UNIVERSITY OF ALBERTA
RISK MANAGEMENT SERVICES

Environment, Health & Safety

Biosafety Guidelines

for use and storage of biological materials

Version 2.0

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All other electronic or paper copies of the document may be out of date.

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List of Abbreviations

ABSA	Alberta Boilers Safety Association
AFDP	Agri-Food Discovery Place
AHS	Alberta Health Services
BSC	Biological safety cabinet
CBS	Canadian Blood Services
CCI	Cross Cancer Institute
CEPA	Canadian Environmental Protection Act
CESO	Chief Environmental Safety Officer
CFIA	Canadian Food Inspection Agency
CL-1	Containment Level 1
CL-2	Containment Level 2
CL-3	Containment Level 3
CL-4	Containment Level 4
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CSA	Canadian Standards Association
DFAIT	Department of Foreign Affairs & International Trade
DGR	Dangerous Goods Regulations
DNA	Deoxyribonucleic acid
EHS	Environment, Health & Safety
EIPA	Export & Import Permits Act
GMO	Genetically modified organism
HBV	Hepatitis B Virus
HAR	Health of Animals Regulation
HEPA	High-efficiency particulate air
HPTA	Human Pathogens & Toxins Act
HPTR	Human Pathogens & Toxins Regulations
HYRS	Heritage Youth Research Summer
IATA	International Air Transport Association
LAI	Laboratory Acquired Infections
LRT	Light rail transit
MSDS	Material safety data sheet
NINT	National Institute of Nanotechnology
PI	Principal Investigator
PHAC	Public Health Agency of Canada

PNT	Plant with novel traits
PPE	Personal protective equipment
ProvLab	Provincial Laboratories
PSDS	Pathogen safety data sheet
rcf	Relative centrifugal force
rDNA	Recombinant deoxyribonucleic acid
REMO	Research & Ethics Management Online
RG-1	Risk Group 1
RG-2	Risk Group 2
RG-3	Risk Group
RG-4	Risk Group 4
RMS	Risk Management Services
RNA	Ribonucleic acid
RSO	Research Services Office
SMS	Supply Management Services
SRM	Specified Risk Material
SSBA	Security sensitive biological agent
TA	Teaching assistant
TDG	Transportation of Dangerous Goods
U of A	University of Alberta
UV	Ultraviolet
VP	Vice-President
WHMIS	Workplace Hazardous Material Information System
WISEST	Women in Scholarship, Engineering, Science & Technology

CHAPTER 1: BIOSAFETY PROGRAM OVERVIEW

The University of Alberta (U of A) is a major centre for research involving biological materials. There are over 450 research and/or teaching groups registered with the University's Biosafety Program as working with one or more types of biological materials. The Biosafety Program operates out of the University's Environment, Health and Safety (EHS) office with oversight provided by the institutional Biosafety Committee and Risk Management Services (RMS).

Many biological materials are not considered hazardous to humans but the classification of a material as biohazardous takes into account much more than just its effect on humans. Essentially, any biological material may be considered biohazardous if it is potentially harmful to any other organism or the environment. Biohazardous materials include the obvious pathogenic microbes (e.g., bacteria, fungi, viruses, eukaryotic parasites) that can cause disease in humans, animals and plants as well as biological toxins and venoms, clinical specimens, recombinant DNA (rDNA) constructs, positive sense RNA and some eukaryotic cells lines. In addition to these, plant, animal and insect species not indigenous to Alberta are considered biohazardous to our local environment. Therefore, not only must the hazardous nature of the biological material itself be taken into account but its source, origin and intended use comes into play. The Biosafety Program's primary goal is to provide guidance, support and tools for research, teaching and testing personnel to help them protect people and the environment from the biohazardous materials they use, store or generate.

The Biosafety Program supports teaching laboratories, peer-reviewed, grant-funded research and faculty or departmentally operated core facilities that use biological materials as part of their programs. These guidelines contain standardized procedures for the safe handling, storage and disposal of biological and biohazardous materials, basic biosafety regulatory requirements, and proper maintenance of common research and safety equipment. These guidelines are biosafety specific but also indicate how to connect to other relevant programs offered by EHS (i.e., hazardous waste collection, incident reporting, etc.). By following the contents of these guidelines, groups will remain compliant with all applicable international, federal, provincial and municipal regulations. For research involving biohazardous agents that falls outside the scope of these guidelines, researchers must consult with the Biosafety Officers before work can begin. **Failure to do so leaves the research group and U of A open to liability and penalty in accordance with the relevant federal regulations.**

These guidelines are a "living" document; sections will be modified or replaced as biosafety regulations evolve and the scope of U of A research changes. The Biosafety Program page of the EHS website will always display the latest version of these guidelines.

1.1 Contacting the Biosafety Program

Environment, Health and Safety
3-107 Research Transition Facility
Edmonton, AB Canada T6G 2V2
E-mail: biosafety@ualberta.ca

For the most efficient response, contact the Biosafety Program via email at biosafety@ualberta.ca. Alternatively, consult the EHS website for individual email addresses and phone numbers.

1.2 Biosafety Legislation

The following legislation and regulatory bodies apply to research, teaching and testing programs involving biohazardous agents. These Guidelines were prepared in accordance with federal and international legislation. The complexity of the legislation highlights the importance for U of A groups to proactively contact the Biosafety Officers to review deviations from the contents of these Guidelines. Copies of the various Acts cited below are available from the website of the overseeing federal or international body, or can be obtained by contacting the Biosafety Officers.

1.2.1 Public Health Agency of Canada (PHAC)

The PHAC is the national regulatory authority for the administration and enforcement of the Human Pathogens and Toxins Act (HPTA, 2009), the Human Pathogen and Toxins Regulations (HPTR, 2015) and specific sections under the Health of Animals Regulations (HAR, 2006) regarding the safe handling, storage and disposal of human pathogens and toxins, and terrestrial animal pathogens. The PHAC Centre for Biosecurity issues licenses under the HPTR for facilities or institutions where pathogens and toxins affecting human and terrestrial animals are handled or stored. When applicable, the Centre for Biosecurity also conducts and issues security clearances for those who use or have access to security sensitive biological agents (SSBAs). The U of A holds institutional licenses under the HPTR on behalf of all U of A research groups that fall into this category and provide support and endorsement for specific personnel requiring a security clearance.

1.2.2 Canadian Food Inspection Agency (CFIA)

The CFIA is the national regulatory authority for the administration and enforcement of several pieces of legislation pertaining to the safety of food, animals and plants. The pieces of legislation that most affect the academic research community are the Health of Animals Act (1990), HAR, Fish Inspection Act (1985), Plant Protection Act (PPA, 1990), Seeds Act (1985) and Feeds Act (1985). The CFIA oversees the acquisition and safe use of animal by-products, pathogens and toxins that may affect plants, bees, aquatic animals and the food and livestock industries, and foreign animal diseases. The CFIA is responsible for issuing importation permits and compliance certification for facilities where these types of pathogens or toxins are handled or stored.

1.2.3 Environment Canada

Environment Canada administers the Canadian Environmental Protection Act (CEPA, 1999) and the New Substance Notification Regulations (NSNR, 2005) 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.

1.2.4 Department of Foreign Affairs & International Trade (DFAIT)

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.

1.2.5 Canadian Border Services Agency (CBSA)

The CBSA assists the DFAIT with the administration of the EIPA and ensures that imports and exports passing through Canadian border control points comply with the provisions of the EIPA. The agency also ensures that imported human and animal pathogens arriving at Canadian points of entry comply with the HPTR and HAR.

1.2.6 Transport Canada

Transport Canada administer the federal 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 substance be trained and certified. Transport Canada also ensures that international shipments of infectious substances leaving Canada comply with the regulations of the International Air Transport Association's (IATA) Dangerous Goods Regulations (DGR).

1.3 Researcher Code of Conduct

The ability to conduct research on the U of A campuses with its administrative and safety support is a privilege extended to all its research, teaching and testing groups. In return, all staff and students are required to adhere to pertinent regulations and health and safety requirements in order to protect the University's personnel, infrastructure, federal certifications and reputation. All members of U of A groups working with biohazardous agents who are expected to conduct independent research activities (including, but not limited to, the principal investigators (PIs), research associates, technical staff, post-doctoral fellows, visiting

scientists, graduate students, undergraduate students and summer students) must read and abide by the contents of these guidelines. 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 these personnel must complete the institutional Concepts in Biosafety eLearning course offered through EHS (Section 1.6.7) and all pertinent sections of these Guidelines should be used as part of the individual's project-specific training.

If U of A groups or personnel are found to be in noncompliance with these biosafety guidelines, a notification of noncompliance with recommended corrective actions will be issued.

Groups that repeatedly ignore the contents of these Guidelines will receive a notification of noncompliance, copied to their Department Chair, the Chief Environment, Health and Safety Officer (CESO) and Institutional Biosafety Committee. 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 Biosafety Officer will freeze the group's research funds through the Research Services Office (RSO) on the grounds the group is in breach of the expectations of its funding agency to conduct research in a safe manner. Funding will not be reinstated until it has been demonstrated to the satisfaction of the Biosafety Officer that the non-compliance issues have been resolved.

Note: While the primary goal of the Biosafety Program and EHS is to advise and support research and teaching activities, the Biosafety Officers and EHS personnel maintain the right to immediately stop any work practice or behavior that presents an immediate danger to personnel, infrastructure or the environment.

1.4 Research Locations

1.4.1 U of A operated facilities

The U of A Biosafety Program supports research, teaching and testing laboratory facilities on the North, South and Augustana campuses, as well as at Campus Saint-Jean with the following buildings covered on the institutional HPTR license:

Table 1-1: HPTR licensed locations

Building Name	Campus Location
Agriculture/Forestry Centre	North Campus
Agri-Food Discovery Place	South Campus
Augustana Classroom Building	Augustana Campus
Biological Sciences Building	North Campus
Brain & Aging Research Building	North Campus
Centennial Centre for Interdisciplinary Science	North Campus
Chemical & Materials Engineering Building	North Campus
Clinical Sciences Building	North Campus
College Plaza	North Campus
Corbett Hall	North Campus
Earth Sciences Building	North Campus
Electrical & Computer Engineering Research Facility	North Campus
Gunning/Lemieux Chemistry Centre	North Campus
Heritage Medical Research Centre	North Campus
Katz Group-Rexall Centre for Pharmacy & Health Research	North Campus
Li Ka Shing Centre for Health Research Innovation	North Campus
Markin/CNRL Natural Resources Engineering Facility	North Campus
McMahon Building	Campus Saint-Jean
Medical Sciences Building	North Campus
National High Field Nuclear Magnetic Resonance Centre	North Campus
National Institute for Nanotechnology (5^{th} and 6^{th} floors only)	North Campus
Research Transitions Facility	North Campus
South Academic Building	North Campus

1.4.2 Spin-off Companies

Start-up or spin-off companies that intend to commercialize a product, technology or business model that originated from academic research activities are encouraged and supported at the U of A. These companies are separate entities that have specific agreements to operate at the U of A that includes a commitment to the U of A's health and safety programs. Therefore, these companies are included in the Biosafety Program and if a spin-off company is conducting activities that require an HPTR license, the company will be

required to sign a Third Party Biosafety Sublicense Agreement and will be included under the U of A's institutional HPTR license.

1.4.3 Field Research

A significant amount of research conducted by U of A personnel occurs away from the University's campuses at field locations across Canada and the around world. Hazard assessment matrices for field research are available on the Field Research Office website.

1.4.4 Other Research Locations

There are also several locations on or near the North Campus that are not owned and operated by the U of A yet frequently used by U of A personnel. These areas are not within the Biosafety Program's jurisdiction. In some cases (as noted below), an agreement exists between the U of A and the neighboring organization that allows for limited biosafety support services to be provided by the U of A Biosafety Officers. Regardless of any agreement in place, any U of A personnel conducting research activities in these locations are required to learn and follow the health and safety requirements of the organization responsible for the building. The locations that this applies to are:

a. **Alberta Health Services (AHS) Medical Facilities** – AHS owns and operates the U of A hospital and medical facilities located on North Campus. AHS is responsible for acquiring and maintaining their certifications and HPTR license(s) as required. The U of A has an agreement in place that allows for the collaboration between the U of A and AHS biosafety programs as necessary to support any cross-appointed U of A personnel who work in AHS controlled facilities. The AHS locations are:

   - **Cross Cancer Institute (CCI)** – The CCI has a fully independent biosafety program.
   - **Kaye Edmonton Clinic** – The Kaye Edmonton Clinic is mainly comprised of AHS clinical space with the exception of the eighth floor which has been leased to the U of A Department of Dentistry. The operation of the Department's dentistry clinic must abide by the U of A Biosafety Program and any research or clinical studies involving biohazard agents must be registered with the U of A Biosafety Program.
   - **Mazankowski Alberta Heart Institute** – A primarily clinical facility that does not currently house any regulated biohazardous research activities.
   - **Walter C. Mackenzie Health Sciences Centre** – This building is home to several clinical facilities as well as the **Provincial Laboratories (ProvLab)** where both diagnostic and research activities are conducted. The support of the U of A Biosafety Program at this location includes issuing Letters of Biohazard Approval (Section 1.6.4) as required for the release of grant funds administered by the Research Service Office (RSO).

b. **Canadian Blood Services (CBS)** – The CBS building is independently owned and operated. The CBS holds its own HPTR license for the 3rd floor research area. The U of A has an agreement in place that allows for the collaboration between the U of A and CBS

biosafety programs as necessary. The support from the U of A Biosafety Program includes issuing Letters of Biohazard Approval (Section 1.6.4) as required for the release of grant funds administered by the RSO or CBS. As part of this agreement, U of A PIs working at this location must register with the U of A biosafety program and a copy of their Registry will be provided to the CBS for record keeping purposes.

c. **Enterprise Square** – Owned by U of A and located in downtown Edmonton, Enterprise Square contains laboratory space for private research and technology companies. These laboratories are leased and administered by TEC Edmonton which has its own health and safety program.

d. **National Institute of Nanotechnology (NINT)** – Floors 1 through 4 and the basement levels of NINT are operated by the National Research Council (NRC). The NRC has indicated that any research group conducting activities that fall under the requirements of the HPTR will be expected to get their own HPTR license; the NRC is not applying for an institutional license to support the building.
Note: The U of A does operate the 5th and 6th floors. Any applicable research conducted on these floors is supported by the U of A Biosafety Program

1.5 Biological and Biohazardous Materials & Activities

Any use or storage of biological or biohazardous materials must be formally registered with the Biosafety Program and declared on the Biosafety Registry for the individual responsible for the material. The following descriptions outline the most common types of materials and activities that must be declared to the Biosafety Program:

1.5.1 Pathogenic Microbes

Pathogenic microbes are self-replicating organisms that can cause infectious disease in humans, animals or plants. Pathogenic microbes include bacteria, viruses, prions, fungi and eukaryotic parasites. The HPTR licensing requirements apply to work with or storage of human pathogens classified as risk group 2 (RG-2) or higher. 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 (for definitions of the various risk groups see Section 2.1).

1.5.2 Eukaryotic Cell Lines

Eukaryotic cell lines include primary and immortalized cell lines many of which are considered biohazardous due to the presence of a pathogenic agent known to be present in primary cell source material or lysogenic viruses that were used to create the immortalized cell line. If a cell line is classified as RG-2, the HPTR licensing requirements apply.

1.5.3 Biological Toxins

Biological toxins are microbe, plant, animal or insect derived poisonous substances which are not capable of self-replication but can cause adverse health effect in humans and/or animals. This category includes lipopolysaccharides isolated and purified from Gram negative

bacteria, as well as insect and animal venoms.

- **Security Sensitive Biological Agents (SSBAs)** - A subset of biological toxins are considered SSBAs due to the potential for misuse with malicious intent. If a PI or research group is in possession of amounts exceeding the published, acceptable trigger quantities, these specific toxins (Table 1-2) have increased handling and security requirements imposed by the PHAC.

Table 1-2: Security Sensitive Biological Agents (SSBAs) and trigger quantities*

Agent/Toxin	Trigger Quantity
Alpha toxin	5 mg
Botulinum neurotoxin	0.5 mg
Cholera Toxin	20 mg
Clostridium botulinum C2 & C3 toxins	5 mg
Clostridium perfringens Epsilon toxin	5 mg
Hemolysin	10 mg
Shiga-like toxin (verotoxin)	1 mg
Shigatoxin	1 mg
Staphylococcus enterotoxins, Type B	1 mg
Staphylococcus enterotoxins, other than Type B	10 mg
Staphylococcus aureus Toxic Shock Syndrome toxin	5 mg

*Taken from http://www.phac-aspc.gc.ca/lab-bio/regul/ssba-abcse-eng.php February 2016

1.5.4 Human Clinical Specimens & Body Fluids

Human clinical specimens include all biological samples derived from human donors including tissue biopsies, blood, saliva, urine and feces. Human clinical samples from the general public are exempt from the HPTR licensing requirements. However, if the samples are known to be derived from case-confirmed infected individual(s) and/or the downstream processing includes the isolation and culturing of a potential pathogen present in the sample, then HPTR licensing does apply.

1.5.5 Animal Specimens

Animal specimens include all biological specimens including tissue, blood, saliva, urine and feces. For the purposes of these guidelines, insects and fish species are included as animal specimens.

1.5.6 Genetic Modification

Recombinant DNA (rDNA) technologies are used for the study of a wide variety or cellular processes in vitro and can also be used to modify microbes, insects, animals (i.e., transgenic animals) and plants (i.e., Plant with Novel Traits; PNT) for the creation of genetically modified organisms (GMOs). Two commonly used systems for genetic modification experiments include:

- **Viral-based recombinant vector systems** – Many commercially available transfection vector systems and transduction particles are based on genetic backbone material from RG-2 human and animal viruses such as, adenovirus, lentivirus, reovirus, baculovirus and vaccinia. In spite of the safety features engineered into third or fourth generation products which render them attenuated and replication deficient, the federal regulators still consider many of these products biohazardous RG2 materials.
- **CRISPR/cas-9 system** – The CRISPR/cas-9 system is a new, highly effective, efficient and flexible genome editing tool. Due to its high efficiency for altering the genetic make-up of a cell and some of the unknowns regarding its long term stability and safe usage, any activities using this system must be treated as potentially biohazardous and follow additional specific guidelines posted on the Biosafety Program page of the EHS website.

Any experiments involving genetic modification must be carefully evaluated to determine if there are any increased associated risks (see Section 2.3 Assessment of Activities or Manipulations Involving Biological Materials).

1.5.8 Isolated Viral Genetic Material

Intact genetic material isolated from positive-sense RNA viruses is considered to be potentially infectious and, in the proper host cells, can generate complete, functional virus particles. Therefore, intact genetic material from these viruses is considered to be hazardous and belong to the same risk group as the parent virus.

1.5.9 Large-scale Culture

Large-scale culture is defined as any single, culture volume of greater than 10 litres. Large scale culture is considered to be a higher risk activity due to the increased possibility of environmental release.

1.5.10 Non-Indigenous Plant, Insect or Animal Species

Non-indigenous organisms refer to any plant, insect or animal species that are not normally found in the Alberta environment. The inadvertent or intentional release of any of these types of organisms could have serious human or animal health, environmental and/or economic impacts and therefore the possession of any living specimens is highly regulated.

1.5.11 Soil Pathogens & Plant Pests

Any soil pathogen or plant pest capable of causing disease in commercial crops is considered

to be a biohazardous material. Soil pathogens and plant pests include species of bacteria, viruses, fungi, parasites, insects and non-indigenous plant species.

1.5.12 Bee Pathogens

Certain species of virus, bacteria, fungi, parasites and insects are classified as bee pathogens and considered biohazardous. These pathogens typically require specific containment when used in research, teaching and testing facilities

1.5.13 Aquatic Pathogens

Bacteria, viruses, fungi and parasites capable of causing disease in aquatic species are considered aquatic pathogens and must be contained as biohazardous materials to prevent their release into the environment.

1.5.14 Animal By-products

Depending on their source population or country, animal by-products, such as animal tissue specimens or processed products derived from animal tissues, may act as fomites to bring non-indigenous diseases into Canada.

1.6 Biosafety Program Components

The Biosafety Program is designed to assist the research community to operate in compliance with biosafety regulations, and to demonstrate the University's success in meeting these requirements in a transparent and concise manner to the pertinent regulators. The program is comprised of the following components:

1.6.1 Biosafety Registry

All PIs who conduct research, teaching and testing activities with biological materials are required to have a Biosafety Registry on file with the Biosafety Program. The Registry tracks where a PI works, who works for them and what biological materials they have in their possession. Teaching laboratories and core facilities that use these materials also require a Registry that is typically held under a PI responsible for the facility, a facility manager or department chair. The Registry also tracks the types of activities being conducted and the containment level of the facilities in use. Once a Biosafety Registry record has been generated, it must be updated annually or as significant changes to personnel, biohazards, or experimental activities occur.
NOTE: An updated Biosafety Registry *is not equivalent* to a biohazards approval letter for a research project. In the absence of a Biosafety Registry, investigators **MAY NOT** work with or store biohazardous agents. For instructions on how to register your group with the Biosafety Program, see Section 3.4.

1.6.2 Institutional HPTR License

The U of A holds institutional HPTR licenses issued by PHAC to support activities involving human pathogens and toxins and related material designated biohazardous under the HPTA as well as terrestrial animal pathogens. The University's Chief Environment, Health and

Safety Officer (CESO), as the designated official and license holder, and the Biosafety Officers have accepted responsibilities directly with PHAC on behalf of the U of A research community.

1.6.3 Biosafety Acknowledgement and Sublicensing

In addition to the Biosafety Registry, PIs are required to accept a biosafety acknowledgement indicating their commitment to biosafety on campus. The type of acknowledgement is dependent on the type of biological materials that are used and/or stored by the PI. The Biosafety Officers use the information provided on a PI's registry to determine which type of acknowledgement is required.

- **Materials regulated under the institutional HPTR license** – PIs are required to accept a *Biohazardous Materials Acknowledgement* that describes the institutional HPTR license and the role of the Biosafety Officers, and outlines the responsibilities of the PI using or storing HPTR regulated biohazardous materials as part of their research, teaching or testing program. This acknowledgement has been specifically designed to address the requirements under the HPTR.

  An up-to-date Biosafety Registry and an accepted acknowledgement document constitute a valid biosafety sublicense under the institutional HPTR license.
- **All other biohazardous materials** – PI's are required to accept a *Biosafety Commitment* that outlines the basic operational practices that are required to stay in compliance with the remaining applicable federal regulations (other than the HPTR) and institutional requirements. ***The Biosafety Commitment is under development with expected implementation in the fall of 2016.***

1.6.4 Biohazards Approval of Research Projects

The Research Services Office (RSO) requires a *Letter of Biohazards Approval* in order to release funding for projects involving biohazardous agents. Similarly, the Research Ethics Office requires a Letter of Biohazards Approval for any Human Ethics or Animal Ethics application involving biohazardous agents. The process to obtain a Letter of Biohazards Approval involves the review of the experimental plan of an awarded grant proposal against the PI's Biosafety Registry on file to ensure that the research group's resources, facility and operating procedures are suitable for the new work. A Letter of Biohazards 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 a Letter of Biohazards Approval for each source and project. For instructions on how to apply for a Letter of Biohazards Approval, see Section 3.4.

1.6.5 Laboratory Safety Inspections

Laboratory safety inspections are federally mandated for facilities handling or storing biohazardous agents. This inspection is conducted by members of EHS, and will also include chemical and radiation safety components, as applicable. EHS will formally schedule the inspection with the group's PI or equivalent supervisor. A copy of the inspection checklist can be found on the EHS website. Any violations noted during the inspection will be cited

verbally to the PI or their designate during the inspection along with possible remediation options and dates for resolution. A formal letter summarizing the inspection will be sent to the PI. On the resolution date, EHS will return to confirm the violation(s) has been corrected. In addition to the EHS laboratory inspection, the Biosafety Officers may also conduct occasional inspections. The frequency of the inspections conducted by the Biosafety Officers is generally based on the risk level of the activities being conducted and the materials involved. For information on safety inspection scheduling, see Chapter 4.

1.6.6 Compliance Certification, Importation Permits and Movement Certificates

Compliance certification, import permits and movement certificates are specifically required for biohazardous materials regulated by the CFIA. Compliance certification and import permits are required for the acquisition of material from an international source whereas movement certificates are required for the transfer of material acquired under a CFIA import permit to a secondary location.

Compliance certification, import permits and movement certificates are not required for materials regulated by the PHAC. The institutional HPTR license now replaces the need for these types of regulatory documents. However, the receipt or transfer of any human pathogen, toxin or terrestrial animal pathogens must be documented with the Biosafety Officers prior to the shipment occurring according to the HPTR.

To help reduce delays, the Biosafety Program operates a service to assist U of A researchers in identifying and preparing the appropriate application documents to support the acquisition or transfer of their biohazardous material regardless of which regulations the material falls under. For information on how to access this program, see Chapter 6.

1.6.7 Biological Safety Cabinet Certification

Federal regulators stipulate that biological safety cabinets (BSCs) must be tested annually. In addition, cabinets must be gaseously decontaminated prior to being relocated, or before the filter housings may be opened to conduct maintenance or repair. Cabinets must also be retested following relocation to ensure proper functioning. EHS offers BSC testing and decontamination services to U of A research groups free of charge. To register your BSC with the EHS as well as find out how to properly install BSCs at the U o A, see Section 10.7.

1.6.8 Incident Investigation

The Biosafety Officers participate in the investigation of incidents and near-misses involving biohazardous agents, and will make recommendations for remediation and prevention. For directions on how to report an incident or near-miss to EHS, as well as incident and near-miss definitions see Chapter 9.

1.6.9 Institutional Level Biosafety Training

All U of A personnel must obtain documented training specific to their work activities. EHS provides institutional level training courses for laboratory personnel, including WHMIS (Workplace Hazardous Materials Information System) Training, General Laboratory Safety,

and Concepts in Biosafety online courses. The Concepts in Biosafety course is mandatory for all personnel handling biohazardous materials.
The EHS courses do not replace nor are equivalent to the site- and activity-specific orientation and training that PIs must provide to their staff and students. For information on how to enroll in the EHS safety training courses and how to properly document staff safety training, see Section 3.3.

1.7 Roles and Responsibilities for Biosafety

The personnel involved with biosafety at the U of A and their primary responsibilities are detailed below:

1.7.1 Chief Environment, Health and Safety Officer (CESO)

(The CESO position is held by the Associate Vice-President, Risk Management Services.)

- Ensures that the effective EHS management systems and associated due diligence programs are in place.
- Acts as the designated official and license holder for the University's institutional license under the HPTA/HPTR.

1.7.2 Biosafety Committee

- Advises the appropriate U of A offices on matters concerning biosafety, and related health and safety issues.
- Advises on and participate in the development and maintenance of institutional biosafety policies, regulations and procedures consistent with applicable legislation.
- Ensures that established institutional biosafety policies, regulations and procedures are being followed.
- Provides consent for any biosafety-related policy or procedure that is developed within the University.

1.7.3 Biosafety Personnel

Biosafety Officer

- Manages the institutional Biosafety Program.
- Acts as the primary liaison between the U of A and federal regulators.
- Maintain documentation on activities involving biohazardous agents to support the institutional registration under the HPTA/HPTR.
- Confirm compliance to all pertinent legislation and regulation for activities involving biohazardous agents.
- Assist U of A research groups in obtaining CFIA pathogen importation permits and compliance letters for the acquisition of applicable biohazardous materials.
- Maintain documentation of the import, export and transfer of biohazardous materials to and from campus

- Review all reports of incidents and near miss events involving biohazardous materials and investigate as required.
- Advise the CESO and RSO of research group non-compliances to federal biosafety regulations which could endanger continued access to grant monies.

Associate Biosafety Officer (Certifications)

- Oversee the application for and maintenance of the institutional HPTR license(s).
- Oversee the annual performance and verification testing of the U of A's enhanced biocontainment research facilities.
- Assist U of A research groups in obtaining CFIA pathogen importation permits and compliance letters for the acquisition of applicable biohazardous materials.
- Maintain documentation of the import, export and transfer of biohazardous materials to and from campus.
- Participate in the investigation of incidents and near miss events involving biohazardous materials, as required.
- Participate in the maintenance and continual improvement of the Biosafety Program.
- Provide business continuity for the Biosafety Officer in the event they are unavailable.

EHS Operations Team Biosafety Technologist

- Oversee annual certification of all biological safety cabinets (BSCs).
- Conduct annual certification testing of BSCs and HVAC systems within enhanced biocontainment facilities.
- Provide gaseous decontamination services as required.
- Conduct laboratory safety inspections.

EHS Operations Team personnel

- Assists with the annual certification of BSCs and gaseous decontaminations.
- Conduct laboratory safety inspections.

1.7.4 Department Chairs & Institute Directors

- Ensure common use areas (i.e., autoclave facilities, core facilities, cold rooms, etc.) have proper oversight and management consistent with regulatory requirements for the materials in use.
- Secure operational funds for common safety equipment (i.e., autoclaves, biological and chemical spill kits, emergency showers, etc.) in the department/institute.
- Organize safety committee to develop safe work practices and procedures for shared equipment, core facilities and other shared resources within the department/institute.
- Identify spill designates, safety training representatives and other pertinent core personnel to support the research activities of their department/institute.

- Review security measures for the common areas of the department/institute to protect personnel and research investments.

1.7.5 Principal Investigators (PI) & Facility Supervisors

- Responsible for all biohazardous agents owned, purchased, created or isolated by their research group until the materials have been properly inactivated and disposed.
- Develop hazard assessments for all research activities under their control, including activities involving biological materials (Chapter 2), and use the outcome of the assessments to develop and update site- and project-specific orientation and training materials for all personnel involved in the activities.
- Provide staff with appropriate personal protective equipment (PPE) and other safety equipment based on the outcome of their hazard assessments.
- Keep all research equipment used with biohazardous agents in good repair and properly maintained.
- Develop an up-to-date inventory of all biological materials studied, handled or stored in their facility (Section 3.7).
- Develop processes to maintain the security of their facilities and biohazardous materials.
- Report any observed questionable behavior that may jeopardize the security of their facilities and biohazardous materials (Section ???).
- Provide the regular updates to the Biosafety Program of the information tracked in their Biosafety Registry (Section 3.4).
- Maintain up-to-date laboratory hazard signage at the entrance(s) to assigned facility space including accurate contact information for laboratory designates (Section 3.2).
- Apply for biohazard approval for any awarded grant funds for projects involving biohazardous materials (Section 3.4).
- Investigate all incident or near-miss events reported by their staff, identify applicable corrective actions and forward results to EHS for review (Chapter 9).

1.7.6 Research Personnel

- Must follow all applicable sections of these Guidelines as well as site- and project-specific orientation and training materials provided by their PI or equivalent supervisor.
- Wear PPE identified in group's hazard assessment at all times when directly handling biohazardous agents or contaminated waste generated from these materials.
- Transparently disclose all experimental plans and results to their PI or supervisor. **Note, no student or technician may conduct experiments without the knowledge and approval of their PI or supervisor.**

1.7.7 Facilities & Operations

- Ensure all centrally supplied infrastructure for research facilities working with biohazardous materials is operated and maintained to meet or exceed the minimum standards as determined by the Biosafety Officer in order to remain in compliance with applicable biosafety regulations.

CHAPTER 2: HAZARD ASSESSMENT BASICS

Documented workplace hazard assessments are a requirement under the Alberta Occupational Health and Safety Code. Federal biosafety regulations also require hazard assessments for any planned activities with biological materials to determine if any of the material is considered biohazardous and to ensure the appropriate containment and handling requirements are properly identified. Activities involving biological and/or biohazardous materials require specific consideration in the hazard assessment process. Following the guidance provided in this chapter in conjunction with Hazard Management Procedure and Hazard Assessment template available on the EHS website will ensure that all applicable regulations are met.

When conducting a hazard assessment, the PI is considered the employer of the group and is responsible for ensuring that 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 to ensure that the safety measures identified in the assessment are properly and consistently implemented.

2.1 Classification of Biohazardous Materials

The first step in the hazard assessment of a biological material is typically to determine its biohazardous classification. Biohazardous material classification is based on the host organism that may be affected (Figure 2-1). Risk Group categories are based on the ability to cause disease in humans and terrestrial animals; Aquatic Pathogen categories identify microbes and non-indigenous aquatic animals that could cause disease in native aquatic species or damage the aquatic environment; and, Plant Pest categories identify microbes, insects and non-indigenous invasive plants that could have serious economic impact or damage the terrestrial environment.

Risk group categories are broken down into different levels. As the category level increases, the danger posed by the biohazardous material increases; in general, the seriousness of the disease or effect caused by the material increases as well as its ability to spread from individuals to the greater community. The risk group classification for human and animal pathogens has been in use the longest and gives a good example of how hazards increases from one level to the next:

- **Risk Group 1 (RG-1)** – These materials are unlikely to have a negative effect or cause disease in healthy individuals or animals (low risk to individual, low risk to community). Generally, RG-1 materials are comprised of microorganisms, nucleic acids or proteins that are either not capable of causing disease or are very unlikely to do so.
- **Risk Group 2 (RG-2)** – These materials can pose a moderate risk to healthy individuals or animals but are not likely or easily transmitted to the general public or animal populations (moderate risk to individuals, low risk to community). In normal laboratory circumstances, RG-2 materials are unlikely to be a serious hazard to laboratory workers, or the surrounding community, livestock or the environment, provided proper containment and laboratory practices are followed. Laboratory exposures can cause disease, but treatments are readily available, and the risk of spread is limited. The most

common types of RG-2 materials are described in Section 1.5.

- **Risk Group 3 (RG-3)** – RG-3 materials are exclusively pathogens that can cause serious disease in humans and/or animals and typically effective treatment and preventive measures are readily available keeping the risk to general public low (high risk to individuals, low risk to community). These pathogens do not ordinarily spread by casual contact from one individual to another however, the risk of spread in an animal population may vary significantly and therefore these agents may still have the potential for causing serious economic consequences.
- **Risk Group 4 (RG-4)** – Any pathogen that produces very serious human and/or animal disease, and is easily transmitted through direct and/or indirect contact between individuals or across species barriers (high risk to individual, high risk to community). These diseases typically lack effective treatment options and are often fatal.

  Note, the U of A does not have appropriate facilities for the storage or handling of any RG-4 pathogens and therefore RG-4 activities are prohibited.

A biohazardous material may belong to more than one category; for instance, *Schistosoma mansoni* is considered both a RG-2 material and an Aquatic Pathogens 2 agent; *Pythium insidosum* is a RG-2 material and a Plant Pest 2 agent. Risk Group designations for many human and terrestrial animal pathogens may be found in the PSDS published on the PHAC website. Designations for Aquatic Pathogen and Plant Pest species may be found on the CFIA website. Commercial suppliers of biological materials are required to provide biohazard designation information about their products; large suppliers like the American Tissue Culture Collection, Sigma-Aldrich and Cedarlane post the biohazard designations of their products in their on-line catalog.

In some cases, the classification of a biohazard may be downgraded to a lower level if the material has been altered in a way that reduces the risks involved in handling it. For example, an attenuated strain of a pathogen may be classified at t a lower risk level than the parental strain or an extensively screened and purified human cell sample is less of a risk than an unscreened human clinical sample from the general population.

If a group is unsure or cannot establish the hazard category and level of the biological materials they are working with based on the information provided here, they should contact the Biosafety Program for assistance. Remember, all biological materials need to be declared on the group's Biosafety Registry (see Section 1.6.1).

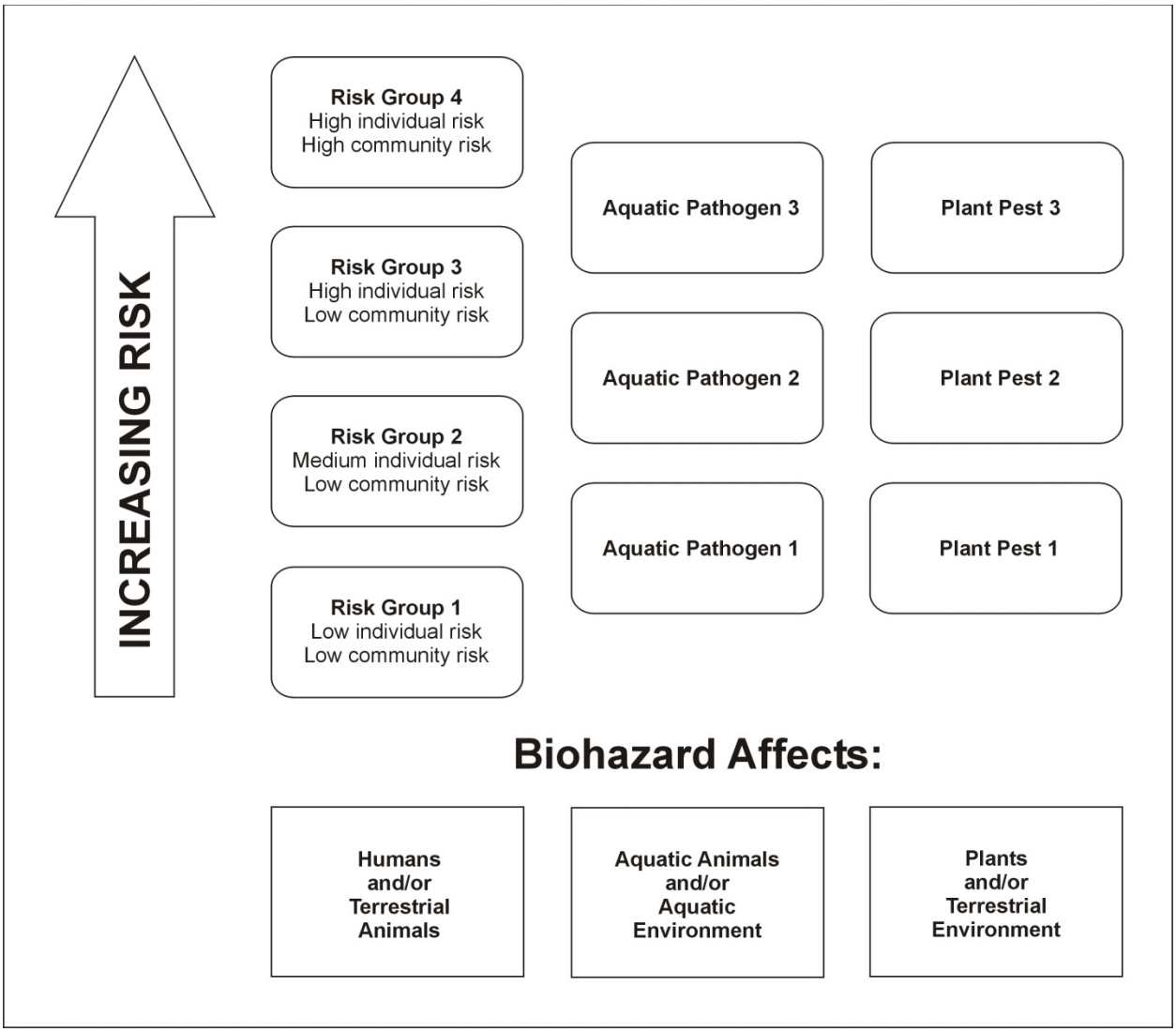


Figure 2-1. Biohazardous classifications and levels.

2.1.1 Clinical Specimens, Animal Tissues & Environmental Specimens

The assessment of any biological specimen acquired from its natural environment and brought into the laboratory for analysis, processing or storage must take into account the history of the population and the location the specimens were taken from (i.e., source and origin) to determine if there is **reasonable probability** a biohazardous agent is associated with the specimens. The following are guidelines for this part of the assessment:

a. All **human clinical and body fluid specimens** are considered RG-2 materials at a minimum regardless of their origin. There are numerous human pathogens that could be present in a donor specimen and no all-in –one test or method exists to track the health status of the patient in real time.
   - The U of A Human Clinical Specimen MSDS provides additional information that should be referred to as part of the assessment process.

This MSDS should also be provided to personnel working with these materials as part of their site-specific training.

- Hepatitis B immunization must be included as part of the mitigation strategies identified on the hazard assessment for these types of materials (see Section 2.3 for more information on immunizations).

Note: If clinical samples come from individuals with confirmed disease status, the material would be classified in the same manner as the causative agent.

b. 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 RG-1 material while the second would be considered a RG-2 material.

c. Categorization of **environmental specimens** is dependent on the location of collection. For example, if the location has a known history of association with an infectious disease (e.g., a river involved in repeated outbreaks of a waterborne illness) or show signs of contamination with suspect organic material (e.g., water collection immediately downstream of a sewage effluent pipe), the specimens are considered RG-2 agents.

d. For all **studies purposely investigating the presence of a pathogen or toxin** (i.e., with reasonable expectation of the presence of a biohazard), all animal, plant, insect, and environmental specimens collected would be classified under the same risk group as the pathogen or toxin being examined.

2.1.2 Toxins and Venoms

Microbial and plant toxins, and animal and insect venoms are considered RG-2 agents. If working with any of these substances, the following must be part of the assessment process:

- For microbial toxins, find an MSDS specific to the toxin rather than relying on the PSDS of the parent microbe for training of personnel.
- Toxins and venoms must be inactivated prior to disposal (Section 8.2.5); waste management procedures must be developed specific to the material in use (e.g., microbial toxins have different susceptibility to decontaminants compared to the parent microbe).
- Toxins often cause very different symptomology that the parent microbe. Symptomology of exposure, if known, must be included in the training of personnel.
- For venoms, determine if anti-venom exists and whether it is available in Alberta for post-exposure treatment. If you need assistance is finding this information, contact EHS to request a consult with an occupational health physician.
- Only handle and reconstitute lyophilized toxin or venom in a BSC or chemical fume hood.

- Strictly limit the use of needles and other sharps with these materials. If needles must be used, select safety engineered models.

2.1.3 Teaching Laboratories

Personnel responsible for teaching laboratory courses are required to investigate possible lower risk substitutions for the proposed biohazardous material in question during their hazard assessment process (i.e., an attenuated vaccine strain of a pathogen, animal tissue in the place of human clinical specimens, etc.). If the intent of the laboratory exercise can be met with a lower risk material, the lower risk material should be implemented in the laboratory exercise. This is especially important for 1st and 2nd year courses where the students have less background and experience handling hazardous materials.

2.2 Assessment of Activities or Manipulations Involving Biological Materials

Once the biohazardous classification of the materials involved has been established, the hazard assessment process for working with biological materials follows the same steps outlined in the EHS Hazard Management Procedure with the exception of Step 2: Identify Potential Health and Safety Hazards. In this step, the assessment must consider if any research plans or experimental activities affect any of the following properties on the biological material itself:

1. **Pathogenicity**: The ability of an organism to cause disease in humans, animals or plants.
2. **Virulence**: The degree of pathogenicity determined by the organism's invasiveness and by its toxigenicity.
3. **Mode of Transmission**: The mechanism(s) by which an infectious agent is spread.
4. **Infectious Dose**: The number of organisms required to initiate an infection.
5. **Communicability**: The ease or difficulty with which direct transmission of the agent occurs.
6. **Survivability**: The stability of the agent outside of its host.
7. **Host Range**: The types of species a pathogen can infect.
8. **Economic/Public Health**: Impact of the agent on economic or public health interests.
9. **Prophylaxis & Therapeutics**: Whether or not preventative measures and effective treatments are available against the pathogen.

When assessing the activity itself, the following are considerations that will help identify which activities are of higher risk:

a. **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 Biosafety Program for direct assistance with setting up large-scale culture facilities.

b. **Degree of Agent Aerosolization**: Experimental activities, such as lyophilisation, French pressing, 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 applicable sections of Chapter 5 for additional instructions to follow when using these types of equipment.

c. **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 applicable sections of Chapter 5 for additional instructions to follow when using sharps.

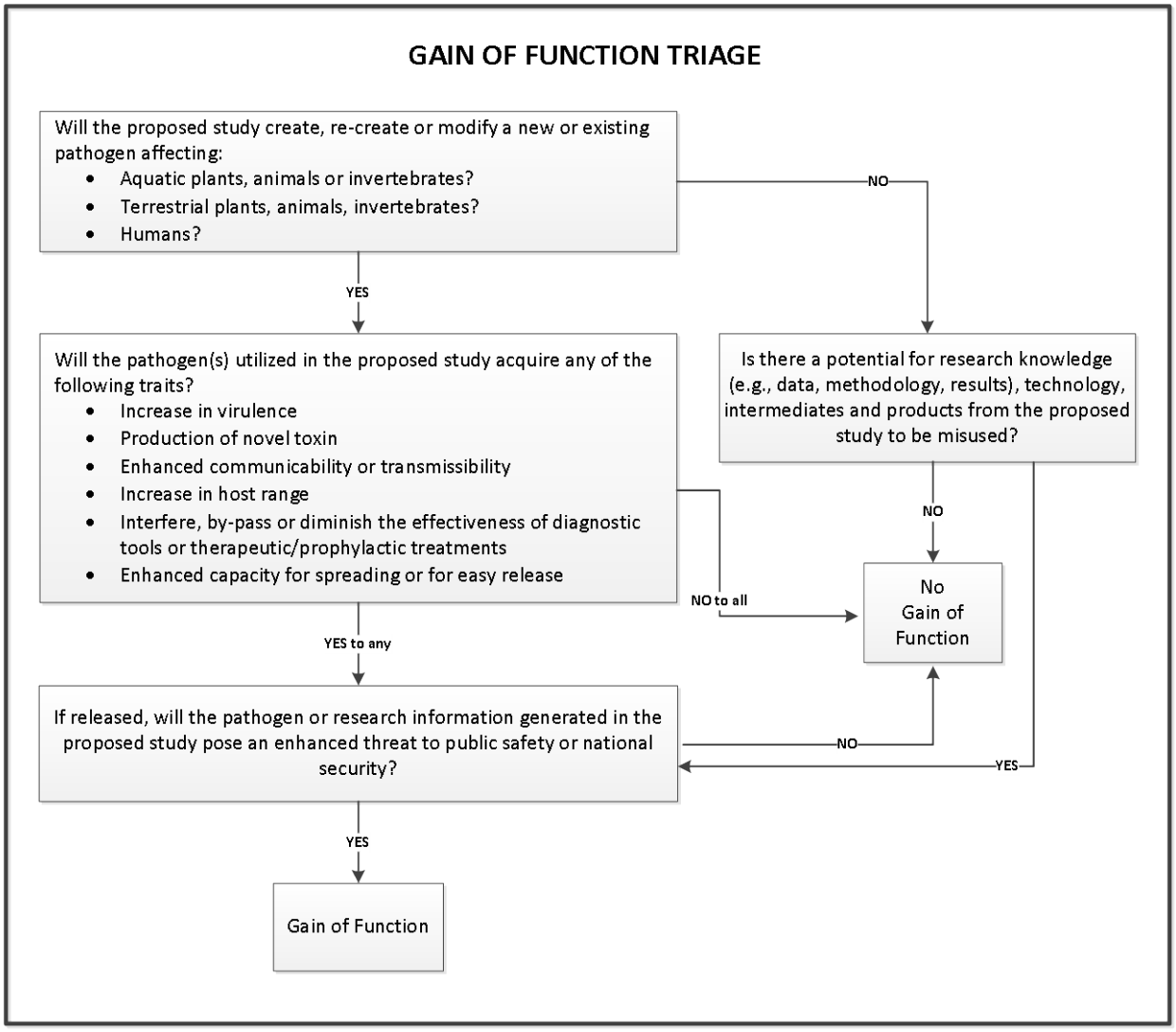
d. **Source of Agent**: If an animal, insect, invasive plant or pathogenic microbe is not indigenous to Alberta, escape from an Alberta research laboratory can have a significant negative impact on the province. Examples of agents include avian or swine influenza strains from Asia, pine beetles from 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).

e. **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.

   One of the newer methods of genetic modification utilizes **CRISPR/cas9** as a gene editing tool. The CRISPR/cas9 system can be very effective and useful but the context in which it is to be used must be carefully evaluated. For example, the use of CRISPR/cas9 to transiently knockout a gene is far less of a risk than an experiment where all the CRISPR/cas9 components could reasonably be expected to incorporate into a living organism and potentially propagate the altered DNA to subsequent generations. The types of promoters used, specificity of the target and guide sequences, and the host system along with the potential effects of changing the intended target gene are all variables needing assessment. Specific CRISPR/cas9 guidelines can be found in Appendix 1 and on the Biosafety Program page of the EHS website.

f. **Dual-Use potential**: Dual-use potential refers to a material, process or technology that could be used for both legitimate and malicious purposes. This definition is extremely broad making it very difficult to practically apply in the hazard assessment process and yet evaluating dual-use potential is a key part of the federal regulations regarding biosecurity. In the context of academic scientific research, dual-use potential essentially refers to gain of function experiments. The following flow chart is intended to help PIs determine if a significant dual-use/gain of function potential exists in their work:

Table 2-1. Decision Tree for Identifying Dual-Use Potential



If a PI does identify a dual-use/gain of function potential, an increased awareness of the security of the biohazardous materials in question and relevant information (i.e., experimental protocols or data) is required. Any applied mitigation strategy should be both practical and proportional to the level of risk identified in the hazard assessment. In some cases, stressing the security requirements in the site-specific training of personnel may be all that is required (e.g., ensure personnel understand that the biohazardous material in question, related protocols and experimental results cannot be shared with other labs without the knowledge and permission of the PI). In other cases, it may be prudent to segregate the biohazardous material in a separate, locked area.

Note: All dual-use or gain of function experiments involving biohazardous materials must be reported to the Biosafety Officers and declared on the PI's Biosafety Registry.

i. **RG-3 Diagnostic Specimens**: Analyses of diagnostic specimens for several types of RG-3 pathogens may be conducted under CL-2 conditions provided the analysis does not involve amplification of the pathogen (i.e., through culturing). Consult the PSDS for the RG-3 agent on the PHAC website to see if CL-2 diagnostic activities are allowed.

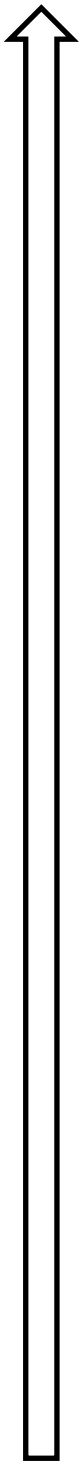
ii. **Location of Study**: Research groups are often required to obtain biohazardous materials from outside the laboratory. The **field research** environment outside the laboratory would be considered Containment Level 0. When working under these conditions, additional administrative controls must be utilized to make up for the lack of engineering controls (e.g., specific PPE mitigations that are practical and appropriate to the material and the location of the study). Guidance documents and planning templates to assist in developing hazard assessments for field research are available at the Field Research Office website.

iii. **Environmental Release**: The intentional release of any biohazardous materials, GMOs or PNTs from a research facility is beyond the scope of this manual. Any research group planning an environmental release of such material must provide their hazard assessment to the Biosafety Program for review in advance of starting their project.

This manual cannot anticipate every research plan or idea. Where the contents of this manual do not provide complete instruction for a biohazardous agent identified in a research group's assessment, the group must identify additional controls to implement (Step 6 of the Hazard Management Procedure). Example controls applicable to mitigating biohazards are given in Table 2-2. If assistance is required, the group should contact the Biosafety Program.

Table 2-2. Mitigation controls applicable to working with biohazardous agents.

Most Effective



Least Effective

Control Type	Explanation & Examples
Elimination	**Eliminate the use of the biohazardous substance** ➢ Rather than receive 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 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 avirulent 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 risk group 1 eukaryotic cell line for a risk group 2 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 biological safety cabinet or equivalent aerosol containment device ➢ Use centrifuges with safety cups or rotors which can be loaded and emptied inside a biological safety cabinet
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 ➢ Equipment 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 ➢ If applicable, ensure personnel are appropriately immunized ➢ Ensure safe and properly organized interim storage of biohazardous waste ➢ Develop effective laboratory work organization layout ➢ Clean up biospills immediately ➢ Report all incidents and potential exposures to supervisor immediately ➢ 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 ➢ Changing out of street clothes into scrubs if working within a containment barrier for immunocompromised animals

2.3 Immunization as a Biohazard Risk Mitigation Strategy

Immunizations can be an effective means for protecting personnel against potential exposures to the pathogens they work with but are only available for a limited number of pathogens. In most cases, the Pathogen Safety Data Sheet (PSDS) will state if a vaccine exists against a given pathogen.

The identification of whether an immunization against a specific agent is a reasonable risk mitigation strategy should occur at the hazard assessment stage of a project. EHS supports occupationally recommended immunizations based on the Canadian Immunization Guide for Laboratory Workers. The following vaccines are listed in the guide as recommended for research laboratory workers:

- Hepatitis A
- Hepatitis B
- Influenza
- Japanese encephalitis
- Meningococcal
- Rabies
- Smallpox
- Typhoid
- Yellow fever

Immunizations, when available, shall be considered by the PI as one of the layers of protection for their personnel and be included as a control in the hazard assessment. The decision to include an immunization shall be based on the type of pathogen involved, the activities to be conducted and the overall risk of a potential exposure. A recommendation for immunization shall be included for personnel who directly handle any materials that could reasonably be expected to contain the pathogen in question, pure cultures or the waste generated from work involving either of these. Whether a hazard assessment recommends immunizations for personnel who only work in the vicinity of, but not directly with these materials, would have to be determined based on the routes of transmission of the pathogen in question and the risk of exposure from the activities being conducted.

For example, the **Hepatitis B immunization*** is indicated for any personnel who work **directly** with:

- Human clinical specimens
- Unscreened human cell lines
- Hepatitis B viral cultures, or
- Waste generated from any of the above sources

Notwithstanding other controls in place, PIs shall include Hepatitis B immunization in the hazard assessment process as a mitigating strategy for any work using these materials

*N.B. Be aware, **the full series of Hepatitis B immunizations and testing for immunity is a 7 month process** (immunization shots at 0, 1 and 6 months followed by a titre check 1 month

after the immunization series is complete). For the safety of the individual, this process should be completed prior to the individual initiating work with any of the source materials listed above.

If a PI is unsure whether an immunization is appropriate for the types of activities being conducted, they should contact EHS to request a consultation with an occupational physician. The occupational physician will need a copy of the hazard assessment in order to evaluate whether immunization is warranted.

For any immunizations listed in the Canadian Immunization Guide for Laboratory Workers the PI should contact EHS to make the appropriate arrangements for their personnel. EHS will provide instructions on how personnel are to go about obtaining their immunization including how and where to connect with the AHS contracted immunization service. AHS will conduct an initial consultation to determine what steps are appropriate for each individual and provide further instructions according to the individual's health history and immunization status. To ensure that personnel are appropriately informed and protected, all personnel working in labs where immunizations are recommended should go for the consultation with AHS regardless of their current immunization status.

Recommended immunizations should be completed prior to work being conducted where a potential exposure could occur. If an immunization series is not complete, the individual's work activities should either be modified or additional mitigation strategies implemented to eliminate or significantly reduce the risk of exposure.

PLEASE NOTE:

- It is the responsibility of the PI to assist their personnel with completing the immunization process for any immunizations identified, as required.
- It is the responsibility of the individual to complete the immunization process as instructed by AHS and notify their PI when the process is completed.
- Neither AHS nor EHS have the capacity to follow-up with individuals who do not complete the immunization process as instructed.

2.4 Risk Group versus Laboratory Containment Level

Once the biohazard classification is established for all the biological material required for the project and the activities or manipulations involving the material have been evaluated, the required containment level of the facility can be determined. Biocontainment laboratories are assigned a containment level which reflects the amount of safety infrastructure installed in the facility and the operational safety procedures workers must follow (i.e., the higher the containment level, the more safety infrastructure and operational procedures in play).

In most cases, the risk group classification level will correspond to the containment level required for the safe handling and storage of the material. That said, materials classified at the same level of risk group, aquatic pathogen and plant pest agents can have different containment requirements; a containment level 2 (CL-2) laboratory set-up to house a RG-2 material is not necessarily prepared to house an aquatic pathogen 2 or plant pest 2 agent.

For simplicity, facilities handling or storing RG-2 materials, aquatic pathogens (level 1 or 2) and plant pests (level 1or 2) are all designated as CL-2 facilities on the facility's Laboratory Hazard Sign (Section 3.2) at the U of A; any required additions or exceptions to infrastructure based on the type of material in question will be verified by the Biosafety Officer and noted on the Biosafety Registry for the research group.

RG-2 prions and RG-3 materials require handling and storage in enhanced biocontainment facilities. These are secure facilities with specific access control and their own biosafety programs.

If several biohazardous materials of different classification levels will be used in a project and the required containment level is not the same for all of them, then the more stringent containment requirement must be followed.

2.5 Documentation of Hazard Assessment

Once a hazard assessment is completed, **keep a copy with the group's training material**. New personnel must review and understand the hazard assessment as part of their orientation 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 hazard assessments must also be available on request from EHS personnel.

2.6 Ongoing Monitoring of Risks

Hazard 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 GMO or PNT.
- 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, or.
- Every three years as per the institutional hazard assessment procedure.

CHAPTER 3: LABORATORY ADMINISTRATIVE PROCEDURES

3.1 Introduction

In addition to completing the Hazard Assessment procedure outlined in Chapter 2, the laboratory administrative procedures described in this chapter must be adhered to in order to remain compliant with the U of A biosafety program. Many of these administrative procedures are not just specific to biosafety but are also required for groups to demonstrate their due diligence against all hazards present in their work space, to meet professional and legal standards, and to facilitate communication with neighboring groups and support personnel.

3.2 Laboratory Hazard Signage

All U of A laboratories and research support spaces where hazardous materials (including biological, chemical and/or radiation hazards) are used or stored must have proper laboratory hazard signage as created by EHS. Signage is required for every entrance into the laboratory off of a public or semi-public space. Signage is also required for common areas, such as cross-corridors and equipment rooms, if hazardous materials are stored in the area.

- To **Request a New Hazard Sign** or **Update an Existing Hazard** Sign for a laboratory or support space (including autoclave rooms, cold rooms and warm rooms) please refer to the Instructions and Information section of the Standardized Laboratory Hazard Signage document. Note: research groups are not to make their own changes to a hazard sign provided by EHS by overwriting the sign or typing new information over top of the sign.

3.3 Training & Orientation of Personnel

Personnel require training to inform them how to work safely with hazardous materials. 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 A personnel (including PIs, technical staff, research associates, post-doctoral fellows, graduate students, visiting scientists and volunteers) directly handling biohazardous agents. 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.

3.3.1 Institutional Courses

The online courses detailed below are for personnel who will be conducting independent work with hazardous materials and are offered at no cost to U of A employees and students.

Note: 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 A laboratories. Minors must work under the direct supervision of qualified and trained laboratory personnel at all times and therefore are exempt from needing to take the 3 online courses described below. Instead minors must receive a truncated WHMIS orientation online course offered by EHS and must still receive Laboratory-Specific Orientation and Training organized by their PI. Most minors are connected to laboratories through organizations, such as HYRS and WISEST, which coordinate with EHS to enroll the minors in the truncated WHMIS online course. If a minor planning to work in a laboratory is not affiliated with such an organization, they can be enrolled in the course by contacting EHS via biosafety@ualberta.ca.

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

a. **WHMIS (Workplace Hazardous Materials Information System) Training** –Alberta Occupational Health and Safety Code requires that employers provide 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. EHS 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 as detailed in Section 3.3. The online course can be accessed via: WHMIS Training Information.

b. **Laboratory Safety Course** - This course outlines basic safety practices and procedures that apply to all laboratory settings on the U of A campuses. The pre-requisite for this course is the WHMIS online course. The online course can be accessed via: Laboratory Safety Course Information.

c. **Concepts in Biosafety Course** - This course deals specifically with the safe handling, storage and disposal of biohazardous materials. It has been designed in a modularized fashion with the basic module being mandatory for all personnel who work with biohazardous materials. The topic specific modules are mandatory if applicable to the work being conducted. Pre-requisites for this course are the WHMIS and Laboratory Safety online courses. The online course can be accessed via: Concepts in Biosafety Information.

3.3.2 Site-Specific Orientation & Training

The institutional courses listed above provide basic safety training presented in the U of A's context but cannot possibly address the nuances of individual research programs or specific procedures. Under WHMIS legislation, the PI is responsible for ensuring that all personnel reporting to them are appropriately trained in the operational procedures and protocols that have been developed for their laboratory facilities and research program. Site-Specific Orientation and Training covers such topics as: location of safety equipment, evacuation routes, location and storage procedures for hazardous materials, location of laboratory

protocols and training materials, waste handling and processing procedures and the safe operation of laboratory equipment. This information is highly specific to the individual location and research program and must be provided in this context by the PI or their designate; the EHS online courses detailed above are not to be considered an equivalent substitute for this orientation and training.

The required documentation of site-specific orientation and training is described below in Section 3.5, Required Documentation and Record Keeping.

3.3.3 Working Alone Procedure

The Government of Alberta has enacted legislation intended to protect individuals who work alone. All U of A personnel who work alone, particularly outside of regular work hours, must have a written Working Alone Procedure. To assist groups with fulfilling this requirement, EHS has prepared a template: Working Alone Template. In addition, U of A Protective Services operates a Lone Worker program which personnel are encouraged to utilize if they are working on a U of A campus in the evening or on the weekend.
Please note, any minors working in a laboratory may not work unsupervised in any circumstance therefore a work alone procedure cannot be implemented for students or workers under the age of 18.

3.4 Biosafety Registration, Licensing and Approvals

3.4.1 Biosafety Registry

All PIs who use or store biological materials as part of their programs, must enroll in the Biosafety Registry. As mentioned in Section 1.6.1, the Registry tracks where a PI works, who works for them and what biological materials they have in their possession, and provides with Biosafety Program sufficient information about the PI's research plans to effectively advocate for the PI and liaise with the federal regulators. An up-to-date Biosafety Registry is also required to obtain a Letter of Biohazards Approval to allow for the release of research funds from RSO (Section 3.4.3).

For PIs new to the Biosafety Program:

- To enroll in the Biosafety Registry, a PI must contact the Biosafety Program and indicate that they work with biological materials and wish to register with the Program. In response, the PI will receive a Biosafety Registry form that they will need to fill in and submit back to the Biosafety Program.

For PI's with an established Biosafety Registry:

- A PI must update their Registry at least annually, or as changes occur to their experimental plans, biological inventories or group personnel. Updated information can be submitted at any time via email to biosafety@ualberta.ca.
- PIs will be notified when it is time for an annual update of their Registry. When contacted, PIs are asked to provide the requested information in as timely a fashion as possible in order to remain compliant with the U of A

biosafety program. Whenever, Biosafety updates a PI's Registry, they will send a pdf copy of the Registry to the PI for their records and to confirm the update was completed.

3.4.2 Biosafety Acknowledgement and Sublicensing

In addition to the Biosafety Registry, PIs are required to accept a biosafety acknowledgement indicating their commitment to biosafety on campus. As indicated in Section 1.6.3, the type of acknowledgement is dependent on the type of biological materials that are used and/or stored by the PI and the Biosafety Officers use the information provided on a PI's registry to determine which type of acknowledgement is required.

Once a PI has submitted their Biosafety Registry, the Biosafety Officers will review the information provided and determine which biosafety regulations apply to their program. Subsequently, the PI will receive an email with a copy of their Registry and a link to an online version of the appropriate acknowledgement document for type of materials that they use. Upon receiving the link, PIs are asked to follow the instructions provided and complete the acknowledgement in a timely manner. Once the accepted acknowledgement has been submitted, the PI will receive a pdf copy of the document for their records.

Please be aware, the acknowledgement can only be accepted by the PI or department Chair responsible for the program and its materials; this cannot be delegated to other personnel.

For all PI's working with materials regulated under the HPTR, an up-to-date Biosafety Registry and an electronically accepted *Biohazardous Materials Acknowledgement* together constitute a valid sublicense under the institutional HPTR license.

3.4.3 Letter of Biohazards Approval

All PIs, students or fellows that have been awarded funding for a research project involving a biohazardous agent must apply for a Letter of Biohazards Approval from the Biosafety Program. As described in Section 1.6.4, funding for such grants or awards will only be released by RSO upon receipt of a Letter of Biohazards Approval that is specific to the funding source. Subsequent renewal or extension of these awards will also require the issue of a new Letter of Biohazards Approval.

There are two submission pathways for grants requiring a Letter of Biohazards Approval:

- **New Grant** – A project that involves new experimental plans or procedures, or the use of biohazardous agents that have not been described in grant applications previously submitted to the Biosafety Program for review. To submit a New Grant for biohazards approval, complete a New Grant Application and submit it to biosafety@ualberta.ca along with a copy of the grant application, research contract or other document containing the experimental plan for the project.
- **Subsidiary Grant** – A project that follows an experimental plan or procedure that has already been reviewed by the Biosafety Program during the approval of a previous grant. Minor differences in the biohazardous agents used in the

procedure are allowed provided the changes do not constitute an increased level of risk. Subsidiary Grants are processed by the Biosafety Program via a truncated review and are generally approved more quickly than a New Grant. To submit a Subsidiary Grant for biohazards approval, the PI should complete a Subsidiary Grant Application and submit it to biosafety@ualberta.ca.

For both submission pathways, the PI must have an up-to-date Biosafety Registry on file with the Biosafety Program. Submissions will not be processed until the up-to-date Registry is received.

In addition, the Research Ethics Office requires a Letter of Biohazards Approval for any Human or Animal Ethics application they receive involving biohazardous agents. When a PI submits an ethics application through the Research and Ethics Management Online (REMO) system and declares the presence of a biohazardous agent, the REMO system automatically forwards the information to the Biosafety Program for review and approval. No further action is required by the PI, other than to ensure their Biosafety Registry is up to date.

For more information regarding the biohazards approval process, please refer to the Application for Biohazards Approval Instructions.

3.5 Required Documentation and Record Keeping

As with any other work situation, proper documentation of any program using biological materials is required. Proper documentation provides the proof that any required action has been completed appropriately. It makes work site inspections easier and more efficient and, if for some reason something has gone wrong, it provides the foundational information required in an incident investigation. In the end, proper documentation can protect the PI, the workers and the university.

There are several records and documents that a PI is required to keep on file. This section describes the additional documentation, beyond the hazard assessment (Chapter 2), that is required, some of which is required for any program and others of which are specific to programs handling and storing biological materials.

3.5.1 Training Records

Training records that document the work-specific training that has been provided to personnel is a requirement for any work environment. For academic research, teaching and testing programs, the training record will likely be comprised of both institutional level training or courses completed as well as the site-specific orientation and training provided for the facilities and procedures to be used (Section 3.3.4). There is no mandatory format for a group's training record. With each program being unique, each group's training needs may be different and therefore their training record may be different. EHS offers a template: Laboratory Specific Safety Training, which may be used by PIs as a starting point and adapted as they require. It is recommended that both the PI and the individual worker keep a copy of the completed training record.

3.5.2 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 PHAC website. 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 Biosafety Program if assistance is required in finding or developing a PSDS or MSDS.

3.5.3 Research-Specific Protocols

PIs must document 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 biological, chemical and other potential hazards involved in the protocol. All personnel in the laboratory must know where to find these protocols and must have read and understood all protocols pertinent to their work activities prior to initiating the activity.

3.5.4 Inventory of Biological Materials

In the course of research, PIs can acquire significant collections of biological materials. The PI is considered the owner and responsible individual for all biological and biohazardous materials that are generated or acquired under their research program. The only way to know what the material is and whether or not it is hazardous is to have it properly labeled and have a record of it kept in an inventory. It is also federal requirement that an inventory of all long term or archival stocks of these materials be maintained at all times. Inventories are considered a fundamental part of a facility's biosecurity (Section 5.2).

For the purposes of these Guidelines, a **long term or archival stock is any biological material that is stored for more than 30 days**; ongoing cultures in an incubator are not considered archival stocks and do not need to be inventoried. The level of detail required in the inventory should be proportional to the risk level of the material itself. The minimum record keeping required for the different types of biological materials is as follows:

For **non-hazardous and/or RG-1 biological materials**:

i. Description of material
ii. Date of creation/acquisition
iii. Origin of material
iv. PI responsible

Essentially, the information recorded must be enough for someone to be able to identify the material, know who owns it and verify that it is indeed non-hazardous (the origin of the material is often overlooked but can be essential to confirming that a material is non-hazardous).

For **biohazardous materials (RG-2 human or equivalently rated animal biohazards)**:

i. Agent (genus and species), material name or description
ii. Date of creation/acquisition
iii. Storage state (frozen, lyophilized, etc.)
iv. Storage location
v. Risk group classification
vi. Date material was used up or destroyed
vii. Usage or transfer restrictions, if any (i.e., import permit, 3rd party or MTA restrictions imposed on the use or transfer of the material).

The inventory for these types of materials must be specific enough that the risk classification of the material and any restriction imposed on it are obvious, but also so that a missing stock could be detected.

For laboratories that use **SSBA toxins**, the inventory must also track the amount of toxin on hand. This is to ensure that it is clear when the regulatory requirements for SSBA toxins in amounts exceeding the allowable trigger limits (see Table 1-2) must be implemented.

For **RG-3 biohazardous materials or prions**, the inventory requirements are slightly more detailed and outlined in the specific facility's Biosafety SOP manual.

Again, there is no mandatory format that an inventory must take. Inventories can be kept as paper or electronic documents. EHS has developed an inventory template that PIs can be adapted as needed. Inventories must be kept up-to-date and must be made available on request to EHS personnel.

3.5.5 Equipment Maintenance Checklists

It is a legislated requirement to ensure equipment and facilities are properly maintained. It is good laboratory practice to use maintenance checklists and schedules to ensure maintenance is not forgotten and faulty equipment is repaired is detected and repaired in a timely fashion. Any maintenance checklists and equipment maintenance records should be kept on file.

Some common maintenance examples include, but are not limited to:

- Benches: Wiped with appropriate disinfectant daily before and after experimentation.
- Fridges/Freezers: Stored materials should 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.

- Autoclaves monitored monthly with biological indicators

Certain types of equipment, such as autoclaves, 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.

3.5.6 Repair or Disposal of Equipment Used with Biohazardous Agents

Any equipment that has been in contact with biohazardous agents must be decontaminated and labeled as such 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.

For guidance on how to properly decontaminate research equipment used with biohazardous material and document the process, follow the instructions given in the Equipment Decontamination Form. The form also provides information on how to clean research equipment of chemical and radiation contamination. A copy of the form should be taped directly to the equipment for service or support personnel to see.

3.5.7 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. Document the process using the Clearance to Work form provided in the procedure and ensure a copy is posted in the area for support and trades personnel to see.

3.5.8 Laboratory Relocations & Close-Outs

Whenever laboratory space is vacated by a research group, either due to the laboratory closing, a major renovation of the space, or a relocation of the research group, it is the responsibility of the PI to ensure that the applicable sections of the EHS Laboratory Closeout and Relocation Guidelines are followed and completed by his research group. The Guidelines help 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 properly disposed of, and that the space is properly cleaned of any contamination. The Guidelines include forms to document the groups cleaning activities and provides guidance on how to set up a laboratory at a new location.
Please note, when a facility is closing, biohazardous materials must be decontaminated and disposed of or transferred to another facility that is appropriately authorized to handle and

store the materials. Contact the Biosafety Program to report any intended transfer of biohazardous materials as part of a laboratory closeout.

CHAPTER 4: BIOCONTAINMENT LABORATORY REQUIREMENTS & INSPECTIONS

4.1 Overview

Containment is generally thought of as the action of keeping something harmful under control or within limits. Federal biosafety regulations regarding containment are comprised of both operational and infrastructural requirements; i.e., required procedures (actions) and physical barriers (limits). These requirements are categorized into containment levels. The higher the containment level, the more complex and stringent the operational and infrastructure requirements are. As mentioned in chapter 2, the containment level typically matches the risk group of the material being handled but the activity or procedure in which the biohazardous material is used may require additional infrastructure support, i.e. a higher containment level. In any circumstance involving a mixture of biohazardous materials with differing containment requirements, the more stringent requirements must be followed.

This chapter describes the different containment levels and provides additional information regarding the requirements for specific types of biohazards or activities. It also provides an indication of the inspection frequency that can be expected for the different types of biocontainment facilities. At a minimum, all facilities must be inspected annually, either through a self-audit checklist or an on-site inspection by EHS personnel. Additional biocontainment specific inspections may also be required as indicated in the facility descriptions below where applicable. All facility inspections conducted by EHS or the Biosafety Officers will be announced and coordinated in advance with the PI and/or Laboratory Manager.

> **N.B.** Regardless of the containment level, the consumption or storage of **food and drink are PROHIBITED** in any laboratory environment where chemical, biological or radiological materials are used or stored.

4.2 Containment Level 1 Facilities

Containment Level 1 (CL-1) facilities may be used for biological material that is deemed non-pathogenic to healthy, immunocompetent humans and animals (e.g., RG-1 materials). CL-1 is typically appropriate for PIs who have only non-hazardous biological materials declared on their Biosafety Registry.

One of the most basic infrastructural requirements of a biocontainment facility is an intact containment barrier. That means, at a minimum, all containment laboratories must have:

- Intact walls, floors, ceilings and windows
- Windows present in a ground floor facility must be secured to prevent unauthorized entry
- Doors that close properly and are lockable; doors must to be kept closed to maintain a containment barrier.
- Bench tops and floors made of materials that are easily cleaned; no carpet is allowed in a laboratory setting.

Note: the use of a biosafety cabinet (BSC) is not required in a CL-1 laboratory. However, if a BSC is present, it should be properly used and maintained (see Chapters 5 and 10, respectively).

Beyond this, there are no additional requirements for a CL-1 facility. However, it is recommended that CL-1 facilities are kept clean and tidy and adhere to following:

- Maintain research equipment and infrastructure in good working order.
-
- Use good microbiological laboratory practices and techniques that serve to protect personnel and ongoing research by preventing cross-contamination of experiments and any contamination of the surrounding environment.

4.3 Containment Level 2 Facilities

Containment Level 2 (CL-2) is the standard biocontainment facility used for research involving RG-2 pathogens affecting humans and terrestrial animals. The CL-2 operational requirements are described in Chapter 5. For the infrastructure, in addition to the intact containment barrier described in Section 4.2, CL-2 facilities also specifically require:

- Non-absorbent interior surfaces (benches, walls, floors, etc.) that are resistant to wear and able to withstand repeated treatment with appropriate decontaminants; no exposed raw wood surfaces are permitted
- Non-absorbent furniture only (i.e., no cloth upholstered chairs)
- Dedicated computer/paper work stations segregated away from bench work areas
- Administrative office areas separated from the containment area by a door
- Certified BSC or other equivalent primary containment devices for the direct manipulation of biohazardous materials; BSCs must be located away from high traffic areas and supply or exhaust air diffusers.
- Vacuum lines fitted with in-line filters to prevent internal contamination.
- Sinks near facility exits for hand washing purposes.
- Emergency eyewash and/or shower based on activities being conducted.
- Provision for personal belongings to be stored away from active bench/research areas or BSCs.

Upon registering with the Biosafety Program (Section 3.4.1) for the first time, an inspection will be arranged to ensure that the infrastructure is appropriate for the biohazardous materials to be handled or stored within the facility. An on-site inspection of CL-2 facilities will be conducted specifically by the Biosafety Officers at least once every three years.

The CL-2 requirements described here are the base requirements for most standard laboratories. However, for many of the biological materials and activities described in Section 1.5, there are additional requirements.

4.3.1 Large-Scale Culture Facilities

Large-scale culture facilities are required to house any culture or fermentation studies with single volume capacities of 10 litres or greater regardless of whether the culture material is considered RG-1 or RG-2. In the event of a spill or equipment breach, there is a significantly

increased risk of contaminating personnel and the surrounding environment. To help mitigate these risks the following conditions must be met:

- Sink and floor drains in the immediate vicinity must be capped.
- Large scale culture equipment and culture vessels must be inspected for flaws or damage prior to every use; damaged equipment is not too be used.
- Culture vessels must be secured and contained during incubation and handling steps, including any transportation to a secondary location.
- Biohazard spill kit must be present in the immediate vicinity and easily accessible.
- Biohazard spill kit (Section 9.7.1) must be supplemented with enough additional supplies to be able to deal with a breach of the full culture volume (e.g., additional bleach*, spill booms or additional towels to act as a dam as necessary).

  *Note: Liquid bleach is moderately unstable with a shelf life of one year. For stocking of spill kits, bleach tablets are more stable and recommended.

Depending on the agent involved and the total culture volume, additional infrastructure may be necessary such as:

- Installation of a berm at the containment barrier
- Implementation of inward directional airflow

During the planning stage of any large scale culture activities, PIs are encouraged to report their intentions to the Biosafety Officers as early as possible in the process. The Biosafety Officers will review the experimental plans and book a site visit with the PI to help ensure the necessary mitigations are in place to support the planned activities. Also, if needed, the Biosafety Officers are willing to review the safety features and installation requirements of any culture/fermentation vessels or equipment before it is purchased. The Biosafety Officers will work with the PI to determine the best way to support the large scale culture work.

Large scale culture facilities will be inspected specifically by the Biosafety Officers at least once a year.

4.3.2 Facilities Working with Species Non-Indigenous to Alberta

Facilities housing live animal, plant and insect species not indigenous to Alberta must be designed to ensure that the non-native organism cannot escape and potentially establish itself in the province. With the broad spectrum of non-indigenous species that could be of interest, it is impossible to list all the potential requirements in these guidelines. Instead, PIs considering work with non-indigenous species are asked to contact the Biosafety Officers as soon as possible. The Biosafety Officers will consult with the PI regarding the required laboratory set up and procedures based on the specific species being addressed.

It is also important to keep in mind that the acquisition of virtually all non-indigenous species will require supporting documentation from the CFIA (e.g., import permit, movement certificate) (see Chapter 6). Typically, any specific handling and containment requirements

are identified by the CFIA during the permit application process and listed on the permit or certificate issued. The Biosafety Officers will work with PIs through the CFIA permit/certificate application process to ensure the appropriate handling and containment requirements are met in as practical a manner as possible.

Facilities housing non-indigenous species will be inspected specifically by the Biosafety Officers every two years.

4.3.3 Facilities Working with Plant Pests & Plants with Novel Traits

An organism designated as a Plant Pest must be housed in a facility that can prevent their escape into the environment. Similarly, PNTs must be housed in a facility that prevents the release of the plant and its pollen or seeds into the environment. Typically, facilities housing these types of organisms must have:

- Soil traps on facility sink and floor drains.
- Screening on any openable windows or ventilation diffusers. Note, screen mesh size must be appropriate to the pest being contained.
- Appropriate waste SOPs* to ensure any pest or plant material is inactivated and all associated materials are appropriately decontaminated prior to disposal.

*Note, inactivation can be difficult due to the density of plant and soil materials. If planning to use an autoclave for this process, the cycle parameters must be validated by the research group to ensure its efficacy. Alternatively, plant and soil waste can be sent for incineration through the EHS Chematix system.

Laboratories and greenhouses to be used with PNTs, or Plant Pest 1 or Plant Pest 2 agents must be inspected by the Biosafety Officers prior to initiation of research or the acquisition of the agents to ensure the infrastructure can properly contain these organisms. Subsequently, the Biosafety Officers will specifically inspect these facilities once every five years.

Work with Plant Pest 3 agents is currently prohibited at the U of A. In addition, the U of A does not have proper infrastructure to support field crop studies of Plant Pests or PNTs.

4.3.4 Facilities Working with Aquatic Pathogens

When working with Aquatic Pathogens, research groups must ensure that not only is the pathogen is contained but also that all water is properly treated before leaving the facility. Depending on the type of research being conducted the infrastructure requirements can be extremely varied. For example, *in vitro* studies of an aquatic pathogen in typical CL-2 facility may only require some additional procedures to ensure all liquids are captured and decontaminated prior to disposal, whereas a study conducted in an aquatic environment requires a completely separate, specialized facility.

PIs planning to conduct research with Aquatic Pathogen 1 or Aquatic Pathogen 2 agents should contact the Biosafety Officers to discuss their plans. Depending on the type of facility required, an inspection by the Biosafety Officers may be required prior to the initiation of research or acquisition of the agent(s). Once a facility is established for work with aquatic

pathogens, it will be inspected specifically by the Biosafety Officers every two years.

Work with Aquatic Pathogen 3 agents is currently prohibited.

4.3.5 Facilities Working with Recombinant DNA Technologies

While the manipulation of genetic material using a variety of rDNA technologies is now considered a common place occurrence, it is not without risk. As mentioned in Section 1.5.6, vector systems based on pathogenic viruses and gene editing systems (e.g., CRISPR/cas-9) are all considered RG-2 materials. Similarly, transduction particles and shRNA systems that are based on viral backbones are also RG-2. In order to protect personnel from potential exposure and prevent the introduction of the resulting genetic materials into an unintended host system due to cross contamination, the use of rDNA technologies requires a CL-2 facility with the following procedural additions:

- Use only centrifuges equipped with safety rotors or safety cups with rDNA preparations and load/unload the safety rotor or cups in a BSC.
- Strictly limit the use of needles and other sharps with rDNA preparations. If needles must be used, select safety engineered models.
- When handling RG-2 rDNA preparations, use laboratory gowns rather than laboratory coats. Laboratory gowns should be dedicated to rDNA work and not used for other activities.
- Wear double-layered disposable gloves when conducting rDNA work with the inner layer of gloves secured to the individual's laboratory gown with masking tape.
- Use 10% bleach as the primary decontaminant for work surfaces used with rDNA work; do not use 70% ethanol as the primary decontaminant with these materials (although 70% ethanol may still be used to rinse metal surfaces following treatment with bleach to prevent corrosion).
- **Under no circumstances are U of A personnel to use any rDNA technology to conduct self-self experiments with their own blood or tissues.**

Facilities working with rDNA technologies can expect a specific inspection by the Biosafety Officers once every five years.

4.3.6 Facilities Working with Specified Risk Material

Specified Risk Material (SRM) refers to the skull, brain, eyes, tonsils and tissues associated with the central nervous system from ruminant animals that have the potential to be contaminated with prion agents. These tissues are not automatically assumed to contain infection prion agents but are the tissues where the prion material would be found if a prion disease is present. Due to this potential risk, SRM is considered a RG-2 agent.

SRM can be used in a standard CL-2 facility without any additional infrastructure requirements. However, enhanced prion-specific decontamination and waste processing procedures must be adopted. Prion agents are difficult to inactivate requiring harsher chemical treatment or higher temperatures to be effective in comparison with other

pathogenic agents. PIs planning research with SRM should consult with the Biosafety Officers prior to commencing work to ensure the waste processing requirements specific to their research activities are understood. After the initial consultation, facilities using these materials can expect to be inspected specifically by the Biosafety Officers once every five years.

It is also worth noting, the acquisition, transportation and disposal of SRM is regulated by the CFIA and requires specific permits and, depending on the proposed experimental plans, the CFIA may identify additional procedural or containment requirements during the permit application process. The Biosafety Officers will work with the PI through the permit application process to ensure any identified requirements are met in as practical a manner as possible.

The U of A also operates a federally certified and licensed enhanced containment facility for the study of prions that can infect animals and humans. This is the only location on the U of A campuses where purified or active preparations of animal and human prions may be handled or stored. PIs wishing to work in the facility should contact the Centre for Prion and Protein Folding Diseases (780-492-9377) as early in the project planning cycle as possible to ensure the facility is available for use and that their research plans are compatible with on-going research. Personnel must complete several prerequisite steps including training and orientation in the facility's standard operating procedures with a Biosafety Officer before they are allowed access into the facility. This facility is inspected annually by the Biosafety Officers.

4.3.7 Facilities Working with Security Sensitive Biological Agent Toxins

SSBA toxins identified in Section 1.5.3 may all be used in a standard CL-2 facility with the following additional requirements:

- A detailed inventory of these toxins must be maintained as per Section 3.5.4
- Increased security requirements (Chapter 5) come into play for any of these toxins held in amounts that exceed the federally acceptable trigger limits (see Table 1-2)

PIs working with these toxins are required to notify the Biosafety Officers if they plan to acquire more than the acceptable trigger limit quantity. The Biosafety Officers will consult with the PI to ensure the proper inventory and security measures are in place prior to the acquisition of the toxin.

4.4 Containment Level 3 Facilities

The U of A currently operates two containment level 3 (CL-3) facilities. These two facilities are the only locations where RG-3 human and animal pathogens may be handled or stored. The smaller CL-3 facility is currently licensed for a limited number of RG-3 viral pathogens that are not categorized as SSBAs. The larger facility is licensed for a wider range of pathogens which include some SSBAs and has the potential to be licensed for the use of non-indigenous RG-3 pathogens as well as small animal work. These facilities are highly regulated, have their own biosafety programs and are inspected by the Biosafety Officers annually.

Personnel requiring access must complete several prerequisite steps including training and orientation in the CL-3 standard operating procedures. PIs wishing to work in the facility should contact the Biosafety Officers as early in the project planning cycle as possible to discuss the requirements for access and confirm the facility is authorized for the RG-3 agent of interest. The Biosafety Officers will also connect the PI with the appropriate Facility Use Committee to ensure that the planned research and any equipment requirements can be accommodated.

4.5 Containment Level 4 Facilities

Work with organisms requiring CL-4 facilities is prohibited; the U of A does not have any Containment Level 4 (CL-4) facilities.

CHAPTER 5: DAILY LABORATORY WORK PRACTICE

5.1 Introduction

This chapter covers the day-to-day procedural requirements that facilities using or storing biological materials must follow. Again, these procedures are mainly focused on biosafety but do cross over at times to procedures that are required for any hazard. Beyond the guidance provided here, research groups are required to follow all additional safety guidelines or requirements that are applicable to any other hazards present as part of their research program (e.g., chemical, radiation). In circumstances where the instructions given in this chapter are at odds with other safety requirements, the research group must follow the more stringent guidelines. If the research group is unable to determine which guideline would be considered more stringent, they are to contact the Biosafety Program.

5.2 Biosecurity

Biosecurity was originally thought of as the preventative practices necessary to protect the environment and economy from the transmission risk of infectious diseases, pests, non-indigenous species and invasive species. Now, biosecurity also encompasses the steps necessary to reduce the risks from theft and intentional utilization of biohazardous materials for malicious purposes. Biosecurity therefore addresses the potential dual-use of biohazardous materials (as described in Section 2.2).

5.2.1 Infrastructure

The same steps taken to secure biohazardous agents in a laboratory will also protect the laboratory against the potential theft of chemicals, computers, research equipment and personal effects as well as the possible loss of irreplaceable research data. The level of biosecurity required under the federal regulations is directly proportional to risk of the materials present. Biosecurity typically focusses on materials that are considered biohazardous, however, all facilities, including CL-1 facilities working with non-hazardous biological materials, must have the following basic security practices implemented to protect their personnel, resources and research data:

- Establish procedures 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 long periods of time.
- Ensure personnel are informed that the keys and access cards provided are for secure facilities; personnel are expected to keep keys and access cards secure, they are not to share or loan them to anyone and the loss of a key or access card must be reported to their PI immediately upon discovery.
- Report suspicious behavior, unauthorized personnel loitering around laboratory spaces or evidence of attempted forced entry to Protective Services (780-492-5050).

- Ensure laboratory keys are returned or access is removed from access cards when personnel leave the group or no longer require access to the area.

CL-2 facilities can have a wide range of biohazardous materials present. The expectation is that any material that has been classified as biohazardous be kept secure; the goal is that no unauthorized person be able to reasonably walk in and gain access to the biohazardous materials without the knowledge of the facility's personnel.

The manner in which a facility and its biohazards are kept secure will vary depending on the age of the building and the availability of security features. Department Chairs and Institute Directors should coordinate with their personnel to review day time hallway access versus room or equipment access to determine security solutions that best meet the needs of the group.

PIs must then assess all the locations they use and incorporate any additional security measures (infrastructure and/or procedures) needed based on the following:

- Evaluate potential security issues caused by location (e.g., is the laboratory beside a high-traffic public corridor, directly next to a major building entrance, etc.?) and determine if extra security features such as obscured window coverings, security alarms, etc., are warranted.
- Evaluate where the biohazardous stocks are stored. Any biohazardous materials that are stored outside the research group's main laboratory (e.g., in an unattended cold room, storage room, equipment room, cross corridor) must be kept locked. Either the room or the storage equipment itself must be locked, whichever is more practical for the research group.

5.2.2 Inventories

An inventory of biological materials is considered to be part of the biosecurity measures for a facility. In order to be able to show that materials are being kept secure, you must know what materials you have. For details on what must be tracked in your inventory, see Section 3.5.4.

> **N.B. Any missing biohazardous materials must be reported to the PI upon discovery**. If after investigation the missing stocks are not located, a University of Alberta Incident Report must be immediately filed with EHS. Provide a clear description of the biohazardous materials that are missing in the incident description. The Biosafety Officers will determine if any further reporting to the federal regulators is required.

5.2.3 Information

Information security is another aspect of biosecurity. In some circumstances, the experimental plans and research data accumulated may contain sensitive information that could be misused by individual(s) with malicious intent or by competitors to gain an advantage. **It is critical that no information regarding the research program or data acquired is ever shared without the knowledge and permission of the PI.**

Research files should only be kept on computers, servers or external storage devices that are

password protected or where the files themselves have been encrypted.

5.2.4 Laboratory Access

Access to laboratories, including places where biological materials are handled and stored, is restricted to authorized personnel. Personnel who have completed the orientation and training outlined in Section 3.3 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:

- Non-research personnel who must cross the laboratory space to reach their office.
- Custodial staff who have completed Facilities and Operations (F&O) safety training.
- Protective Service, F&O and EHS 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.

N.B. Infants and children are prohibited from entering facilities where biohazardous agents are handled and stored.

5.3 Computers & Tablets & Cellphones

Depending on the type, pathogens can live on surfaces for extended periods of time and be transferred from one place to another on objects (fomites) that they come in contact with. Computer components, especially keyboards and touchscreens, are difficult items to decontaminate. Computer and paper work stations should be kept well away from work areas where biohazardous materials are handled or stored to minimize any potential contamination. 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 cellphones, laptops 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 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.

Alternatively, these items can be placed in waterproof electronics bags that still allow for the use of the touch screens and buttons but are easier to wipe down. The bags can be kept for laboratory use only, minimizing any potential transfer of any hazardous materials to the outside environment.

5.4 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 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 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, and,
5. Clothing that does not expose any skin below the waist.
6. Additional PPE may be required as determined by the research group's hazard assessment as outlined in Chapter 2.

Figure 5.1 Minimum Personal Protective Equipment for working in a laboratory with biohazardous agents.

Other considerations:

- Remember, food and drink are PROHIBITED in any laboratory environment; food, dinnerware, utensils and drink containers must not be stored or consumed in the laboratory. Note, gum, candy and lozenges are considered food items.
- Long hair must be tied back.
- Do not apply or remove cosmetics in the laboratory.
- 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.

- Waste containers for gloves and other disposable PPE should be placed in convenient locations
- Laboratory coats and gowns should be hung on individual wall hooks spaced sufficiently far apart that coats and gowns do not brush against each other. A coat stand should not be used with laboratory coats and gowns.
- Street jackets, coats and personal belongings 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 of the laboratory or research support areas. The wearing of laboratory PPE, regardless of whether it is "clean" or not, is prohibited in any U of A public areas. An exception to this guideline is allowed when personnel transport research material between areas on a building floor (for instance, moving material down a semi-public corridor between a laboratory and a cold room). In this case PPE may be worn but one hand should be kept "un-gloved" to allow for the opening of doors. The ungloved hand should not come into contact with the research material.

5.4.1 Additional Face Protection and Respirators

Any time a potential splash hazard exists, additional face protection must be used. For example, a face shield must be worn when retrieving specimens from a liquid nitrogen dewar.

A suitable 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). robotic enclosure or other appropriate aerosol containment device (Sections 5.6 and 5.7).

N.B. Surgical masks are not equivalent to fit-tested respirators to protect against biohazardous agents.

5.5 Aseptic Technique for Bench Work

Working at the bench is one of the most common activities conducted in a 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 the procedures and techniques designed to avoid and prevent cross-contamination of the worker, the work environment and the specimens/material being handled and is appropriate for any laboratory using biological materials, hazardous or not.

Aseptic technique can be summarized with three rules:

1. Maintain a clean, organized work area
    - Keep laboratory benches clear of clutter
    - Avoid reading, writing or using a laptop or tablet 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 aerosolization
   - 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

5.6 Biological Safety Cabinets & Other Aerosol Containment Devices

Experiments involving materials classified as RG-2 or higher (pathogenic microbes, cell lines, human clinical samples, etc.) 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.

Aerosols can unknowingly be generated by some of the simplest and most common manipulations (e.g., pipetting, micropipetting). Aerosol containment devices provide a means to protect the user and the immediate environment from any potential exposure to a biohazard but also serve to protect the experimental materials from external contamination. Due to the latter, aerosol containment devices are often used with biological materials regardless if they are considered biohazardous or not.

The most commonly used piece of aerosol containment equipment is a biological safety cabinet (BSC). Two classes of BSC are commonly used at the U of A:

1. **Class II-A BSC** - remove aerosolized biological materials from the air in the cabinet via a highly-efficient particulate air (HEPA) filter and recirculates 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 **NOT** appropriate for combined projects involving biological materials with volatile chemicals, anaesthetics or radioactive isotopes.
2. **Class II-B2 BSC -** filters the air from the cabinet through a HEPA filter and exhausts the filtered air out of the laboratory through a hard-ducted ventilation system; no air from a II-B2 is recirculated back into the laboratory. This class of cabinet is appropriate and required for experiments involving biological materials with volatile chemicals, anaesthetics or radioisotopes. Class II-B2 cabinets are also recommended for use with nanoparticle technology as HEPA filtration may not fully contain aerosolized nanoparticles due to their extremely small size.

Figure 5.2. Biological safety cabinet. Example here is 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.

Three additional types of aerosol containment devices that may be used in a laboratory with biological materials are:

- **Cage Change Station** – Basically a Class II-A BSC with some minor modifications to allow personnel to change and clean small animal cages without being exposed to allergens or waste in the cage.
- **Robotic Enclosures** – Purpose-built devices equipped with HEPA-filtered ventilation systems that are used to enclose robotic systems used for the processing of large numbers of biological and medical specimens in analytic metabolome, proteome and genome studies.
- **Soft-walled, Negative Pressure Containment Devices** – Customizable, soft-walled enclosures that can be constructed to any size and configured to suit the research needs (e.g., bioBubble™). They are particularly useful for enclosing large pieces of equipment that will not fit in a biosafety cabinet (e.g., flow cytometer).

Personnel working with one of these alternative aerosol containment devices should follow the guidelines for cabinets below. Purchase, registration and maintenance of these items is the same as for BSCs (Section 10.7).

5.6.1 Setting-Up Work in a BSC

All BSCs are designed for continuous operation and the fan does not need to be turned off when the cabinet is not in use. For the sake of maintaining a sterile environment within the BSC, it is recommended to leave the fan running at all times, especially for BSCs with a fixed view screen. Only BSCs with sliding view screens that can be fully shut or BSCs within a sterile room are recommended to have the fan turned off. If a BSC fan has been turned off, personnel should turn on the fan and let it equilibrate for at least 5 minutes prior to initiating work within the cabinet. This is to allow several air changes to occur, essentially cleaning the air in the cabinet, and ensures the air curtain at the front of the cabinet has been properly established.

Before beginning an experiment within a BSC, the following steps are considered best

practices to ensure proper airflow has been established and assist with ease of work flow:

- Test the airflow of the cabinet by holding a piece of tissue paper at the middle of the edge of the view screen and ensuring that the top of the tissue paper is being pulled toward the inside of the cabinet. Alternately, a commercial smoke generating device, such as a Wizardstick™, can be passed along the outside of the sash to visualize and confirm the cabinet's inward air flow.
- Record the static pressure reading from the magnehelic gauge on a log chart posted on the side of the cabinet (template chart available at Static Pressure Chart). The actual number is not important, however users should monitor for abrupt changes to this reading. Changes in the reading of ±0.25 or more must be reported to the PI or laboratory manager who should put the cabinet out of service until it can be inspected by EHS personnel (see Section 10.7.5).
- Wipe down all work surfaces in the cabinet with a suitable decontaminant.
- Load the cabinet with only the supplies and equipment needed for the planned experiment; do not overcrowd the BSC. Overcrowding a BSC with clutter and excess equipment can disrupt the interior airflow which may compromise the safety of the user and/or the integrity of the experiment.

IMPORTANT:

- The use of an open flame within a BSC is **prohibited**. Flames disrupt the airflow and can damage the cabinet's HEPA filter putting both the user and the experiment at risk.
- UV lights must never be used to replace chemical decontamination of the work surfaces and equipment. Many BSCs on campus have ultraviolet (UV) lights installed. These lights have been proven to be an ineffective method of decontamination, especially if not maintained to the manufacturer's standards. Their use is not recommended by the Biosafety Program. UV lights may be used to supplement, but must not be used as the sole decontamination method.

5.6.2 Working in BSC

While working in the BSC, take the following precautions to minimize both the risk of contamination of the sample and exposure to the user:

- Never block the air grilles. Conduct all experimental manipulations and operations at least 10 cm away from the front and back grilles.
- Avoid excessive movements, both within and adjacent to the cabinet.
- Surface decontaminate **ALL** items that are added or removed from the cabinet. This also applies to gloved hands.
- Never rest arms on front edge of cabinet while handling or manipulating open containers of biohazardous material.

5.6.3 Clean-Up of BSC

Clean the BSC after every experiment as follows:

- Spray or wipe down **ALL** materials to be removed from the BSC (equipment, discard beaker, bagged material, sample tubes, etc.) with an appropriate decontaminant. Microbial and tissue culture plates that could easily spill or become contaminated are exceptions to this rule – instead, place these, in a sealable container that can be sprayed down with decontaminant prior to removing them from the BSC.
- Wipe down waste containers used in the cabinet with decontaminant and remove them from the BSC. If sharps were used during work activities, discard them into an appropriate sharps container.
- Once work is complete and all items have been removed from the BSC, surface decontaminate the cabinet work surface and inner walls.
- If the cabinet will be turned off, after clean-up is completed leave the BSC fan on for an additional 5 minutes before shutting it down to allow any potential aerosols generated during the cleaning process to completely clear.

5.7 Airflow Containment Devices

There are several types of fume hoods and flow hoods that differ from BSCs in their purpose and level of aerosol containment. The following are **not** biocontainment devices and should not be used as such:

5.7.1 Laminar Flow Hoods & Clean Air Benches

These are **NOT** aerosol containment devices. They only protect the product and do not offer any protection to the user or environment against aerosolized biohazardous materials or allergens.

Figure 5-3. Laminar flow hood. Note the lack of a protective sash across the front. The back wall of the flowhood is a HEPA filter system. The clean filtered air is blown across the work surface and out towards the user and room. Aerosols generated from the product will be blown into the face of the user and dispersed into the laboratory.

5.7.2 Chemical Fume Hoods

Chemical fume hoods protect the user from the product but do not protect the product inside from contamination nor the environment from the product. With no HEPA-filter on a fume hood's exhaust ventilation, aerosolized agents are drawn up the ventilation and released into the environment. Decontamination of chemical fume hood ventilation is very difficult to achieve and therefore chemical fume hoods are not recommended for use with biohazardous materials. For directions on how to operate a chemical fume hood safely,

consult the Laboratory Chemical Safety Manual.

Figure 5-4. Chemical fume hood. Note the hard ducted exhaust vent leading from the back of the fumehood into the room ceiling. The height of the front sash is adjustable, however the higher the sash is raised, the more likely the protective air flow at the front of the work area will be disrupted by passing traffic.

5.8 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.

If sharps must be used, the following precautions must be taken to minimize the risks:

- Use sharps with engineered injury protection. 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.
- Anesthetize or secure an animal with hands-free restraints prior to initiating any procedures that require the use of needles or scalpels.
- 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).
- Use only sharps disposal containers that are specifically designed for this purpose. Commercially available sharps disposal containers are 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 them via the U of A CHEMATIX system. Do not attempt to over-fill a sharps container.
- In the event of a needlestick or sharps injury at the University, report the incident to the PI as soon as possible and submit a University of Alberta Incident Report to EHS.

5.9 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 µL filter.
- Use micro-pipettors for the delivery or transfer of small volumes of liquid.
- Use aerosol-resistant, filtered pipet tips when contamination is of particular concern.
- Avoid mixing infectious substances by pipetting up and down (may generate aerosols).
- Submerge contaminated pipets in disinfectant after use with biohazards.

5.10 Blenders, Grinders, Sonicators & Other Tissue Homogenizing Equipment

The use of blenders, grinders, homogenizers and sonicators with biological materials **will** aerosolize the material. When using these types of equipment with biological materials, adhere to the following safety precautions:

- After sonication or blending a sealed preparation, allow aerosols to settle for at least five minutes before opening container.
- Wear double gloves when handling equipment. Discard outer gloves when procedure is complete.
- Conduct all homogenization with biohazardous materials in a BSC.
- After sonication or blending of a preparation in an open container, clean the exterior of the sample tubes and the surrounding work surface at the end of the procedure. Use an appropriate decontaminant if samples are considered biohazardous.
- Wear appropriate hearing protection when using a sonicator.

5.11 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 must be observed:

- Check all rotors, tubes and buckets for cracks or breaks prior to use. Never use any damaged tubes or equipment.
- 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 materials.
- Fill and balance all tubes and rotors in a BSC when using biohazardous materials.
- Only fill tubes to a maximum of 75% capacity to prevent spills.
- After centrifugation is complete, unload biohazardous materials from the rotor or safety cup in a BSC.
- Keep the top of the tube pointed away from you when opening the tubes after centrifugation.

- 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.

5.12 Vacuum Pumps & Liquid Filtration

Vacuum systems are 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 micron 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 biohazardous materials must be done inside a BSC.
- A vacuum flask partially filled with a suitable decontaminant (e.g., a reservoir trap) should be installed between the flask storing the drawn off liquid and the vacuum source.
- Glass vacuum flasks should be taped on the outside to reduce shattering 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.

5.13 Incubators & Warm Rooms

Incubators and warm rooms are often shared laboratory spaces and all users should be aware of any biohazardous materials being used in the space by other groups. All warm rooms holding biological materials are considered research support spaces and must be labeled with a Laboratory Hazard Sign (Section 3.2).

To ensure the optimal use of incubators and warm rooms and to minimize contamination, the following must be observed:

- All cultures must be clearly labeled with the name of the microbe (including strain, if applicable), date started and name(s) of the person running the experiment.
- Walk-in warm rooms should have their floors mopped and shelves wiped down with an appropriate decontaminant at least once every 3 months (groups sharing a warm room should coordinate this activity amongst their members).
- If equipped with an alarm, incubators and warm rooms must have contact information posted at the equipment and on file at the F&O Control Centre to ensure that appropriate action can be taken if equipment fails outside of regular working hours (this contact information should be reviewed by the user group for accuracy at least annually).

5.14 Cold Rooms, Refrigerators & Freezers

Cold rooms, refrigerators and freezers are often shared by many users; all users should be aware of any biological materials being used or stored by other groups. As with warm rooms, cold rooms and storage areas housing fridges and freezers are considered research support areas and must be labeled with a Laboratory Hazard Sign (Section 3.2) and any archival stocks of biological materials held in these spaces must be logged in an inventory as per Section 3.5.4.

Refrigerators and cold rooms must be kept clean and organized, and should not be used for long-term storage of liquid cultures. In order to ensure the optimal use of cold rooms, refrigerators and freezers, and to minimize contamination, the following must be observed:

- Never store food or drink in a laboratory refrigerator, freezer or cold room.
- Biological materials must be stored in adequately sealed 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 and file contact information with the F&O Control Centre to ensure that action can be taken if a unit fails outside of regular working hours (this contact information should be reviewed by the user group for accuracy at least annually).

5.15 Chemicals Used with Biological Materials

There are a wide variety of chemicals used in conjunction with biologicals. 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 Chemical Safety Program webpage.

CHAPTER 6: SHIPPING & RECEIVING OF BIOLOGICAL MATERIALS

6.1 Introduction

The acquisition of biohazardous material has always been regulated. Acquisitions include any materials to be received from sources within Canada or imported from international sources. Historically, the emphasis had been on the receiving facility to obtain all necessary permits and compliance documentation verifying that their personnel and facility were properly equipped to handle the material being received. In recent years, this has all changed. Now, there has been a federally mandated increase in the oversight of any biological material received or shipped. The two main regulators involved are the PHAC and the CFIA.

The documentation required to support a shipment of biological materials is depends on whether the type of material falls under the HPTR and the control of PHAC, under the various regulations administered by the CFIA, or both. The Biosafety Program provides a service to assist researchers with obtaining all the necessary documentation to support their shipment.

N.B. Do NOT attempt to fill in any forms or documents provided by the federal regulators or suppliers on your own.

Instead, fill in the Biological Transfer Form on the Biosafety Program page of the EHS website. The Biosafety Officers will use the information provided to determine which regulations apply and what documentation will be needed in order to proceed. They will continue to help throughout the process. Note, **all shipments of biological materials to or from the U of A must be reported to the Biosafety Program** to ensure all regulatory requirements are met. Reporting must occur prior to the shipment being sent.

The remaining sections of this chapter list the requirements and what can be expected after the submission of the Biological Transfer Form.

If at any point they are unsure how to proceed, researchers should contact the Biosafety Program.

6.2 Acquisition of Biological Material

Once a PI or their designate submits the Biological Transfer Form indicating the intent to acquire a regulated biological material, the Biosafety Officers will check the Biosafety Program records to confirm the PI is both registered and up-to-date with all institutional program requirements. In some circumstances, the Biosafety Officers may need to conduct a site inspection to support the acquisition request (e.g., a new type of biohazardous material is requested that may require changes to local infrastructure or procedures). Once all the required information is verified, instructions will be provided back to the PI, or their designate, indicating how to proceed. It is critical that the instructions provided are followed.

Canadian commercial distributors have generally developed their own processes and documentation for complying with the various regulations. The Biosafety Officers will assist with any required documentation and provide compliance or license information to the company on the PI's behalf. The acquisition of material from a Canadian collaborating institution will require a transfer form (Section 6.3) where the U of A PI will be designated as

the recipient.

6.2.1 Importation Requirements

a. HPTR Regulated Materials

Under the HPTR import permits are no longer required. However, the facility receiving the material, whether being imported or received from a Canadian source, must have a valid HPTR license for the type of material being acquired. Here at the U of A, this means individual facilities must remain in good standing with the Biosafety Program as outlined in Sections 1.6.1 and 1.6.3 and be compliant with the regulations in order to be covered by the institutional HPTR license (Section 1.6.2).

The Biosafety Officers have developed a supporting process with Supply Management Services (SMS). When the research group receives their instructions, SMS will also be notified that the researcher is approved to acquire the specified material. One of the instructions provided to the research group will always be to provide SMS personnel with copies of the shipping documentation and the tracking number for the shipment. This information is essential for SMS to be able to monitor the shipment and ensure the appropriate information regarding the institutional license is provided to the appropriate border authority.

b. CFIA Regulated Materials

Import permits are required for any of the various types of materials that the CFIA regulates and deems hazardous. The hazard may be from the material itself but in many cases the hazard may simply be potentially associated with the material. The CFIA does not have standardized processes and evaluate requests for import on a case-by-case basis.

The Biosafety Officers will use the information submitted on the Biological Transfer Form to prepare all the necessary permit application documents. In most cases, a laboratory inspection is required as part of the application process. Import permit applications must also be signed by the PI and include credit card information to cover the cost of the permit. The Biosafety Officers will contact the PI to make the necessary arrangements.

For imports involving animals or animal by-products, a zoosanitary certificate is often required. This is a certificate issued by a veterinarian in the exporting country verifying the animal or material being shipped and the region, country or zone of origin. It must also include certain health status criteria that are dependent of the type of animal involved. In circumstances where zoosanitary certificates are difficult to obtain, the Biosafety Officers will advocate for the researchers to the CFIA to determine what alternative documentation would be deemed acceptable.

Typically, the CFIA requires a site visit to verify the information provided in the application and review local documentation (e.g., training records, inventories, SOPs). The Biosafety Officers will work with the PI and their research group to make the

arrangements for the site visit and will be in attendance to support the researchers and speak to any institutional questions that may arise.

Processing of the application by the CFIA can take anywhere from 25 days up to several months. Research groups are recommended to fill in the Biological Transfer Form as soon as they know the details of the material they wish to receive and where it is coming from. Once documentation is received from the CFIA, the Biosafety Officers will provide copies to the research group along with instructions on how to use them.

Do not attempt to acquire any regulated biological material without the assistance of the Biosafety Program. Without the Biosafety Officer's approval, Canadian commercial distributors will not release your shipment and imported material will be at risk for being refused entry into Canada.

6.2.2 Receipt of Biological Materials at Your Facility

When any biological materials arrive, open the package in the laboratory wearing appropriate PPE. Inspect the package to confirm it is intact and report any breakage or leakage to your PI or supervisor. Broken or leaking containers must be cleaned up using the Biological Spill Remediation Procedure (Section 9.6). After clean-up, report the broken or leaking container to EHS by filling out a University of Alberta Incident Report.

If the material arrived safely and intact, log the material into inventory and make note in the inventory of any usage restrictions indicated on the import permit or imposed by the supplier of the material (in vitro use only, material may not be shared with a third party, etc.).

Any shipment that does not arrive when expected must be investigated. Follow up with the supplier of the material to verify when the material was shipped. Use the courier's tracking number to determine where the material might be and, for imported material, contact SMS and ask for their assistance tracking down the package. If the material cannot be located, it must be reported to the Biosafety Program.

N.B. If the material is classified as an SSBA or as RG-3, missing shipments must be reported to the Biosafety Program immediately upon discovery and prior to initiating the investigation into its whereabouts.

6.3 Shipment of Biological Materials

This section deals with the transfer of any biological material from the university to an off-campus location. For example, this could refer to transporting materials to another institution within the city, shipping to a facility within Canada or exporting to another country. Depending on the type of material and its final destination a transfer document, movement certificate, export permit or combination of these may be required. As indicated above, the Biosafety Officers will use the information provided on the Biological Transfer Form to determine what documentation will be needed.

In recent years, there have been several changes to requirements for biological shipments. For materials regulated under the HPTR, not only does the biosafety officer need to be informed of

the shipment, there is also a due diligence expectation written into the regulations stipulating that the sender must take reasonable steps to ensure the receiving facility is an appropriate containment facility authorized to handle the material being shipped. For materials regulated by the CFIA, transfer documentation or movement certificates are required for any material that had originally been obtained under a CFIA import permit. These documents allow for the tracking of material but also, similar to the due diligence requirement in the HPTR, verify the receiver has an authorized facility for the material being shipped.

The Biosafety Officers will provide a transfer form to PIs or their designate along with instructions on how to use it. The form is designed to capture the necessary information from both the shipping and receiving facilities to ensure the regulatory requirements are met for all parties involved. This transfer form, or a functional equivalent, has been implemented by several of the larger academic institutions across Canada.

With all the required documentation in hand, arrangements can be made for the shipment of the material. When shipping biological materials:

- Only commercially available packaging products designated as P620 or P650 should be used.
- Primary containers must be ringed with parafilm or tape to ensure a complete and steadfast seal prior to being placed in the secondary container.
- Glass primary containers must be wrapped in absorbent padding if more than one container is to be placed in a single secondary container to prevent direct contact and reduce the risk of breakage.

Transfer of any biohazardous material off campus**,** including between university campuses**,** falls under Transportation of Dangerous Goods (TDG) regulations. Any material shipped on dry ice, hazardous or non-hazardous, also falls under TDG regulations; dry ice is considered dangerous goods.

6.3.1 Transportation of Dangerous Goods

The TDG Act is federal legislation designed to regulate the movement of dangerous goods via roads, rail, air, and ship to protect personnel involved in the transport as well as the general public and the environment. The TDG regulations specify the required packaging and labeling of any hazardous materials. In case of an incident, 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. **Under no circumstances is the transporter to use Edmonton Public Transit, including the city's Light Rail Transit (LRT), to transfer biological materials between U of A campuses**. All individuals who are involved in packaging and transfer of hazardous materials off campus must have valid TDG certification. This certification can be obtained by taking the online EHS TDG Training.

a. Shipping Materials with Dry Ice

The shipment of biological material on dry ice carries the same TDG training requirements described above. Dry ice is considered hazardous during transportation

for three reasons:

- Explosion hazard - Dry ice releases a large volume of carbon dioxide gas as it sublimates. If packaged in a container that does not allow for release of the gas, it may explode, causing personal injury or property damage. Dry ice must never be packaged in a sealed container.
- Suffocation hazard **-** A large volume of carbon dioxide gas emitted in a confined space may create an oxygen deficient atmosphere.
- Contact hazard **-** Dry ice is a cryogenic material that causes severe frostbite upon contact with exposed skin.

CHAPTER 7: TRANSPORT OF BIOLOGICAL MATERIALS ON CAMPUS

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 conditions listed below are followed. Remember, any movement of biohazardous agents off campus, including between U of A campuses, falls under TDG regulations and is covered in Section 6.3.

In all cases, the primary containers used to hold the biological material must be in good condition with tightly fitting lids. Damaged containers must not be transported. Personnel are to proceed directly from the pick-up location to the delivery location and are not to deviate from the task to conduct other errands, i.e., personnel are not to stop along the way to use washroom facilities, purchase or consume food or drink, etc.

7.1 Between Adjoining Laboratory Space

When transporting biological material between rooms on the same floor, use a cart when transporting large containers or more than one item; never carry multiple containers by hand. Wear PPE but keep one hand ungloved to open doors.

7.2 Between Floors within a Building

When transporting biological material between floors of the same building:

- 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 a cart with the primary containers of material contained on a tray or in a bin; never hand carry biological materials when moving between floors.
- Place bottles of liquid biohazards in a secondary container large enough to contain the volume of liquid being transported. Include absorbent material on the cart or in a secondary container.
- Wear appropriate PPE but keep one hand ungloved to open doors and push elevator buttons.
- Avoid the use of passenger elevators. Freight elevators should be used whenever possible. Do not use stairs when transporting hazardous materials.

7.3 Between U of A Buildings

This section applies ONLY when transporting biological material between U of A buildings on foot (when materials are being transported in a vehicle, TDG regulations apply).

- Wearing appropriate laboratory PPE, place the primary container of biological material in a zip-lock bag along with enough absorbent material to contain the sample if a leak from the primary container occurs. Once the bag is sealed, surface-decontaminate it with an appropriate decontaminant. Label the bag with the researcher's name, date and sample contents.
- If the material to be transported contains a biohazardous or chemical agent, label the zip-lock bag with the appropriate WHMIS symbols. Note: once the material has been successfully delivered, cross out or deface the WHMIS symbols prior to disposing of the bag.
- Place the zip-lock package in a cooler or equivalent safety container with a water-tight lid that could withstand a fall from waist height. Label the outside of the cooler with the name of the researcher, their laboratory address and phone number. The outside of the cooler should be free of biohazard symbols.
- **Do not** wear laboratory coats and gloves during transport.
    - Some AHS departments will only release clinical specimens to personnel who are wearing laboratory coats. In this case, personnel picking up the material shall wear a clean laboratory coat dedicated to this task and not one that has been used within the laboratory for research manipulations.
- Once at the destination, standard laboratory PPE must be put on before opening the cooler to empty the contents.

7.4 What if Something Goes Wrong?

The most important component in spill response is preparation. Individuals should be aware of the particular hazards associated with the material they are transporting. During transport, if materials begin leaking out of the container, immediately contact F&O Control Centre (780-492-5555) via the nearest phone to activate a Spill Response for assistance with the clean-up. Alternately, call back to your Department or Institute for assistance if they maintain a list of trained spill designates. At least one person must remain at the site and prevent anyone from walking in the spill area. A University of Alberta Incident Report must be filed with EHS as soon as reasonably possible after the remediation of the spill.

CHAPTER 8: CLEANING, DECONTAMINATION & WASTE MANAGEMENT

8.1 Cleaning & Decontamination

Cleaning and decontamination are fundamental steps in preserving the integrity of the work being conducted and protecting personnel in any containment facility.

All work surfaces and equipment used with biological material (whether or not it is considered biohazardous) 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 projects in addition to protecting an 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.

Personnel working with biological materials may use a commercial bench coat to cover their work surfaces but it should be used with caution. Bench coat material that is used repeatedly day after day can easily become a source of contamination. Any bench coat material should be replaced as soon as it becomes visibly soiled or at the completion of the day's work, whichever is sooner. Bench coat material used for any activity involving biological materials must be autoclaved prior to disposal or disposed of via incineration.

All biological materials used in a research, teaching or testing setting must be decontaminated or inactivated prior to disposal via one of the methods described in Section 8.2. Under no circumstances may personnel dispose of untreated waste potentially contaminated with biohazardous materials 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.

8.2 Decontamination Methods

Biological materials may be decontaminated by one of three methods; chemical decontamination, autoclaving or incineration.

If biological waste must be stored while awaiting decontamination, it must be stored as follows:

- No more than 24 hours at room temperature
- No more than 42 days at $0^{o}C$ to $+4^{o}C$
- No more than 90 days below $0^{o}C$

Chemical decontamination is most commonly used for work surfaces, equipment and some liquid cultures. Autoclaving is the preferred method of decontaminating typical solid wastes and liquid cultures (eukaryotic cell culture or microbial cultures) regardless of their risk group designation. Incineration services are available for items that cannot be safely autoclaved or facilities that do not have access to an autoclave. However, whenever possible, it is preferable to treat biological waste on site rather than transporting it to an off-campus location for processing. Personnel with access to an autoclave or autoclaving services within their area are expected to use them.

8.2.1 Chemical Decontaminants

The most common chemical decontaminants recommended for use at the U of A 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**™ – 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-spore-forming bacteria.
- **10% bleach** – Is the all-purpose decontaminant effective against human clinical specimens, animal specimens, eukaryotic cell lines, viruses, fungi bacteria and rDNA technologies. Used at a minimum contact time of 5 minutes it can be used to clean surfaces and equipment.

  10% bleach (final concentration) can be used to treat liquid waste (e.g., eukaryotic cell culture or microbial culture waste) assuming the bleach treatment is allowed to stand for a minimum of 30 minutes.

  10% bleach with a contact time of 30 minutes is also used for the remediation of all spills of biological materials (Section 9.7). Note, metal surfaces treated with 10% bleach should be rinsed with water (or 70% ethanol if wanting to maintain sterility) after the contact time in order to prevent corrosion.

Once used, these three decontaminant solutions may be poured down a sink or sewer drain for disposal provided there are no other hazardous chemicals in the solution. Subsequently, the drain must be flushed with a copious amount of water (i.e., run cold water with tap fully open for a minimum of 60 seconds). For disposal of any other chemical decontaminants or mixed hazardous solutions, consult the MSDSs for the components involved.

Personnel preparing chemical decontaminant solutions must read the associated MSDS(s) and wear appropriate PPE. If one of the above three decontaminants is not appropriate for a specific task, alternative types of chemical disinfectants are listed in Table 8-1 and can be used provided they are effective against the biohazardous material in use (for pathogens, verify by referring to the PSDS for the microbe(s) involved).

Table 8-1. Properties of some common chemicals for the decontamination of work surfaces

Decontaminant	Active Ingredient Concentration [a] (%)	Minimum Contact Time (min)	Effective Against[b]					
			Tissue specimens	Vegetative bacteria	Lipophilic Spores	Tubercle bacilli	Hydrophilic viruses	Bacterial Spores
Alcohols (e.g., ethanol, isopropanol)	70 - 85	10 - 30	+	±	+	+	±	NA
Chlorines (e.g., bleach, Presept™)	5 - 10	5 - 30	+	+	+	+	+	+
Phenolics (e.g., Dettol™, Lysol™)	0.2 - 3	10 - 30	+	+	+	+	±	NA

Iodophor Compounds (e.g., Wescodyne™)	0.47	10 - 30	+	+	+	+	±	NA
Quaternary Ammonium Compounds (e.g., Roccal™)	0.1 - 2	10 - 30	+	+	+	NA	NA	NA

[a] See manufacturer's guidelines for dilution of commercially available disinfectants

[b] + means the decontaminant is effective against the indicated biological material, ± means the decontaminant is effective against some but not all members of the indicated biological material, and NA stipulates the decontaminant should not be used against the type of microbe indicated.

8.2.2 Autoclaves versus Tabletop Sterilizers

Autoclaves are high pressure, high temperature devices that internally monitor these parameters throughout a cycle to ensure the proper temperature and contact time have been met and maintained throughout the cycle. Many of the newer autoclaves also operate under vacuum which greatly improves their temperature penetrating ability. As such, autoclaves provide an effective means of sterilizing and decontaminating biological materials. They are also routinely used to sterilize laboratory supplies, solutions and media. These functions often lead to autoclaves being referred to as sterilizers, however, not all sterilizers can be used as an autoclave.

Tabletop sterilizers usually operate at a lower pressure than an autoclave and do not monitor the set temperature throughout the cycle. These units are useful for sterilizing equipment or glassware that has already been cleaned by another process but must NOT be used for decontaminating biological waste.

For an autoclave to be used for biohazardous materials, it must have a recording device that records the temperature throughout the cycle and must be regularly verified using biological indicators (section 10.9.3). The use of biological indicators confirms the effectiveness of the process and verifies that the temperature calibration remains within an effective range over time.

The nature of autoclaves being pressure vessels operating at high temperatures makes them very effective but also means improper usage can pose a significant injury risk to personnel (contact burns, steam burns, fluid scalds, containers exploding causing bodily harm, etc.). In order to ensure that autoclaves function properly and to minimize the risk of injury to personnel, the following steps are required:

a. Safe Operation

- Personnel operating an autoclave must be trained to do so.
- Always wear appropriate laboratory PPE (use additional heat-insulated gloves for unloading).
- Follow manufacturer's recommendations for daily checks (e.g., ensure drain screens are clear, door gaskets are clean and free from nicks or damage) and maintenance.
- Ensure cycle conditions are appropriate for the type of material being autoclaved

(see Table 8.2 for minimum cycle conditions).

- Understand what types of materials are in the load to be autoclaved; always be sure the materials are safe to be autoclaved. **NEVER autoclave volatile chemicals or unknown chemical mixtures.**
- Upon initiation of a cycle, remain in the area and monitor until the sterilization phase of the cycle has begun.

b. Material Preparation

- Use clear autoclave bags with no WHMIS symbols; whenever possible, do NOT use orange biohazard bags.
- Do not overstuff waste containers or autoclave bags.
- Do not overfill liquid containers. As a general rule, never fill liquid containers more than 2/3 full to reduce the risk of them boiling over.
- Affix a piece of autoclave tape to the exterior of each item in the load. The colour change of the tape will help distinguish those items that have been autoclaved versus those that have not.

c. Loading

- Always place materials to be autoclaved in autoclave safe bins. Do not place materials directly on the autoclave rack.
- Do not over load the autoclave.
- Always loosen caps on containers of liquids.
- Loosen or remove closures on any autoclave bags
- Use a temperature probe if available. The probe should be placed directly in 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.
- Make sure the temperature probe wire is position out of the way of the rack; do not allow the probe's wire to be run over or pinched by the cart
- Make sure the door is closed and sealed appropriately.

d. Unloading

- Ensure the pressure of the chamber is "0" before attempting to open the door.
- Stand away from the autoclave door opening and open the door slowly to release residual steam.
- Leave autoclave door open and let materials stand for at least 10 minutes before pulling out the rack to allow temperature to drop and pressure in liquid containers to normalize.
- Allow contents to cool prior to unloading.

Fully autoclaved solid waste is no longer hazardous and can be disposed of in the building's regular waste stream provided there are no other hazardous materials present in the waste mixture (e.g., hazardous chemicals, sharps) that were not rendered inactive by the

autoclaving process (see Section 8.2). Also, there cannot be any identifiable hazard symbols anywhere on the packaging. If a biohazard symbol is present after autoclaving, then it must be defaced prior to disposal.

Autoclaved liquid wastes may be poured down the drain provided there is no significant particulate matter present that may clog the sink drain and no hazardous chemicals present that were not inactivated by the autoclaving process.

NEVER dispose of biological waste from a failed autoclave cycle into the regular waste stream or down a sanitary drain. If the autoclave cycle aborted or did not maintain its sterilization temperature for the full sterilization time, the load contents must be re-autoclaved prior to being disposed of.

Table 8.2. Common autoclave cycle parameters

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

***** When autoclaving liquids, the larger the volume of liquid, the longer it will take to come to the set sterilization temperature. It is recommended to restrict the total volume of liquid per container to no more than 2 L. If larger individual volumes must be autoclaved, the research group must conduct cycle validation tests using a temperature probe or biological indicators to ensure the cycle parameters are appropriate and effective.

[a] It is important to note that these are minimum requirements only. If your research group or department has higher standards, defer to those.

8.2.3 Incineration

Incineration services are available through the EHS CHEMATIX system for all biological waste that either cannot be reasonably or safely autoclaved, or if there isn't an available autoclave within the research group's area.

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

- Animal carcasses and body parts.
- Human tissue specimens.
- Volatile chemicals or unknown hazardous chemical mixtures.

Materials to be incinerated must be packaged in either plastic biohazard pails with lids or disposal boxes for hazardous materials. Disposal boxes are typically used for mixed solid wastes. Pails should always be used for any materials that may leak during transport. If research personnel are unsure how to properly package biological waste for incineration, contact EHS for additional information.

8.2.4 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 equipment and electronic devices. The Biosafety Program utilizes these methods 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 and monitoring devices. Any group considering gaseous decontamination for their area or equipment must contact EHS for assistance.

8.2.5 Inactivation of Biological Toxins

All biological toxins must be inactivated prior to disposal. For most proteinaceous toxins (e.g., cholera toxin, shigatoxin), autoclaving for 1 hour at 121°C will effectively inactivate the toxin. However, for low molecular weight toxins (e.g., microcystin) autoclaving is not sufficient. Chemical inactivation must be used for any toxin that is not susceptible to heat inactivation. Adequate inactivation of most biological toxins, including small molecular weight peptide toxins and mycotoxins, can be achieved by treating with 2.5% NaOCl + 0.25N NaOH (final concentration) for a minimum of 30 minutes.

It is critical that personnel understand which inactivation method is effective for the biological toxin they are using. Always consult the MSDS, product information sheet and/or published technical information to determine the appropriate inactivation method. If personnel are unable to determine which inactivation method should be used, contact the Biosafety Program prior to conducting any experiments with the biological toxin.

8.3 Waste Management

8.3.1 Transport of Waste within a Facility

Personnel must use a cart when transporting biological waste from a facility for treatment in a wash-up area or autoclave room; NEVER hand-carry waste materials from one facility to another. The primary containers of waste material are to be place in a leak-proof, sealable

plastic or metal secondary container on the cart. The secondary container must be of sufficient size to contain waste material if the primary container leaks.

8.3.2 Laboratory Waste Pick-Up

Building Services personnel are only authorized to collect laboratory waste that has been decontaminated. The waste bags and containers must not have any identifiable hazard symbols left after decontamination.

If waste cannot be decontaminated by the research group, the material must be picked-up by EHS for disposal as hazardous waste. To arrange for EHS pick-up of properly packaged biohazardous, chemical or radiological waste, register with the EHS Hazardous Waste Management online program (CHEMATIX).

8.3.3 Waste Packaging

All personnel must package and segregate the waste generated in their laboratories as outlined in Table 8-3.

Failure to follow the guidelines in Table 8-3 may result in the research group or their department having to cover hazardous waste disposal costs for improperly segregated material. EHS personnel have the right to refuse pickup of any waste that appears unsafe, is not properly packaged and labeled or if the type of waste material is not identifiable. If research personnel are unsure how to package their waste or where to acquire waste packaging containers, contact EHS.

8.4 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** – Must be initially packaged in a clear plastic Radiation Bag that may be obtained from EHS. Once sealed in a Radiation Bag, the waste may need to be placed in an additional container from Table 8-3 to guard against leakage.
- **Biohazards with flammable, combustible, volatile or corrosive chemical waste, or sharps** - Package in appropriate container from Table 8-3 and arrange through CHEMATIX for pick-up and disposal by EHS. Never autoclave flammable, highly-reactive chemicals or sharps.
- **Biohazards with other types of chemical waste** – May be autoclaved and then disposed of following disposal methods for the chemical involved provided there is no information on the chemical's MSDS indicating that autoclaving may be contraindicated. If in doubt regarding a chemical's compatibility with autoclaving, contact EHS prior to proceeding with the autoclaving.

Table 8.3. Waste packaging containers approved for University of Alberta laboratories.

Container	Description
Regular Black Garbage Bags 	The waste bins in the laboratory containing black garbage bags are emptied by Building Services custodial personnel. **Regular black garbage bags are for the collection of non-contaminated paper and office waste only.** Laboratory consumables, glass waste or sharps **MUST NEVER** be discarded into black garbage bags.
Uncontaminated/Non-Hazardous Laboratory Consumables 	Laboratory consumables are any laboratory waste materials used to conduct research (e.g., disposable gloves, tissue culture plates, microcentrifuge tubes, etc.). Laboratory materials that are not contaminated with chemical, radioisotope or biohazardous materials should be collected in semi-transparent garbage bags. The research group must seal the bag themselves, label it with the date and the phrase "Non-Hazardous Material", and place it at the designated location for waste pick-up by Building Services personnel. Unlabeled materials may be refused by Building Services; Building Services had the right to refuse pickup of any material they believe is unsafe.
Clear Autoclave Bags for Biohazardous Agents 	Clear autoclave bags may be autoclaved following the guidelines presented in section 8.2.2. After autoclaving is complete, allow the sterilized waste to cool to room temperature, then reseal it and place it at the designated location for waste pick-up by Building Services personnel. If the autoclave bag is leaking and/or has been damaged during autoclaving, repackage material into an additional bag to contain the material.
Disposal Boxes for Hazardous Materials 	Package non-autoclaveable solid and/or dry biohazardous waste in designated disposal boxes and arrange for their pick-up through the CHEMATIX system. Place no more than 10 kg of material into a single box. Do not use disposal boxes for any wet waste material or mixed hazardous materials; use a pail with a lid for these types of waste (see below)

Pail *without Lid* for Non-hazardous Glass for Recycling 	Glass waste includes empty glass chemical containers, glass reaction vessels and specimen containers, glass pipettes and large, sharp hard plastic ware. **Glassware must be cleaned and free of any contaminating hazardous material prior to disposal in the pail** (for biohazardous agents this means the glassware must be autoclaved). Pails of non-hazardous glass waste will be picked up by Building Services personnel and after the pail is emptied it will be returned to the laboratory for reuse.
Plastic Pail *with Lid* 	Wet biological waste, mixed hazardous waste and glass waste that cannot be cleaned of hazardous materials must be packaged in a plastic pail outfitted with a lid. Do not fill the pail past the three-quarters full mark. The research group must make arrangements utilizing the CHEMATIX system for the material to be picked-up for hazardous waste disposal. While awaiting pick-up by EHS, the pail must be stored in a secure location away from other waste material and under conditions compatible with the hazardous materials involved (i.e., stored at 4°C for biological materials, stored in a chemical fumehood for noxious chemical contaminants, etc.). Lidded pails for hazardous waste disposal are single-use items that are destroyed with the hazard and therefore are not returned to the research group following pick-up.
Sharps Containers 	Sharps must only be disposed of in commercially available containers that are leak-proof, puncture-proof and specifically designed for sharps disposal purposes; repurposed plastic chemical containers are not acceptable. Discard needle/syringes as whole assemblies. Do not attempt to recap or clip the needle or remove it from the syringe. Do not fill the containers past the three-quarters mark. Once filled, seal the container, label with the research group's name, ensure the WHMIS symbol(s) on the container is (are) appropriate for the hazards used with the sharps and place it at the designated secure location for sharps waste pick-up by EHS. Do not autoclave sharps.

CHAPTER 9: MEDICAL SURVEILLANCE & EMERGENCY RESPONSE PLANS

9.1 Medical Surveillance

9.1.1 Self-Monitoring Health

Personnel working with biohazardous material causing infectious disease or toxigenic effects in humans must read the PSDS or MSDS associated with the material. Personnel must be aware of the potential exposure routes through which the biohazardous material is typically transmitted and self-monitor their own health for symptoms of disease or exposure associated with the material they are handling.

If a laboratory acquired infection (LAI) or exposure is suspected, regardless of whether the individual can identify a known exposure event, the individual must consult with their PI/supervisor. If symptoms are severe enough to seek medical attention, the individual must identify where they work and what biohazardous materials they work with to the attending physician. This information may help the physician with their diagnosis. Any potential exposure to a biohazardous material must be reported to EHS (see Section 9.2)

Existing illnesses and immunocompromised conditions may make individuals more susceptible to a potential infection with the biohazardous materials they are working with. Personnel should refrain from entering a biohazard containment laboratory if they are sick with an active infection, or are immunocompromised due to medication or other conditions.

Women who become pregnant should advise their PI/supervisor of the pregnancy as soon as possible. Together, the PI/supervisor and worker should review the hazard assessment(s) for the applicable work activities and determine if any of the biohazardous materials, chemical hazards or other hazardous conditions in the laboratory pose undue risks to the unborn child. If hazards are identified that pose an elevated risk to the unborn child, the associated activity should be transferred to another member of the research group for the duration of the pregnancy. It is also **strongly recommended** that the pregnant worker review their work activities and the results of this assessment with their physician. If personnel do not have their own physician or would like further assistance with a risk evaluation for pregnancy, personnel may contact EHS and request a consultation with an occupational physician.

9.1.2 Immunizations

LAIs are a real risk for personnel working with infectious biological agents. Immunizations can be an important part of protecting personnel against the infectious agents they work with. If a vaccine is available, immunizations should be considered. The evaluation of whether immunizations are appropriate for personnel involved in a given research project should occur at the hazard assessment stage and is fully described in Section 2.3.

It is important to note, that while immunizations are valuable, they should not be relied upon as complete protection against any exposure. It is always better to prevent an exposure than to rely on the immunization alone for protection. The best protection for personnel comes from multiple, redundant mitigation strategies working together that help ensure personnel are still protected even if one strategy should fail. For example, wearing

appropriate PPE, reducing sharps usage or using safety engineered sharps, conducting all work with biohazardous materials in a BSC and immunization of personnel all act together to significantly minimize the risk of a LAI.

9.1.3 Allergens

Allergens may be encountered in research when working with biological organisms or related tissue specimens, or when cleaning up waste materials from these 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 elicit human allergies.

Allergy symptoms generally consist of rashes where the allergen made 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 aerosolized material contacting eyes and mucous membranes or through inhalation. Personnel may also be inoculated with allergens through uncovered wounds, animal bites or needlestick 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 exposure to the source of the allergens. Personnel should also not self-medicate with off the shelf antihistamines without consulting a physician; while the medication can alleviate symptoms, it may mask an overall worsening of the condition.

To reduce individual exposure to animal allergens, consider the following:

- 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 (Section 5.6.1).
- Avoid wearing street clothes while working with potential allergen sources; change into facility-dedicated laboratory scrubs.
- Keep areas where potential allergen sources are handled or stored clean and free of dust; regularly mop and wipe down surfaces with wet cleaning towels or mops 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 aerosolization 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 5.4. For field research or working with livestock, personnel should determine appropriate PPE using Section 5.4 as a reference.
- Use a suitable 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.

9.1.4 First Aid

Only trained individuals should administer first aid to an injured person. Contact your department/institute office to determine the first aid attendants in your work area. First Aid training is currently provided by outside training agencies. To arrange for First Aid training go to: First Aid & CPR/AED. Further information, including appropriate first-aid kit contents, can be found in Section 10.4.

All research personnel should be familiar with the location of the following relative to their work area:

- First aid room and/or first aid kit(s),
- List of first aid attendants, and
- Location of nearest medical facilities.

Table 9-1 provides basic guideline for an initial response to some of the more common injuries and potential exposures that might occur in a containment facility.

Table 9-1. Initial response for injuries and potential exposure events occurring in the laboratory.

Injury or Potential Exposure Type	Recommended Immediate Actions
Needlesticks	• Remove PPE if covering affected area • Wash affected area well with soap and water and flush with water for at least 5 minutes. Allow wound site to bleed freely while washing. • If there was the potential for exposure to human blood or clinical specimens or live pathogen seek immediate medical attention
Cuts & puncture wounds	• Remove PPE if covering affected area • Wash affected area well with soap and water and flush with water for at least 5 minutes • Apply appropriate skin disinfectant and bandage with water-proof dressing • Seek medical attention as necessary
Animal bites	• Remove PPE if covering affected area • Wash affected area well with soap and water and flush with water for at least 5 minutes • Apply appropriate skin disinfectant and bandage with water-proof dressing • Seek medical attention as necessary • In Incident Report to EHS, be sure to indicate if the animal was naïve or had been inoculated with a biohazardous agent or chemical hazard
Eye splash	• Rinse eyes at eyewash station for at least 5 minutes • Seek medical attention as necessary
Splash onto body	• Remove PPE and affected clothing • Wash affected area well with soap and water and flush with water for at least 5 minutes • Use emergency shower or drench hose as necessary • If splash made contact with broken skin, wound should be treated as per cuts & puncture wounds above
Ingestion	• Seek immediate medical attention (Poison Control: 1-800-332-1414) • Note quantity of material ingested, report quantity to attending physician and in Incident Report • Self-monitor health for symptoms according to physician's instructions
Inhalation	• Seek immediate medical attention • Self-monitor health for symptoms according to physician's instructions

9.2 Incident Reporting

Any incident involving U of A faculty, staff, students or visitors must be reported to EHS using the University of Alberta Incident Report. Whenever possible, the report should be submitted within 48 hours of the incident occurring. Descriptions of the various types of incidents that may occur and any additional instructions can be found on the Report an Injury or Incident page of the EHS website.

For personnel who work with biological materials, any incident involving a potential exposure, accidental release or missing biohazardous material must be reported as soon as possible via the University of Alberta Incident Report. In the incident description, provide a complete description of the biological material involved, clearly indicate if the material was additionally inoculated with a pathogen or toxin and how the incident occurred. The Biosafety Officers review all incidents involving biological materials and will follow-up with the individual and their PI/supervisor if required. Also, the Biosafety Officers will use the information to determine if any additional reporting of the incident is required under the applicable federal regulations.

9.3 Near Miss Events

A near miss event is defined as "an event where no actual harm was done but where there was the potential for serious injury, hazardous spill, or property damage". Near miss events offer the opportunity to refine practices and protocols which may prevent an actual event occurring in the future. These events may also point to degrading equipment and infrastructure which have the potential to fail in the future. When a near-miss event occurs, individuals should discuss the event with their PI/supervisor, and together complete a University of Alberta Incident Report.

9.4 Fire & Evacuation Alarms

All fire and evacuation alarms are to be treated seriously; never ignore an alarm. Always be aware of the nearest exit point from the laboratory and building, and muster point. The U of A has a Fire Warden program in place, each floor of every building has an individual designated to assist in the event of a fire alarm.

When a fire alarm sounds in a building, immediately secure all biological materials in use. Shut off all equipment, remove PPE and exit the laboratory as soon as possible turning off the lights and closing doors as you leave. Follow any additional instructions provided by the floor's fire warden.

In the event of a fire within the laboratory, immediately notify personnel in close vicinity and ensure that the laboratory is evacuated. Activate the fire alarm in the corridor as soon as possible. Attempts to fight the fire should not be made unless the individual has received fire extinguisher training, and only after any personnel in immediate danger have left the area.

9.5 Power Failures

In the event of a power failure, seal and secure all biohazardous materials in use. Research groups are not to continue work with biohazardous materials when power is not available for

BSCs and laboratory ventilation. If a BSC is equipped with emergency power, personnel should finish essential tasks only and still secure all biohazardous materials as soon as possible; non-essential tasks are not to be started when a BSC is running on emergency power.

As much as possible, avoid opening freezers, cold rooms and incubators to preserve temperature control for as long as possible during the power failure.

9.6 Biological Spill Remediation Protocols

All spills of biological material must be remediated as per the protocols below. Even if the material involved was not biohazardous, improper remediation can result in biological material being left behind to rot and cause foul odors in the laboratory, or to cross-contaminate other experiments.

Personnel should be familiar with the location of the chemical and biological spill kit and be familiar with how to respond should a spill occur. Departments or institutes may have set up chemical and biological spill kit stations within their areas for communal use. If not, then groups working with biological material must assemble their own biological spill kit as detailed below.

9.6.1 Biological Spill Kit

All biological or medical laboratory spaces must have ready access to a biological spill kit. The kit must be equipped as follows:

- Dedicated mop and bucket (minimum capacity of 15 L)
- Jug of household bleach (write date of purchase on side and replace annually to ensure efficacy)
- Old bath towels (minimum of three)
- Package of J-cloths or box of cheesecloth
- One pair of large forceps
- Face-shield or safety goggles
- Two single-use self-adhesive N-99 respirators (example is a Fitseal™ FS-400 particulate respirator)
- Large garbage bags or clear autoclave bags
- Laminated copy of the biohazard spill remediation protocols below (print-friendly copy available at: Biospill Remediation Protocol)

9.6.2 Clean-Up of Biological Spills Outside of a Biological Safety Cabinet

1. When a biological spill occurs, immediately secure all other biological materials in the vicinity of the spill.
2. Personnel should already be wearing appropriate laboratory PPE. Don N-99 respirator.
3. If spill liquid is spreading from the initial site, use paper towels, bath towels or chemical spill dams, as necessary to stop the spread. Close all doors leading to the spill area, place signage on the doors to prevent entry of others, and otherwise cordon off the spill area.

4. Make up fresh 10% solution of bleach in spill kit bucket (1 part household bleach to 9 parts tap water). Make at least half a bucket full.
5. Beside the spill site, depending on the size of the spill, soak spill kit bath towels, J-cloths or cheesecloths in the bucket of bleach.
6. Without wringing out, gently lay the soaked cloth/towel over the spill. Repeat, as necessary, with additional cloths/towels until the entire spill area is covered.
7. Leave cloths/towels in place for 30 minutes. They will hold the bleach solution in place to disinfect the spill site and will prevent aerosolization of material from the site. Once towels are in place over the spill site, personnel may remove N-99 respirator.
8. After 30 minutes, lift up the cloths/towels and transfer into garbage bag for discard. Clean up any solid materials. NOTE: Use forceps to transfer any broken glass/sharps to laboratory sharps disposal container.
9. If the initial spill was known or suspected to have a high organic load (e.g., sewage sample, blood sample), repeat steps 5 through 8.
10. Use mop, J-cloths or cheesecloths and remaining bleach solution in the bucket to thoroughly wash the spill area.
11. After washing is complete, the spill site is considered clean. Add cloths used in washing to garbage bag. Pour the remaining bleach solution in bucket down the drain. If mop was used, make up a new 10% bleach solution in the bucket and soak the mop in it for at least 30 minutes before pouring solution down drain and storing the mop and bucket.
12. Sealed garbage or autoclave bags of used cloths/towels may be thrown out in the regular waste stream.
13. Remove spill signage from laboratory entrances.
14. Report the biological spill to PI/supervisor and together complete a University of Alberta Incident Report. Make arrangements with group to restock spill kit.

9.6.3 Clean-Up of Biological Spills within a Biological Safety Cabinet

1. When a biological spill occurs within a BSC, leave BSC fan on and immediately secure all other biological materials in the vicinity of the spill.
2. Wipe down the cabinet interior and any items inside the BSC and not in contact with the spilled material with appropriate decontaminant.
3. Remove all items not in contact with the spilled material from BSC.
4. Make up a fresh 10% solution of bleach in the spill kit bucket (1 part household bleach to 9 parts tap water). Make at least half a bucket full. Carry the bucket over to the BSC.
5. Depending on the size of the spill, soak spill kit bath towels, J-cloths or cheesecloths in the bucket of bleach.
6. Without wringing out, gently lay the soaked cloth/towel over the spill. Repeat, as necessary, with additional cloths/towels until the entire spill area is covered including any equipment splashed by the spill.

7. Leave cloths/towels in place for 30 minutes. They will hold the bleach solution in place to disinfect the spill site and will prevent aerosolization of material from the site.
8. After 30 minutes, lift up the cloths/towels and transfer into an autoclave bag for discard. Clean up any container material. NOTE: Use forceps to transfer any broken glass/sharps to laboratory sharps disposal container.
9. If the initial spill was known or suspected to have a high organic load (e.g., sewage sample, blood sample), repeat steps 5 through 8.
10. Use J-cloths or cheesecloths and remaining bleach solution in the bucket to thoroughly wash the spill area. Afterwards rinse the inner surfaces of the BSC and items still in the BSC with 70% ethanol to prevent corrosion.
11. If the spill contacted the front grille of the cabinet, then; after the cabinet work area has been disinfected; the work surface must be lifted and its underside and the catch pan beneath must be treated with 10% bleach for 30 minutes following steps 5 through 10.
12. Seal clean-up material in an autoclave bag and place with laboratory autoclave or incineration waste.
13. Report the biological spill to PI/supervisor and together complete a University of Alberta Incident Report . Make arrangements with group to restock spill kit.

9.6.4 Clean-Up of Biological Spills on Individuals

1. Contamination of PPE or personnel must be remediated before clean-up of other affected surfaces.
2. Remove affected clothing, place in an autoclave bag and make arrangements to have the clothing autoclaved using the research group's regular solid waste autoclave parameters. Affected clothing must be autoclaved before it can be returned to the individual or sent for laundering.
3. If spilled material made contact with an individual's skin, hair, eyes, mouth or nose, the individual should treat the affected area as per guidelines in Table 9-1.

CHAPTER 10: LABORATORY EQUIPMENT MAINTENANCE

Proper maintenance of laboratory equipment and the surrounding infrastructure is essential to maintaining a safe and productive work environment. This chapter covers some of the basics that pertain to containment laboratories working with biological materials.

10.1 Laboratory Surfaces

Unless their access to a laboratory is restricted, building custodial staff only pick-up non-laboratory waste in black garbage bags and mop floors once a month. All other surface cleaning must be conducted by the members of the research group(s) utilizing the space. Research groups working with biological materials should select suitable chemical decontaminants as outlined in Section 8.2.1 for the regular cleaning of laboratory surfaces.

Research groups must keep their laboratory clean and tidy. Groups should refrain from storing surplus laboratory consumables and equipment on top of cabinetry as the surplus could fall and injure personnel.

10.2 Laboratory Differential Airflow Patterns

Heating, ventilation and air conditioning (HVAC) systems clean and filter indoor air and help to regulate temperature, humidity, and odours from cultures, animals and chemicals. HVAC systems can be designed to maintain a laboratory under negative differential air pressure so that clean air flows into the containment zone, thereby reducing the spread of contamination by establishing a physical containment barrier of air. Depending on the type of materials used and the activities being conducted, negative differential air pressure for a facility may be identified as required in the PI's hazard assessment or by the Biosafety Officers as an appropriate additional mitigation. Remember, laboratory doors must be kept closed at all times to maintain a containment barrier but if negative differential air pressure is set up for a facility, the directional airflow can only be maintained if the doors are closed.

10.3 Emergency Eyewash & Shower

In accordance with the *Alberta OHS Act, Section 24,* all laboratories that work with hazardous materials (including biohazardous agents) must have an eyewash station and/or an emergency shower either within the laboratory, or located in close proximity to the laboratory. Eyewashes and emergency showers must be easily accessible and kept free of obstructing equipment and supplies. Laboratory personnel must know where to find safety showers and eyewashes, and how to use them.

Maintain plumbed eyewashes by **flushing eyewash stations for three minutes, once a week.** Document this maintenance using the Eyewash Testing Record.

Non-plumbed eyewash bottles should be changed in accordance with the manufacturer's expiry dates listed on the bottles.

Do not attempt to test or flush an emergency shower. Emergency showers are tested through Facilities & Operations.

10.4 First Aid Kit Selection

All U of A Departments are responsible to provide their staff with First Aid Kits and keep them properly maintained. First aid supplies must be restocked if they have been used. First aid equipment and supplies on hand must be appropriate for the work hazard, distance to medical help, and the different types of trained First Aiders available on site. Refer to the First Aid Information Module at the EHS website to determine which first aid kit applies to your work site.

10.5 Location of Spill Kits

All research groups must maintain spill kits appropriate to the hazards present in the laboratory. Chemical and biological spill kits should be easily accessible. Spill kit supplies must be restocked as soon as possible after they have been used. The required contents of a biological spill kit are listed in Section 9.7.1.

10.6 Equipment Manuals & General Maintenance

As per *Alberta Occupational Health and Safety (OHS) Act, Section 5,* all equipment which requires work to be done in accordance with a manufacturer's specifications must have a manual. The manual must be readily available to all personnel and stored near the equipment. Review of equipment manuals must be part of the Laboratory-Specific Orientation and Training given to all personnel working in the laboratory (Section 3.3.4).

Alberta OHS legislation also requires that all work site equipment be properly maintained as per the manufacturer's preventative maintenance schedule provided in the manual. Any deviation from the maintenance and operation outlined in an equipment manual or any modification of the equipment must be approved by a registered professional engineer. Where information in this guideline contradicts the equipment manual provided by the manufacturer, personnel should follow the equipment manual and inform the Biosafety Program of the discrepancy.

10.7 Biological Safety Cabinet/Aerosol Containment Device Installation & Maintenance

10.7.1 Purchasing

Research groups wishing to purchase a BSC or aerosol containment device (e.g., cage change station, robotic enclosure or soft-walled negative air pressure containment device) must consult with the Biosafety Program prior to ordering the cabinet. For the consultation, groups should provide the following information:

- The kind of biological materials to be handled.
- The laboratory location and containment level.
- Need for use of volatile toxic chemicals, radioisotopes, chemotherapeutic drugs or carcinogens inside of the cabinet.

The Biosafety Program will review the submitted information with the PI, recommend the cabinet type best suited for the group's research needs and confirm the model selected is compatible with the EHS in-house filter certification programs (Section 10.7.5). Please be

aware, groups failing to consult with the Biosafety Program prior to purchasing a cabinet may have to hire an outside contractor to conduct the mandatory annual certification of the cabinet filters.

10.7.2 Placement

An uninterrupted curtain of inward flowing air at the front of its workspace is critical to BSC performance, therefore a BSC (or other aerosol containment device) should be situated in an area where there will be no interference with this air barrier and **must be**:

- Located away from high traffic areas, doors and air supply ducts.
- Not directly facing another cabinet or chemical fume hood (there should be a minimum of 2 metres between BSCs and/or fumehoods that are facing each other).
- Have a minimum unobstructed clearance of 40 cm above the exhaust outlet on top of the cabinet.
- Have a minimum of 30 cm clearance on each side of the cabinet to allow for maintenance access.

10.7.3 Registration

All BSCs on campus must be registered with EHS in order to be included in the annual BSC testing services offered (Section 10.7.3). PIs are asked to list the BSCs they use and their locations on their Biosafety Registry. If a new BSC has been purchased or acquired from another facility, contact EHS to notify them of its type and location.

10.7.4 Annual Testing

Federal regulations require BSCs to be tested annually. EHS provides annual testing of BSCs free of charge to all U of A facilities. Testing is done in accordance with NSF standards or to manufacturer's specifications to ensure that they are operating as intended and providing the proper protection to personnel, the surrounding environment and the research materials themselves.

EHS Operations Team personnel will contact laboratories to schedule testing. To prepare for the BSC testing, personnel must:

- Empty the cabinet of all equipment and supplies.
- Decontaminate the interior surfaces of the cabinet.
- Lift the cabinet work surface, and clean and decontaminate the underside of the work surface and the catch pan below it.

10.7.5 Cabinet Malfunctions or Relocation

A malfunctioning BSC must be shut down immediately. If some aspect of the BSC has failed, proceed as follows:

1. Decontaminate and remove all equipment and biohazardous materials from the cabinet.
2. Inform PI or laboratory manager of the problem.
3. Place an "out of service" sign on the front sash of the BSC.
4. Contact EHS to request a gaseous decontamination of the BSC prior to scheduling servicing.

A BSC must also be decontaminated prior to being moved to another location (within or between facilities). Before the BSC can be used in the new location, it will need testing again to ensure the HEPA filters were not damaged or unseated during the move. Contact EHS well in advance of the proposed moving date to arrange for the necessary gaseous decontamination and subsequent filter testing.

10.8 Centrifuge Maintenance

Regular maintenance of a centrifuge is recommended to extend the life of the unit and ensure it continues performing to manufacturer's specifications. In addition to conducting centrifuge maintenance according to manufacturer's specification:

- Always inspect rotors and buckets for chips, cracks or damaged seals prior to use. Never use a visibly worn or damaged rotor.
- Never use a rotor beyond its maximum rated speed.
- Always use the appropriate type of rotor for the centrifuge; never try to make a rotor from a different manufacturer "work" in a centrifuge it was not intended for.
- For refrigerated centrifuges: Remove any accumulated condensation from the rotor chamber after each use with a dry cloth.
- Keep record of repairs and service calls.

10.9 Autoclaves

10.9.1 Registration

PIs are required to list the autoclave(s) they use on their Biosafety Registry. Autoclaves being operated by departmental wash-up or decontamination facilities must be declared on the department's Biosafety Registry for the facility.

10.9.2 Maintenance

In addition to maintenance recommendations listed in the manufacturer's manual for the autoclave or sterilizer, personnel should also ensure:

- The area around the unit is kept tidy and free of clutter.
- Service panels for the unit remain accessible and are not obstructed with other equipment.
- Leaking water and pressure lines are reported immediately to the Facilities & Operations Maintenance Desk (492-4833).
- Water leaking from the unit is promptly cleaned up.

- The drain filter inside the unit's chamber is inspected for debris on a weekly basis.
- The door seals are scrubbed on a weekly basis with a brush and water to prevent a build-up of residue which could interfere with proper sealing of the door.
- Pressure safety valves are in place and functional.
- Pressure and temperature gauges are operating properly and are calibrated.

10.9.3 Quality Control

Documented quality control of autoclaves is federally mandated and must occur monthly at a minimum. Test records must be kept on file and made available upon request by EHS personnel or the Biosafety Officers. Quality control verifies that autoclaves and sterilizers are functioning properly. If an autoclave fails to properly sterilize media, subsequent experiments may be compromised by contamination and waste containing biohazardous agents that is improperly autoclaved can present serious hazards to personnel as well as the environment. For these reasons, personnel operating autoclaves and sterilizers at the U of A must use the following quality control measures:

a. **Autoclave Tape –** contains markings that change color when the tape has been exposed to normal autoclave sterilization temperatures for a few minutes. Tape indicators should be used on all material placed in the autoclave or sterilizer to show that the material has been processed. **Note: autoclave tape indicates that an autoclave has reached the proper temperature but does NOT prove that organisms have been killed.**

b. **Biological Indicators -** use of biological indicators must occur at least monthly to ensure that autoclaves and sterilizers are effectively sterilizing materials. There are several commercially available validation tests generally containing *Bacillus stearothermophilus* spores, either on strips or in vials. Biological Indicators are available from several laboratory supply distributors (i.e., VWR, Fisher Scientific, etc.).

   Consult with personnel responsible for the autoclave to find out how to assist with biological indicator testing and where test results are stored. Follow manufacturer's instructions when using indicators.

   To properly validate an autoclave (or sterilizer):

   1. Obtain an indicator vial and label it with the date and the autoclave to be tested.
   2. Tape the indicator vial to the bottom end of a 10-ml pipet and carefully insert it into the densest part of the load. Tie one end of a piece of brightly colored yarn or string to the top end of the pipet and affix the other end of the yarn to the autoclave rack for ease of retrieval after autoclaving.
   3. Load the rack into the autoclave, close the door and initiate the run.
   4. After the run is complete; open the autoclave and unload the rack as described previously (Section 8.2.2). Allow the load to cool to room temperature.
   5. Wearing gloves, untie the yarn from the autoclave rack and retrieve the pipet with the indicator attached to it. Remove the indicator from the pipet.
   6. Follow manufacturer's instructions for incubation of the vial.

7. Incubate a positive control vial from the same lot of indicators which has not been autoclaved to compare with the sample.
8. Check indicators according to the manufacturer's instructions. Most will be complete within 48 – 72 hours of incubation.
9. Record test results on the Autoclave Biological Indicator Quality Control Record. Keep results of all tests for a minimum of three years. Results should be kept organized and made available on request to EHS personnel. Report failed test results immediately to the PI or the Departmental Safety Designate.
10. Re-autoclave all waste from failed tests prior to disposal.

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