposure
   - vaccination status

6. Report any incident through the CAIR (Campus Accident Incident Report).

Appendix J: Chemical Release Response Guidelines

If a chemical release occurs in your area, you must determine whether it can be handled locally or if it requires the attention of the Chemical Release Officer (CRO). If you are unsure, or if the release is significant (see guidelines below) call Security (2345) and they will contact the CRO.

Response Guidelines by Class:

1) Highly Flammable Liquids – fire and explosion hazard

This would include most organic solvents: diethyl ether, methylene chloride (dichloromethane), methanol, acetone, acetonitrile, tetrahydrofuran, ethyl acetate, ethanol, petroleum ether, toluene, xylenes and others. **Any spill of more than 500 mL requires the immediate attention of the CRO.** If spill pillows are available, try to contain and absorb the spill. It is critical than any local ignition sources – flames or electrical contacts – be shut down. The area should be evacuated in case of an explosion.

2) Flammable and Nonflammable Organic Liquids – toxicity hazard

This would include less volatile or nonflammable solvents like chloroform, carbon tetrachloride, dimethyl sulfoxide, dimethyl formamide and high boiling organic specialty chemicals**. Any spill of 1 L or more requires the attention of the CRO.** Evacuate the area.

3) Acids and Bases – Corrosion Hazard

Acids would include hydrochloric acid, hydrobromic acid, glacial acetic acid, nitric acid, sulfuric acid and phosphoric acid, concentrated or solutions of 1 M or greater. Bases would include sodium or potassium hydroxide, calcium oxide, etc. Any spill in excess of 500 mL liquid or 500 g solid requires the attention of the CRO. Small spills may be cleaned up by local personnel if they have the necessary expertise and materials. Otherwise, have security call the CRO.

ALL HYDROFLUORIC ACID SPILLS REQUIRE THE IMMEDIATE ATTENTION OF THE CRO. ANY PERSONS SPLASHED WITH HF OR HF LIBERATORS REQUIRE IMMEDIATE MEDICAL ATTENTION.

ALL PERCHLORIC ACID SPILLS REQUIRE THE ATTENTION OF THE CRO.

4) Mercury

Local personnel can clean up mercury spills if they have the necessary equipment and expertise. **Spills in excess of 30 mL require the attention of the CRO.**

5) Oxidizers – reactivity, toxicity hazards

This would include potassium permanganate, dichromate and chromate salts, chromium oxide and chromium based oxidants. **Spills in excess of 500 mL liquid or 250 g solid require the attention of the CRO.**

6) Highly Toxic Materials

This would include bromine, cyanide and sulfide salts, mutagenic organic halides (benzyl halides, allylic halides, haloethers), phosphines etc. **Spills of more than 100 mL liquid or 50 g solid require the attention of the CRO.**

7) Low Hazard Materials

Pump oil, alkali salts, sand etc. – materials that are not toxic or flammable. These can usually be dealt with by local personnel. When in doubt, contact the CRO.

8) Air and Water Reactive Materials

This includes hydrides (sodium borohydride, lithium aluminum hydride, calcium and sodium hydride), calcium carbide, all alkali metals (lithium, sodium, potassium). It also includes solutions of organometallics (Grignards, alkyllithium reagents, DIBAL and other hydride reducing solutions). **All such spills require the attention of the CRO.**

9) Compressed Gas Leaks

Gas leaks can be detected by sound or by applying leak solutions (Snoop or soapy water) and observing bubbles. Leaks downstream of the main tank can be stopped by closing the cylinder valve off. If the main valve is not operating, call Security.

Leaks of flammable gases such as acetylene, hydrogen and natural gas present significant explosion hazards – call Security and evacuate the area.

For leaks of toxic gases (carbon monoxide, hydrochloric acid, chlorine, fluorine, the nitrogen oxides, ammonia etc.) and oxygen, where the tank is not in a ventilated enclosure, call security and evacuate the area.

Leaks of inert gases (nitrogen, carbon dioxide, helium, argon etc.) can usually be dealt with by local personnel. When in doubt, contact the CRO.