

# BIOSAFETY PROGRAM

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## 1.0 PURPOSE

The purpose of this program is to provide a guideline for working with biological materials to ensure compliance and minimize risk to workers, students, the public and the environment.

## 2.0 SCOPE

These guidelines apply to all work conducted under the auspices of the University of Waterloo using material that is regulated by the Human Pathogens and Toxins Act, Health of Animals Act, and Plant Protection Act. These Acts are administered by the Canadian Food Inspection Agency and the Public Health Agency of Canada. It also includes work with Human blood, tissue, and body fluids. This includes researchers, instructors, students, workers, and other individuals.

## 3.0 DEFINITIONS

### **Biological Safety Officers (BSO)**

An individual designated for overseeing the facility's biosafety and biosecurity practices.

### **Institutional Biosafety Committee (IBSC)**

The purpose of this committee is to provide oversight regarding activities dealing with bio-hazardous materials.

See the [Glossary](#) for a complete list of terms used in this program.

## 4.0 ROLES AND RESPONSIBILITIES

### 4.1 WORKERS AND STUDENTS

Workers and students handling potentially biohazardous material are required to:

- Undergo any training as required by the University and your supervisor.
- Follow procedures developed for a specific laboratory or project.
- Follow University of Waterloo procedures for handling biohazardous material.
- Wear personal protective equipment.
- Participate in medical surveillance programs, when appropriate.

### 4.2 LICENSE HOLDER

At the University of Waterloo, the license holder is the Vice President of Research. Their role includes the following duties:

- Oversee the Biosafety Program at the University of Waterloo.

- Apply for a license for materials that require it. Appoint two biological safety officers to service the University of Waterloo.
- Report the status of biological safety issues to the Senior Management Safety Committee.
- Ensure unresolved non-compliance issues are resolved in a timely manner.
- Provide resources to researchers and workers to ensure work can be conducted in a compliant manner.

### **4.3 THE INSTITUTIONAL BIOSAFETY COMMITTEE (IBSC)**

- Review planned laboratory activities to ensure appropriate hazard identification and risk evaluation of activities has been completed.
- Assess requirements for laboratory users training and laboratory safety procedures and recommends revisions, when indicated.
- Review reports related to laboratory safety services, activities, incidents, and interventions in laboratory areas and recommends corrective actions, when indicated.
- Reports as required to the Vice-President of Research at the University.

### **4.4 BIOLOGICAL SAFETY OFFICER (BSO)**

#### **4.4.1 THE BIOLOGICAL SAFETY OFFICER MUST HAVE THE FOLLOWING QUALIFICATIONS**

- Knowledge of microbiology appropriate to the risks associated with the controlled activities authorized under the license, attained through a combination of education, training and experience.
- Knowledge of the provisions of the Act and the regulations and any applicable federal or provincial legislation.
- Knowledge of the applicable biosafety and biosecurity policies, standards and practices appropriate to the risks associated with the controlled activities authorized under the license.

#### **4.4.2 DUTIES OF THE BIOLOGICAL SAFETY OFFICER (BSO) WITH RESPECT TO THE UNIVERSITY**

At the University of Waterloo, the biological safety officer is responsible for the following:

- Verifying that license applications are accurate and complete.
- Communicating with the PHAC and CFIA on behalf of the license holder.
- Promoting and monitoring compliance with the provisions of applicable legislation, standards, and the University's license by, among other things:

- Arranging for and documenting appropriate training related to biosafety and biosecurity policies, standards and practices for all persons who conduct controlled activities under the license.
- Informing the PHAC of all occurrences of inadvertent possession of a human pathogen or toxin.
- Informing the PHAC when the licensee does not receive an expected shipment.
- Conducting periodic inspections and biosafety audits and reporting the findings to the license holder.
- Informing the license holder in writing of any non-compliance by a person conducting controlled activities under the license that is not being corrected by that person after they have been made aware of it.
- Assisting in the development and maintenance of the University's biosafety manual and standard operating procedures related to biosafety and biosecurity.
- Assisting with internal investigations of inadvertent possession or creation, accidental release, an incident causing disease, or if the University has reason to believe that the bio-hazardous material was stolen.
- Managing the internal permitting system for the use, procurement, and handling of bio-hazardous materials.
- Coordinating the training needs of the University with regards to bio-hazardous materials use, handling, and storage.

#### **4.4.3 DUTIES OF THE BSO WITH RESPECT TO THE BIOSAFETY COMMITTEE**

- Function as the link between the Biosafety Committee and users of biohazardous materials within the institutions.
- Prepare or review in consultation with the Biosafety Committee a comprehensive Biosafety Program.
- Provide direction pertaining to:
  - Facility and equipment design
  - Work practices and procedures
  - Waste storage and disposal management
  - Evaluation, issuance and enforcement of internal permits
  - Disciplinary action necessitated by noncompliance
  - Biosafety training
- Prepare in consultation with the Biosafety Committee, an annual report to the V.P. of University Research.

#### 4.5 PERMIT HOLDERS (PRINCIPAL INVESTIGATORS)

The primary responsibility for the safety of workers, students, and the public lies with the permit holder in charge of the research or teaching that involves use of the biohazardous materials. Permit holders must be familiar with, follow, and ensure that all individuals working within their laboratories comply with procedures outlined in this Biosafety Program. Principal investigators and instructors shall:

- Obtain a biosafety permit when using:
  - Risk Group 2 material (or organisms)
  - Risk Group 1 material (or organisms used in volumes greater than 10L)
  - Human blood, tissue or body fluids (permit is dependent upon risk)
  - When requested by a BSO
- Keep an up-to-date inventory of all biohazardous materials kept in the laboratory.
- Ensure all work is done in accordance with procedures set out by the University's Institutional Biosafety Committee (IBSC).
- Perform appropriate risk assessments for any project or undertaking that will involve the use of a biohazardous material – see section on Risk Assessments.
- Based on the local risk assessment, implement engineering and administrative controls to minimize risk. This should include a combination of:
  - Laboratory design – more information: [Physical Containment Requirements](#).
  - Specific operating and emergency procedures – more information: [Work Practices](#).
  - Make appropriate PPE available to minimize risks to workers, students, and other individuals who may be exposed to the bio-hazardous materials to minimize risk.
  - Train all workers, students, interns, and other individuals handling biohazardous materials on their risks and how they are controlled at the University and in your specific lab.
- Immediately contact the biological safety officer when any one or more of the situations occur:
  - Want to import or export biohazardous materials.
  - Inadvertently come into possession of a Risk Group 2 or higher organism.
  - Inadvertently create a Risk Group 2 or higher organism.
  - Have any biohazardous material stolen.
  - Lose a Risk Group 2 or higher material in transit.

- You become aware of a possible or confirmed infection from a Risk Group 2 organism as a result of work being performed at the University.
- You have the intention to increase the virulence, pathogenicity, communicability, or resistance of a human pathogen.
- You have the intention to increase the toxicity of a toxin.
- Immediately investigate and report all incidents involving direct worker exposure to biological agents or personnel.
- All work conducted in the permit holder's facilities will be in accordance with applicable federal, provincial, municipal and institutional guidelines and policies.
- Perform annual refresher training as outlined in the Annual Refresher Training form.

## **5.0 WORKING WITH BIOLOGICAL MATERIALS - PERMITS AND OTHER CONTROLS**

The control of biological materials at the University of Waterloo is based on risk. Low risk materials (RG 1) do not require permits and may be worked with in a basic laboratory that has been designed as such. This means that containment is achieved using good standard microbial practices, and open bench work is permitted.

Some materials or processes that do not require permits include:

- Risk Group (RG) 1 materials in volumes less than 10L
- Biological materials that are known to be pathogen free
- Animal blood, tissues, and bodily fluids that are known to be pathogen free
- Human cell lines (including oncogenic cell lines) known to be pathogen free
- Materials found naturally in the environment (e.g., raw sewage, environmental samples – provided the material is not being cultured; if the material is being cultured, the Risk Group may change)

Materials of moderate risk (Risk Group 2) require a permit for use. Facilities must meet the design and physical containment requirements outlined in the Canadian Biosafety Standards (CBS). Individuals must develop operational practices and administrative controls that are proportionate to the risk that a Risk Group 2 material may pose. For these reasons, the IBSC will require a permit application for the intended work area and a local risk assessment for each material that will be worked with.

The following materials are subjected to permitting by the IBSC or permitting by the CFIA:

- Risk Group 2 (RG2) materials – Human pathogens
- Risk Group 2 (RG2) materials – Terrestrial Animal Pathogens, Aquatic Animal Pathogens, and Plant Pests.
- Risk Group 1 (RG1) materials in quantities greater than 10L



## 6.0 RISK ASSESSMENT

### 6.1 PATHOGEN RISK ASSESSMENTS

To understand how the properties of the material contribute to its risk, the material needs to be categorized into a Risk Group based upon the following characteristics:

- Pathogenicity
- Virulence
- Availability and effectiveness of preventative or treatment measures
- Mode of transmission/route of infection
- Infectious dose
- Host range
- Environmental stability
- Economic impact of release into the environment or public
- Endemicity
- Recombinant DNA – modifications that may alter the materials other properties

By rating the material in each of the above categories, one can get a sense of which risk group the material should belong to. For a majority of the work being performed with biological materials at the University of Waterloo, risk group ratings have been established by the Public Health Agency of Canada (PHAC). PHAC has published several lists categorizing many of the most common organisms, toxins, and pathogens. These can be found using the links below:

- [PHAC Pathogen Data Sheets](#)
- [PHAC Lists of Toxins, RG2, RG3, and RG4 Human Pathogens \(scroll to bottom of link\)](#)

Note – items listed by PHAC as prohibited human pathogens, and security sensitive biological agents are strictly prohibited from use at the University of Waterloo.

Supplier information can also be used as a reliable source to categorize your materials. ATCC or Cedar Lane often categorize the materials that they offer for sale. For example, HELA cells purchased from ATCC and listed in their catalogue as Risk Group 2 material would be considered an acceptable source of information to categorize material you received from that supplier.

If risk group categorization of your material is not available from PHAC, the supplier, or other credible source, you must determine the risk group yourself. The Safety Office has developed a [Pathogen Risk Assessment Worksheet](#) to assist you with this process.

If you are having trouble assigning a risk level to your material, please contact the Safety Office.

- Phone: extension 33587
- Email: [biosafety@uwaterloo.ca](mailto:biosafety@uwaterloo.ca)



## 6.2 LOCAL RISK ASSESSMENTS

Once the risk group for the material you are working with is identified, you must identify the hazards of the specific work you are doing – more specifically, you are identifying how an exposure to the material being worked with could happen. By understanding this, appropriate controls can be implemented to minimize risk. To assist you in this process, the Safety Office has created two Local Risk Assessment Worksheets (LRA).

For human pathogens and toxins that are Biosafety Risk Group 2, you must submit the LRA Worksheet for Human Pathogens and Toxins to the Safety Office (via [biosafety@uwaterloo.ca](mailto:biosafety@uwaterloo.ca)).

For animal, aquatic, or plant pathogens and materials that are considered Biosafety Risk Group 2, you must submit the LRA Worksheet for Animal, Aquatic, or Plant Materials or Pathogens to the Safety Office (via [biosafety@uwaterloo.ca](mailto:biosafety@uwaterloo.ca)). These forms have been designed to help the researcher and the Safety Office determine what controls are necessary to ensure work is done in compliance with applicable legislation.

If you are having trouble assigning a risk level to your material, contact the Safety Office.

### 6.2.1 NEW PERMIT APPLICATIONS

If you intend on working with one of the following materials, you will need a permit for the containment zone where the work takes place:

- Material containing a Risk Group 2 (RG2) pathogen
- Material containing a Risk Group 1 (RG1) pathogen in excess of 10L
- A scheduled toxin

Complete the [permit application](#) and submit it to [biosafety@uwaterloo.ca](mailto:biosafety@uwaterloo.ca). Once received, one or both biosafety officers will review and contact you to arrange a site visit and inspection.

### 6.2.2 HUMAN BLOOD, BODILY FLUID AND TISSUES

If you intend on working with human blood, bodily fluids, or tissues, complete the [Human Blood, Bodily Fluids, and Tissues Risk Worksheet](#) and submit it to [biosafety@uwaterloo.ca](mailto:biosafety@uwaterloo.ca).

Once received, the biosafety officers along with the IBSC will review to determine the risk level. Low risk level materials will not require permits, but the material must be handled with “Routine Practices” (see the [Glossary](#) for definitions). If the IBSC determines that the material is of high risk, the material requires permitting and one of the biosafety officers will communicate that to you.

## 7.0 LEGISLATION

In Canada, both the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) regulate work with biological material. The determination of which agency oversees a particular type of work is organism or material dependent.

### 7.1 LABORATORY SAFETY GUIDELINES

The Canadian Biosafety Standards (CBS) 2nd Edition, published by the Public Health Agency of Canada (PHAC), is used in the classification, use, and disposal of biohazardous materials. These guidelines have been adopted by the University IBSC to be followed by principal investigators and instructors when using biohazardous materials or agents. The principal investigator and/or instructors are responsible for ensuring their students, workers, or visitors [follow these guidelines](#).

### 7.2 REPORTING REQUIREMENTS

If you are working with potentially hazardous biological materials, you must contact a University BSO should any of the following events occur:

- Inadvertently come into possession of a Risk Group 2 or higher organism
- Inadvertently create a Risk Group 2 or higher organism
- Have any biohazardous material stolen
- Lose a Risk Group 2 or higher material in transit
- You become aware of a possible or confirmed infection from a Risk Group 2 organism because of work being performed at the University

If these events are not reported immediately, the University's license status could come into jeopardy resulting in problems for other researchers.

You must also inform the biological safety officer prior to performing any of the following activities:

- Importing or exporting bio-hazardous materials
- Intention to increase the virulence, pathogenicity, communicability, or resistance of a human pathogen
- Intention to increase the toxicity of a toxin

The processes for importing, exporting, and transferring biological materials are described in the following section.

Once informed, the biosafety officer will decide if reporting to PHAC is required. If reporting is required, the report will be made immediately.

## **7.3 RESEARCH WITH HUMANS AND ANIMALS**

Work and research conducted with animals and humans may be subject to other legislative bodies. This Biosafety Program only covers work that may involve pathogenic organisms or materials.

### **7.3.1 LABORATORY ANIMALS**

All aspects of the proposed use of animals in research and the operational procedures for the care and maintenance of animals must satisfy:

- The requirements of the Animals for Research Act
- Guidelines for the care and use of experimental animals by the Canadian Council on Animal Care
- University of Waterloo's guidelines for the care and use of animals in research and teaching
- Work with animals exposed to or infected with biological agents is subject to approval by the IBSC

### **7.3.2 HUMAN RESEARCH FACILITIES**

Research involving humans is subject to the Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans. Where appropriate, this type of research may be subject to other legislation and policies, such as:

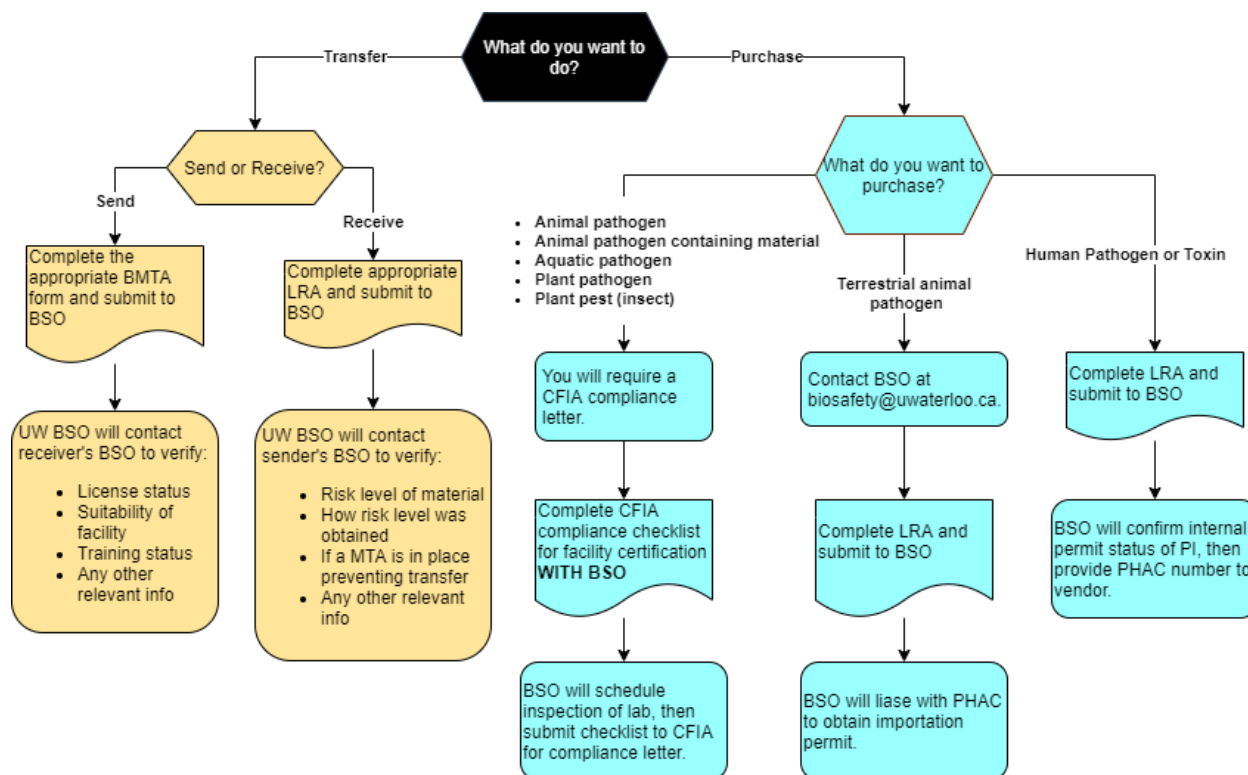
- The University of Waterloo's guidelines and policies on [research involving humans](#)
- The Quebec Civil Code
- Provisional and federal legislation on privacy, confidentiality, intellectual property, competence and other areas
- Canada Food and Drug Act and Regulations
- Guidelines and policies of the Therapeutics Product Directorate of Health Canada
- Relevant laws, regulations and/or policies of other countries, where research is to be conducted in those countries
- Good Clinical Practices: Consolidated Guidelines for Clinical Trials sponsored by industry, published by the International Conference on Harmonization

## **8.0 TRANSFERRING, IMPORTING AND EXPORTING BIOLOGICAL MATERIALS**

The process for importing and exporting materials is generally the same regardless what it is. The difference is in who regulates the material (PHAC or CFIA). Items regulated by PHAC are governed by our institutional license and importation permits are not

required. However, approval is required from the BSO's of the importing and exporting facilities.

When the CFIA regulates the material, compliance letters are required. Please review the flowchart presented in Figure 2. Sections 8.1 to 8.3 provide instructions on importation, exportation and transferring materials.



**Figure 2: Outline of the processes involved in transferring, importing, or exporting human and animal pathogens or toxins, and other related materials**

Note: BMTA refers to Biological Material Transfer Agreement, LRA refers to local risk assessment, and BSO refers to Biological Safety Officer

### 8.1 HUMAN PATHOGENS OR TOXINS AND RELATED BIOLOGICAL MATERIALS

For human pathogens and toxins, the HPTA and HPTR place responsibility on the facilities intending to transfer, import or export regulated material. The legislation specifically indicates that prior to arranging for a transfer or transport of material, the person intending to make the transfer must notify their institutional biological safety officer (BSO). Considering this requirement, you cannot proceed with the transfer until you have contacted and received a response from the University's BSO. This includes transferring within UW. To be clear, you MUST notify a University BSO before completing any transfer, including those within the University.

If you do not contact the University BSO prior to beginning your transfer, your permit may be revoked as this may affect the status of the University's license and the ability of all other researchers to work with their materials.

For animal pathogens and toxins, the rules are different. To import an animal pathogen or toxin a permit is required.

### **8.1.1 TRANSFER OF HUMAN PATHOGENS OR TOXINS WITHIN CANADA -SENDING AND RECEIVING**

There are two distinct roles when a material is being transferred from one user to another - the sender and the receiver.

The sending facility must verify that the receiving facility has:

- Facilities that meet the minimum requirements in the Canadian Biosafety Standards for the risk level of the material.
- The individuals handling the materials are suitably trained to properly store, handle and use the materials being transferred.
- The receiving facility has a valid institutional license issued by PHAC.

The receiving facility must verify:

- Material identification
- Material Risk Group Classification (and how it was classified)

This information will only be accepted if it is coming from the institutional biological safety officer at each respective facility. If you are the sender or provider of the material in a material transfer, you must complete one of the following two forms:

1. Internal BMTA (for transfers to and from PIs within UW, including the School of Pharmacy and Velocity)
2. External BMTA (for transfers outside of UW)

### **8.1.2 IMPORTING HUMAN PATHOGENS OR TOXINS TO CANADA**

The University BSO will need the following information to facilitate the importation process:

- Contact information of the exporter and their BSO
- Material identification
- Material Risk Group Classification and how it was classified

The University BSO must provide verification that the importing researcher has adequate training and facilities for the handling of the material being received. If you're training and laboratory does not meet our internal requirements your importation will be denied.

### 8.1.3 EXPORTING HUMAN PATHOGENS OR TOXINS OUTSIDE OF CANADA

Exportation of pathogens, toxins, and other materials of biological origin are not governed by the PHAC or CFIA. It is governed by the Export and Import Control Bureau of the Department of Foreign Affairs and International Trade (DFAIT). Each situation will be unique, therefore contact the Safety Office for guidance on exporting biological materials that contain or may contain a pathogen or toxin.

## 8.2 ANIMAL PATHOGENS OR TOXINS AND RELATED BIOLOGICAL MATERIALS

The Health of Animals Act (HAA) and the Health of Animals Regulations (HAR) regulate the transport of animal pathogens and toxins. The basic requirements are outlined below.

### 8.2.1 TRANSFER OF ANIMAL PATHOGENS, TOXINS, AND RELATED BIOLOGICAL MATERIALS

Materials transferred within Canada are governed by the Transportation of Dangerous Goods Legislation and by the requirements set forth here.

Prior to shipment, contact the BSO:

- If you are transferring materials from a lab at UW to another lab at UW, you must complete the Internal Biological Material Transfer Agreement (BMTA) form and submit it to the University BSO.
- If you are transferring materials from the University to another facility, the University BSO will verify the receiver's ability to safely handle, store, and work with the material. To initiate the process, you must complete the External Biological Material Transfer Agreement (BMTA) form.
- If you are the receiver, you must complete one of the following forms and submit it to the University BSO:
  -

**Note:** If the animal pathogen or toxin was previously imported from another country, the importation permit may place specific transfer restrictions on the material. Please contact the Safety Office for guidance on how or if the transfer can proceed.

### 8.2.2 IMPORTATION OF ANIMAL PATHOGENS OR TOXINS INTO CANADA

Importation of an animal pathogen or toxin is not permitted unless an importation permit is obtained from CFIA or PHAC. For Terrestrial Animal Pathogens or Toxins the importation permit is obtained from PHAC. Follow this process:

1. Complete the LRA Worksheet for Animal, Aquatic, or Plant Materials or Pathogens and submit it to biosafety@uwaterloo.ca
2. The importer needs to obtain a compliance letter (CL2 for level 2 pathogens) from the PHAC.

3. With a valid CL2, the importer can then apply for an importation permit and in some cases, the compliance letter and the importation permit can be applied for simultaneously.

If the pathogen or toxin is one that is non-indigenous or newly emerging, the importer must obtain an importation permit from the CFIA. This will involve completing:

- Complete the LRA Worksheet for Animal, Aquatic, or Plant Materials or Pathogens and submit it to biosafety@uwaterloo.ca
- A facility certification form
- A CL2 inspection checklist
- Application for permit to import

Importation of a material (animal product, by-products, tissues, sera, blood) carrying an animal pathogen or part of one is regulated by the CFIA. This will involve completing:

- Complete the LRA Worksheet for Animal, Aquatic, or Plant Materials or Pathogens and submit it to biosafety@uwaterloo.ca
- A facility certification form
- A CL2 inspection checklist
- An application for permit to import

### **8.2.3 EXPORTING ANIMAL PATHOGENS OR TOXINS OUTSIDE OF CANADA**

Exportation of pathogens, toxins and other materials of biological origin are not governed by the PHAC or CFIA. The Export and Import Control Bureau of the Department of Foreign Affairs and International Trade (DFAIT) govern this. Each situation will be unique, therefore contact the Safety Office for guidance on exporting biological materials that contain or may contain a pathogen or toxin. Figure 2 summarizes the transfer, import and export of human or animal pathogens and toxins.

### **8.3 PLANT PATHOGENS OR TOXINS AND PLANT PESTS (INSECTS)**

The importation of plant pathogens, toxins and plant pests may require permits. Please contact the one of the Biological Safety Officers to help you determine the requirements. To expedite the process, contact the BSOs well in advance of date you wish to begin the import by completing the LRA Worksheet for Animal, Aquatic, or Plant Materials or Pathogens and submit it to biosafety@uwaterloo.ca

## 9.0 TRAINING

### 9.1 MANDATORY BIOSAFETY TRAINING AT THE UNIVERSITY OF WATERLOO

Researchers, workers, and students handling biosafety Risk Group 2 organisms and materials or human blood, bodily fluids, and tissues are required to complete biosafety training. Biosafety training consists of two elements:

- University of Waterloo's [Biosafety training module \(online\)](#)
- Laboratory and project/procedure specific training (hands-on)

Generic training is available online and is accessible by any University of Waterloo worker or student with a valid UWaterloo user ID and password. The material covered in this course provides the attendee with general biosafety procedures.

Laboratory and project specific training shall be provided by the principal investigator to any student/worker who is working with regulated materials in the containment zone under their permit. The PI must also ensure annual refresher training is completed. At minimum, this annual training should contain the following items:

- Actions to take upon exposure to regulated materials
- Clean up and disinfection of regulated material spills on floors and countertops
- What to do in case of a power-outage while working with regulated materials
- Refresher training on the SOPs and waste disposal processes
- Location and use of biological materials inventory

The following training is only required if biological safety cabinets and/or centrifuges are used by the researchers:

- Clean up and disinfection of regulated materials spills in centrifuges
- Clean up and disinfection of regulated material spills in biological safety cabinets.

This training should be documented on the Annual Refresher Training Form, and completion of this training will be an annual requirement to keep the permit in “compliant” status.

### 9.2 RECOMMENDED TRAINING

The Public Health Agency of Canada has numerous online training modules available that outline the best practices expected when working with biological agents. If you will be working with biological agents please consider completing the following free online training modules:

- [PHAC Biosafety 101](#)
- [PHAC Biosafety Cabinets](#)
- [PHAC Spills and Waste Management](#)



- [PHAC Laboratory Procedures](#)
- [PHAC Risk Management, Risk Management, Inventory](#)
- [PHAC Cell Link Risk Assessment](#)
- [PHAC Additional Operational Procedures](#)
- [PHAC Use of Animals](#)
- [PHAC Legislation](#)

Consider taking these other [online courses offered by PHAC](#).

## 10.0 RECORD OF REVISIONS

Date	Author/Editor	Change	Version
November 2021	Dhananjai Borwankar Doug Dye	<ul style="list-style-type: none"> <li>• Updated section 2.0 Scope to include relevant legislation</li> <li>• Updated emergency procedures training in section 4.5 Permit Holders</li> <li>• Updated incident reporting in section 7.2 Reporting Requirements</li> <li>• Updated refresher training in section 9.1 Mandatory Training</li> </ul>	v.4.1_NOV2021
November 2020	Dhananjai Borwankar	<ul style="list-style-type: none"> <li>• Updated roles and responsibilities in section 4.5 Permit Holders (Principle Investigators)</li> <li>• Updated section 5.0 Working with Biological Materials – Permits and Other Controls</li> <li>• Updated section 8.0 Transferring, Importing and Exporting Biological Materials</li> <li>• Added section 10.0 Record of Revisions</li> </ul>	v.4.0_NOV2020
March 2019	Dhananjai Borwankar	No changes	3.1_MAR2019

## 11.0 GLOSSARY

### Administrative Area

Dedicated room or adjoining rooms used for activities that do not involve infectious materials or toxins. These areas do not require containment equipment, systems, or operational practices.

### Aerosol

A suspension of fine solid particles or liquid droplets in a gaseous medium (air) that can be created by any activity that imparts energy into a liquid/semi-liquid material (ie, centrifugation, sonication, mixing, etc.).

### Animal pathogen

Any pathogen that causes disease in animals including those derived from biotechnology. In this context, "animal pathogen" refers only to pathogens that cause disease in terrestrial animals including those that infect avian and amphibian animals but excluding those that cause disease in aquatic animals and invertebrates.

### **Biosafety Cabinet (BSC)**

A primary containment device that provides protection for personnel, the environment, and the product (depending on BSC class) when working with biological material.

### **Containment**

The combination of physical design parameters and operational practices that protect personnel, the immediate work environment, and the community from exposure to biological material.

### **Containment barrier**

The boundary between "clean" and "dirty" areas (i.e., between the laboratory work areas, animal rooms, animal cubicles, or post-mortem rooms, and outside of that containment area). Where inward directional airflow is provided, a physical containment barrier of air is established to protect against airborne or aerosolized infectious material or toxins from reaching the "clean" areas.

### **Containment level (CL)**

Minimum physical containment and operational practice requirements for handling infectious material or toxins safely in a laboratory, large scale production and animal work environments. There are four containment levels ranging from a basic laboratory (containment level 1 [CL1]) to the highest level of containment (containment level 4 [CL4]). The University's highest containment level is 2.

### **Containment system**

Dedicated equipment that provides and maintains containment. This includes, but is not limited to, primary containment devices (e.g., biological safety cabinets), heating, ventilation, and air conditioning (HVAC) and control systems, and decontamination systems (e.g., autoclaves).

### **Containment zone**

A physical area that meets the requirements for a specified containment level. A containment zone can be a single room (e.g., containment level 2 [CL2] laboratory), a series of co-located rooms (e.g., several non-adjoining but lockable CL2 laboratory work areas), or it can be comprised of several adjoining rooms (e.g., containment level 3 [CL3] suite with dedicated laboratory areas and separate animal rooms, or animal cubicles). Dedicated support areas, including anterooms (with showers and "clean" and "dirty" change areas, where required), are considered to be part of the containment zone.

### **Contamination**

The undesired presence of infectious material or toxins on a surface (e.g., benchtop, hands, gloves) or within other materials (e.g., laboratory samples, cell cultures).

## **Controlled activities**

Any of the following activities referred to in Section 7(1) of the Human Pathogens and Toxins Act:

- Possessing, handling or using a human pathogen or toxin
- Producing a human pathogen or toxin
- Storing a human pathogen or toxin
- Permitting any person access to a human pathogen or toxin
- Transferring a human pathogen or toxin
- Importing or exporting a human pathogen or toxin
- Releasing or otherwise abandoning a human pathogen or toxin
- Disposing of a human pathogen or toxin

## **Culture**

The in vitro propagation of microorganisms, tissue cells, or other living matter under controlled conditions (e.g., temperature, humidity, nutrients) to generate greater numbers or a higher concentration of the organisms/cells. In the context of the Canadian Biosafety Standard, "cell culture" refers to cells derived from a human or animal source.

## **Decontamination**

The process by which materials and surfaces are rendered safe to handle and reasonably free of microorganisms, toxins, or prions; this may be accomplished through disinfection, inactivation, or sterilization.

## **Disinfection**

The process that eliminates most forms of living microorganisms; disinfection is much less lethal to infectious material than sterilization.

## **Dual-use potential**

Qualities of a pathogen or toxin that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause disease (e.g., bioterrorism).

## **Exposure**

Contact with, or close proximity to, infectious material or toxins that may result in infection or intoxication, respectively. Routes of exposure include inhalation, ingestion, inoculation, and absorption.

## **Good microbiological laboratory practices**

A basic laboratory code of practice applicable to all types of activities with biological material. These practices serve to protect workers and prevent contamination of the environment, and the samples in use.

## **Inventory**

A list of (biological) assets associated with a containment zone identifying pathogens, toxins, and other infectious material in storage both inside and outside of the containment zone.

## **In vitro**

Latin for "within glass"; describes experimentation involving components of a living organism within an artificial environment (e.g., manipulation of cells in petri dish), including activities involving cell lines or eggs.

## **In vivo**

Latin for "within the living"; describes experimentation conducted within the whole living organism (e.g., studying the effect of antibiotic treatment in animal models).

## **Laboratory**

An area within a facility or the facility itself where biological material is handled for scientific or medical purposes.

## **Local risk assessment (LRA)**

Site-specific risk assessment used to identify hazards based on the infectious material or toxins in use and the activities being performed. This analysis provides risk mitigation and risk management strategies to be incorporated into the physical containment design and operational practices of the facility.

## **Medical surveillance program**

A program designed to prevent and detect personnel illness related to exposure to infectious material or toxins. The focus of the program is primarily preventive, but provides a response mechanism through which a potential infection or intoxication can be identified and treated before serious injury or disease occurs.

## **Microorganism**

A cellular or non-cellular microbiological entity capable of replication or transferring genetic material and that cannot be reasonably detected by the naked human eye. Microorganisms include bacteria, fungi, viruses, and parasites, and may be pathogenic or non-pathogenic in nature.

## **Non-indigenous animal pathogen**

A pathogen that causes an animal disease listed in the World Organization for Animal Health's OIE-Listed diseases, infections and infestations (as amended from time to time) and that is exotic to Canada (i.e., foreign animal disease agents that are not present in Canada). These pathogens may have serious negative health effects to the Canadian animal population.

## **Operational practice requirements**

Administrative controls and procedures followed in a containment zone to protect personnel, the environment, and ultimately the community, from infectious material or toxins, as outlined in Chapter 4 of the Canadian Biological Standards.

## **Pathogen**

A microorganism, nucleic acid, or protein capable of causing disease or infection in humans or animals. Examples of human pathogens are listed in Schedules 2 to 4 and in Part 2 of Schedule 5 of the Human Pathogens and Toxins Act, but these are not exhaustive lists. Examples of animal pathogens can be found through the automated import reference system on the Canadian Food Inspection Agency website.

## **Pathogen risk assessment**

The determination of the Risk Group and appropriate physical containment and operational practice requirements needed to safely handle the infectious material or toxins in question.

## **Pathogenicity**

The ability of a pathogen to cause disease in a human or animal host.

## **Personal protective equipment (PPE)**

Equipment and/or clothing worn by personnel to provide a barrier against infectious material or toxins, thereby minimizing the risk of exposure. PPE may include, but is not limited to, lab coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks, and respirators.

## **Physical containment requirements**

Physical barriers in the form of engineering controls and facility design used to protect personnel, the environment, and ultimately the community, from pathogens or toxins, as outlined in Chapter 3 of the Canadian Biosafety Standards.

## **Primary containment**

The first level of physical barriers designed to contain pathogens and toxins and prevent their release. This is accomplished by the provision of a device, equipment, or other physical structure situated between the infectious material or toxins and the individual, the work environment, or other areas within the containment zone. Examples include biological safety cabinets, glove boxes, and animal microisolators. In animal cubicles, the room itself provides primary containment, and personal protective equipment serves as primary protection against exposure.

## **Prion**

Small proteinaceous infectious particles generally considered to be responsible for causing a group of neurodegenerative diseases in humans and animals known as transmissible spongiform encephalopathies.

**Risk**

The probability of an undesirable event (e.g., accident, incident, breach of containment) occurring and the consequences of that event.

**Risk Group (RG)**

The classification of biological material based on its inherent characteristics, including pathogenicity, virulence, risk of spread, and availability of effective prophylactic or therapeutic treatments, that describes the risk to the health of individuals and the public as well as the health of animals and the animal population.

- Risk Group 1 – (low individual and community risk)
- Risk Group 2 – (moderate individual risk, and low community risk)
- Risk Group 3 – (high individual risk, and low community risk)
- Risk Group 4 – (high individual and community risk)

**Security sensitive biological agents (SSBAs)**

The subset of human pathogens and toxins that have been determined to pose an increased biosecurity risk due to their potential for use as a biological weapon.

**Standard operating procedure**

A document that standardizes safe work practices and procedures for activities with infectious material and toxins in a containment zone, as determined by a local risk assessment.

**Sterilization**

The process that completely eliminates all living microorganisms, including bacterial spores.

**Strict animal pathogen**

A pathogen that causes disease exclusively in animals (i.e., not capable of causing disease in humans).

**Toxin (microbial)**

A poisonous substance that is produced or derived from a microorganism and can lead to adverse health effects in humans or animals. Human toxins are listed in Schedule 1 and Part 1 of Schedule 5 in the Human Pathogens and Toxins Act.

**Terrestrial animal pathogen**

A pathogen that causes diseases in terrestrial animals, including avian and amphibian animals, but excluding aquatic animals and invertebrates.

**Transfer**

A change in possession of pathogens, toxins, or other regulated infectious material between individuals from the same or different facilities (i.e., the movement from the place or places specified in the license or animal pathogen import permit to any other place).

**Virulence**

The degree or severity of a disease caused by a pathogen.

**Waste**

Any solid or liquid material generated by a facility for disposal.

**Zoonoses**

Diseases that are transmissible between living animals and humans.

**Zoonotic pathogen**

A pathogen that causes disease in humans and animals, and that can be transmitted from animals to humans and vice versa (i.e., zoonoses). They are considered both human and animal pathogens.