

# Biosafety for Education & Research

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## Biosafety for Education & Research

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The University of Regina Biosafety for Education and Research Program (3rd Edition) has been created in accordance with the Public Health Agency of Canada's *Canadian Biosafety Standards*, 3<sup>rd</sup> Edition 2022, *Human Pathogen and Toxin Act and Regulations*, the Canadian Food Inspection Agency's *Health of Animals Act and Regulations*, the *Plant Protection Act and Regulations*, the Saskatchewan Government Ministry of Labour Relations and Workplace Safety *Occupational Health & Safety Act and Regulations*, Canadian Council on Animal Care's numerous guidelines, and World Health Organization's *Laboratory Biosafety Manual*, 2020

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## Biosafety for Education and Research Activities

### Introduction

The University of Regina is committed to providing a safe and healthy work, learning, and living environment for all members of the University community. To meet this commitment the **Biosafety for Education and Research Program** administrated by Health & Safety, Human Resources, provides resources and guidance for the safe and responsible use and management of biological materials on campus. The University of Regina *Health and Safety Policy* (GOV-100-005) provides the guidance and authority to this Program and forms part of the Health and Safety Management System.

This Program is intended for use and reference by Academic Staff Members, Staff, Students, and others with responsibility for biosafety related to research and teaching activities.

There are various Federal, Provincial, and Municipal regulations for controlling the acquisition, use, storage, transfer, decontamination and disposal of biological materials. The University is responsible to ensure that these regulations are being enforced to protect the safety of staff, students and the public, while at the same time, the use of the biological material for the benefit of the public and the furtherance of the aims of the University is encouraged.

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## Definitions, Acronyms, and Abbreviations

**Academic Staff Members** are Faculty, Librarians, Laboratory Instructors, Instructors, and Sessionals at the University of Regina.

**Administrator** means senior administration of the university, including the Vice-President (Administration), Deans, Directors, or designates.

**Administrative Area** is a dedicated room or adjoining room(s) that are used for activities that do not involve regulated materials. Administrative areas do not require any containment equipment, systems, or operational practices. Examples of administrative areas include offices, photocopy areas, and meeting/conference rooms.

**Aerosol** is a suspension of fine solid particles or liquid droplets in a gaseous medium (e.g., air) created by any activity that imparts energy into a liquid/ semi-liquid material. Aerosol production consists of droplets that contaminate surfaces, splashes to mucous membranes, and airborne particles that are inhaled.

**Animals** are defined as non-human, living vertebrates, and any living invertebrates of the class of cephalopoda, including free-living and reproducing larval forms, used for research, education, or breeding purposes.

**Anteroom** is a room, or series of rooms, inside the containment zone, used to separate “clean” areas from “dirty” areas for personnel, materials, and animal entry/exit across the containment barrier, and for the entry/exit from animal rooms, animal cubicles, and PM rooms. The negative differential air pressures in containment zones where inward airflow is required can be more effectively maintained through the presence of an anteroom. An anteroom may also provide appropriate space at the points of entry/exit to don, doff, and store dedicated and additional PPE, as required.

**Authorized Personnel** are individuals who have been granted unsupervised access to the containment zone by an internal authority (Director, BSO, or other person responsible for containment access). Access is dependent on personnel completing training requirements and demonstrating proficiency in the SOPs, as determined necessary by the facility.

**Bacteria** (singular: bacterium) are a large group of unicellular microorganisms.

**Biohazard** is an organism or material derived from an organism that poses a threat to human or animal health.

**Biological material** are pathogenic and non-pathogenic microorganisms, proteins, and nucleic acids, as well as any biological matter that may contain microorganisms, proteins, nucleic acids, or parts thereof. Examples include, but are not limited to, bacteria, viruses, fungi, prions, toxins, GMOs, RNA, DNA, tissues



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samples, diagnostic specimens, environmental samples, live vaccines, and isolates of a pathogen or toxin (e.g., pure culture, suspension, purified spores).

**Biological Safety Cabinet (BSC)** is a primary containment device that provides protection for personnel, the environment, and the product (depending on BSC class), when working with biological material.

**Biosafety** are the containment principles, technologies, and practices that are implemented to prevent unintentional exposure to regulated materials, and their accidental release.

**Biosafety Advisory Committee (BSAC)** is responsible for the oversight and administration of the University's Biosafety Program, which is designed to ensure the safe management of biological materials in education and research at the University.

**Biosafety Committee (BSC)** implements and leads University of Regina day-to-day procedures governing the safe management of biological materials, in education and research in accordance with the University's Health and Safety Policy.

**Biosafety Officer (BSO)** is the individual designated by the Pathogen and Toxin License Holder (Vice-President (Research)) to oversee the University biosafety and biosecurity practices.

**Biosecurity** are the security measures designed and implemented to prevent the loss, theft, misuse, or intentional release of regulated materials, and other related assets (e.g., personnel, equipment, non-infectious material, animals, and sensitive information).

**Canadian Council on Animal Care (CCAC)** is the national peer-review organization responsible for setting, maintaining, and overseeing the implementation of high standards for animal ethics and care in science throughout Canada.

**Canadian Food Inspection Agency (CFIA)** as a science-based regulator, the CFIA has a broad mandate that encompasses food safety, animal health and international market access. The governance includes importation of animal products, non-terrestrial animal pathogens, aquatic pathogens and plant pathogens.

**Containment** is 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 Level (CL)** is the minimum physical containment and operational practice requirements for handling regulated materials safely in laboratory and animal work environments. There are four containment levels ranging from a basic laboratory (CL1) to the highest level of containment. (CL4).

**Containment Zone** is a physical area that meets the requirements for a specified containment level. A containment zone can be a single room (e.g., a 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., a CL3 suite with dedicated laboratory areas, and separate animal rooms or animal cubicles). Dedicated

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support areas, including anterooms with showers and “clean” and “dirty” change areas where required, are considered to be part of the containment zone.

**Contamination** is the presence of regulated materials on a surface (e.g. bench top, hands, gloves, etc.) or within other materials (e.g. laboratory samples, cell culture).

**Culture(s)** involve the *in vivo* propagation microorganisms, tissues, cells, or other living matter under controlled conditions (eg. temperature, humidity, nutrients, etc.) to generate greater numbers or a higher concentration of the organisms or cells.

**Decontamination** is 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.

**Disease** refers to a disorder of structure or function in a living human or animal, or one of its parts, resulting from infection or intoxication. It is typically manifested by distinguishing signs and symptoms.

**Disinfectant** is a chemical agent capable of eliminating viable biological material on surfaces or in liquid waste. Effectiveness can vary depending on the properties of the chemical, concentration, shelf life, and contact time.

**Disinfection** is a process that eliminates most forms of living microorganisms; disinfection is much less lethal to microorganisms than sterilization.

**DNA** (deoxyribonucleic acid) is an organic molecule that contains the genetic instructions used in the development and functioning of all known living organisms.

**Emergency Response Plan (ERP)** is a document outlining the actions to be taken and the parties responsible in emergency situations such as spills, exposures, release of regulated material, animal escape, personnel injury or illness, power failure, or other emergency situations.

**Exporting** is the activity of transferring or transporting regulated materials from Canada to another country or jurisdiction.

**Exposure** is the contact with, or close proximity to, pathogens or toxins that may result in infection or intoxication, respectively. Routes of exposure include inhalation, ingestion, inoculation, and absorption.

**Facility** refers to structures or buildings, or defined areas within structures or buildings, where regulated materials are handled or stored. This could include individual research and diagnostic laboratories, large scale production areas, or animal housing zones. A facility could also be a suite or building containing more than one of these areas.

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**Fungi** (singular: fungus) is a member of a large group of eukaryotic organisms that include microorganisms such as single-celled yeasts and multi-cellular molds.

**Genetic Engineering** is a term that applies to the direct manipulation of an organism's genes using techniques of molecular cloning and transformation.

**Genetically Modified Organisms (GMOs)** are microorganisms whose genetic materials have been altered using genetic engineering techniques such as recombinant DNA.

**Good Microbiological Laboratory Practice** is the basic code of practice applicable to all types of laboratory work with biological material. These practices serve to protect and prevent contamination of lab workers, the lab environment, and the samples in use.

**Gross Contamination** is the accumulation of organic material (eg. Bedding, blood, tissues, excrement, etc.) on a surface that can be removed by physical methods, such as scraping, brushing, and wiping.

**Hazard** is a source of potential damage, harm, or adverse effects. In the context of biosafety, examples include objects (e.g., sharps, needles), materials (e.g., pathogens, toxins), animals (e.g., bites, scratches), and situations (e.g., containment system failure).

**Health & Safety** is the unit within Human Resources that is available to assist faculty, staff, students, and visitors in making the University a safe place to live, work, and learn.

**High Concentration** refers to regulated materials that are concentrated to a degree that increases the risks associated with manipulating the materials (ie. Increases the likelihood or consequence of exposure).

**Human Pathogen and Toxin Act (HPTA)** and **Human Pathogen Toxin Regulations (HPTR)** are legal documents under the Ministry of Justice that establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins in Canada.

**Human/Primary/Diagnostic/Clinical Specimen** is defined as any bodily substance taken from a person for the purpose of analysis, such as blood, urine, stool, tissue, and fluid. This definition also applies to samples collected from humans for the purpose of research.

**Importing** is the activity of bringing (e.g., transferring, transporting) regulated materials into Canada from another country or jurisdiction.

**In Situ** is Latin for "on site" or "in place". This term is used to describe a fixed location at which a procedure or experiment is conducted.

**In Vitro** is Latin for "within glass". This term is used to describe experiments involving components of a living organism within an artificial environment (eg. cells in a petri dish), including activities involving cell lines or eggs.

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**In Vivo** is Latin for “within the living”. This term is used to describe experiments conducted using the whole living organism (eg. studying the effects of antibiotic treatment in animal models).

**Inactivation** is a process that destroys the activity of pathogens and/or toxins.

**Incident** is an event or occurrence that has the potential of causing injury, harm, infection, intoxication, illness, disease, or damage. Incidents include accidents and near misses.

**Infectious Material** is any isolate of a pathogen or any biological material that contains human or animal pathogens and therefore, poses a risk to human or animal health.

**Infectious Dose** is the amount of pathogen required to cause an infection in the host, measured in number of organisms. Often defined as an ID<sub>50</sub>, which is the dose that will cause infection in 50% of those exposed.

**Intoxication** refers to a substance-induced disorder or disease resulting in a symptomatic or asymptomatic condition, or other physiological change resulting from exposure (ie. Ingestion, inhalation, absorption, inoculation) to a toxin produced by, or derived from, a microorganism. This includes a response from exposure to synthetically produced microbial toxins.

**Laboratory (Lab)** is an area within a facility or the facility itself where biological material including regulated materials are handled and/or stored for *in vitro* and/or *in vivo* work.

**Laboratory (Lab) Work Area** is an area within a containment zone designed and equipped for *in vitro* activities (e.g., for research, diagnostics, and teaching purposes).

**Laboratory (Lab) Manager** is the person most responsible for the day to day activities being conducted in the lab work area.

**Large Volume** is a volume of regulated materials that is sufficiently large to increase the risk associated with the manipulation of the material when compared with laboratory or bench-scale volumes (i.e., increases the likelihood or consequences of exposure or release).

**Limited Access** is access to a containment zone that is limited to authorized personnel and other authorized visitors through either operational means (e.g. having authorized personnel actively monitor and check all individuals entering a designated area) or through the use of a physical barrier (e.g. a controlled access system, such as key locks or electronic access cards).

**Local Risk Assessment (LRA)** is the site-specific risk assessment used to identify hazards based on the regulated materials 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.

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**Local Safety Committee (LSC)** is a committee in the Faculties and/or Departments that have been identified as a higher risk to establish a process where health and safety concerns can be addressed at a local level.

**Long-term Storage** refers to possession of regulated materials beyond 30 days or receipt or creation.

**Medical Surveillance Program** is the program designed to prevent and detect personnel illness related to exposure to regulated materials. The focus of the program is primarily preventative, but provides a response mechanism through which a potential infectious can be identified and treated before serious injury and disease occurs, and to reduce the potential of disease spread within the community.

**Member of the Community** is all persons associated with the University of Regina, including, but not limited to, the Board of Governors, President, VP's, AVP's, Deans, Directors, employees, students, contractors, visitors, and volunteers.

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

**Non-Indigenous Animal Pathogen** is a pathogen that causes an animal disease listed in the World Organization for Animal Health's "OIE-Listed Diseases, Infectious and Infestation" (as amended from time to time) and that is exotic to Canada, or any other animal disease that is exotic to Canada which has a significant impact on animal health as determined by the CFIA (i.e. FAD agents that are not present in Canada). These pathogens may have serious negative health effects on the Canadian animal population. The CFIA Office of Biohazard Containment and Safety (OBCS) must be contacted for permission and laboratory certification before research activities commence.

**Opportunistic Pathogen** is a pathogen that does not usually cause disease in a healthy host but can cause disease when the host's resistance is low (e.g., compromised immune system).

**Over-Arching Risk Assessment (ORA)** is a broad risk assessment that supports the biosafety program as a whole and may encompass multiple containment zones within an institution or organization. The overarching risk assessment identified hazards, risks, and mitigation strategies for the proposed activities involving regulated materials. Mitigation and management strategies reflect the type of biosafety program needed to protect personnel from exposure and to prevent the release of regulated materials.

**Pathogen** is a microorganism, nucleic acid, protein, or other infectious agent that is transmissible and capable of causing disease or infection in humans or animals. This can include bacteria, viruses, fungi, parasites, prions, recombinant DNA, genetically modified microorganisms, viral vectors, and synthetic biology products. Classified human and animal pathogens can be found on the PHAC's ePATHogen – Risk Group Database: [ePATHogen - Risk Group Database \(canada.ca\)](http://ePATHogen - Risk Group Database (canada.ca))

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**Pathogen Safety Data Sheets (PSDS)** are technical documents describing the hazardous properties of pathogens and recommendations for the safe handling of them. A PSDS may include information such as pathogenicity, drug susceptibility, first aid treatment, PPE, and risk group classification. *Note: there is not a PSDS for each microorganism. For more information including Risk Group and federal regulatory oversight consult the ePathogen-Risk Group Database on PHAC's website.*

**Pathogenicity** is the ability of a pathogen to cause disease in a human and/or animal host.

**Personal Protective Equipment (PPE)** is equipment and/or clothing worn by personnel to provide a barrier against regulated materials, 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.

**Phlebotomy** is the practice of drawing or collecting blood from a venous or capillary blood source.

**Post Mortem Room (PM Room)** is a room within the containment zone where necropsies and dissections are conducted on animals outside a primary containment device.

**President's Committee on Animal Care (PCAC)** is responsible for overseeing all animal care and use undertaken by members of the University of Regina, and ensuring compliance with institutional and Canadian Council on Animal Care standards.

**Principal Investigator (PI)** is the holder of an independent grant administered by a university and the lead researcher for the grant project, usually in the sciences, such as a laboratory study or a clinical trial. The phrase is also often used as a synonym for head of the laboratory or research group leader.

**Primary Containment** is the first level of physical barriers designed to contain regulated materials, and prevent their release. This is accomplished by the provision of a device, equipment, or other physical structure situated between the regulated materials and the individual, the work environment, or other areas within the containment zone. Examples include BSCs, glove boxes, and microisolator cages. In animal cubicles, the room itself serves as primary containment, and PPE serves as primary protection against exposure.

**Primary Containment Device** is an apparatus or equipment that is designed to prevent the release of regulated materials, and to provide primary containment (i.e. provide a physical barrier between the regulated materials and the individual or the work environment). Examples include BSCs, isolators, centrifuges with sealable cups or rotors, process equipment, fermenters, bioreactors, microisolator cages and ventilated cage racks.

**Prion** is a small proteinaceous infectious particle generally considered to be responsible for causing a group of neurodegenerative diseases in humans and animals known as transmissible spongiform encephalopathies.

**Public Health Agency of Canada (PHAC)** is the national authority on biosafety and biosecurity for human pathogens and toxins. PHAC is responsible for the regulation of human pathogens and toxins under the authority of the HPTA and HPTR. Under the HAA and HAR, PHAC is also responsible for the importation or transfer of pure cultures of terrestrial animal pathogens or part of one (e.g. toxin), with the exception of non-indigenous terrestrial animal pathogens and pathogens causing emerging animal diseases (EADs). PHAC is part of the federal health portfolio focusing on preventing disease and injuries, and responding to public health threats.

**Recombinant DNA (rDNA)** is a form of DNA that is created by combining DNA sequences that would not normally occur together using genetic engineering techniques.

**Regulated material:** in the context of the CBS, regulated materials includes:

- Human pathogens and toxins (under the HPTA and HPTR);
- Terrestrial animal pathogens (under the HAA and HAR); and
- Terrestrial animal pathogens in animals, animal products, animal by-products, or other organisms (under the HAA and HAR).

**Restricted access** is access to a containment zone that is restricted to authorized personnel by means of a physical barrier (i.e. a controlled access system, electronic access card, access code or key lock). Restricted access is required in areas of higher containment and where Security Sensitive Biological Agents are stored.

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

**Risk Assessment** is a thorough review of all the risks based on the probability, severity, and frequency of exposure to the hazard/event.

**Risk Group (RG)** is the classification of a biological agent (i.e., microorganism, protein, nucleic acid, or biological material containing part thereof) based on its inherent characteristics, including pathogenicity, virulence, communicability, and the availability of effective prophylactic or therapeutic treatments. The risk group describes the risk to the health of individuals and the public, as well as the health of animals and the animal population.

**Secondary Container** refers to the leak-proof container that encloses the primary container (eg. an autoclave bag (primary) within a solid impact-resistant container (secondary)).

**Security Barrier** is a physical obstruction designed to prevent access to regulated materials or other related assets by unauthorized personnel (eg. locked doors, controlled access systems, padlocked storage equipment) that increases the security of a containment zone by restricting access to authorized personnel only.



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**Security Sensitive Biological Agents (SSBAs)** are 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. Further explanation is found in the Canadian Biosafety Standards, 3<sup>rd</sup> Edition, 2022 and a list is found using ePathogen's advanced search function.

**Standard Operating Procedures (SOPs)** is a document that standardizes safe work practices and procedures for activities with regulated materials in a containment zone, as determined by an LRA. Examples of SOPs include experimental protocols, entry and exit procedures, decontamination protocols, and emergency response procedures.

**Sterilization** is the process that completely eliminates all living microorganisms, including bacterial spores.

**Supervisor** is a person who is authorized by the University to oversee or direct the work of employees or students, including, but not limited to, Deans, Directors, Department and Unit Heads, Academic Staff Members, and Managers.

**Terrestrial Animal Pathogen** is a pathogen (microorganism, nucleic acid, protein, or other infectious agent) that causes disease or infection in terrestrial animals; including those derived from biotechnology. These include pathogens that cause disease in avian and amphibian animals but excludes pathogens that only cause disease in aquatic animals and invertebrates. This also includes terrestrial animal pathogens or part of one (e.g., toxin) present on or in animal products, animal by-products, or other organisms.

**(Microbial) Toxin** is 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 or Part 1 of Schedule 5 in the HPTA.

**Transportation** is the act of transporting (e.g. shipping, conveyance) regulated materials to a building or another location (i.e. different address), within Canada or abroad in accordance with the *Transportation of Dangerous Goods Act and Regulations*.

**University Community Member** is all persons associated with the University of Regina, including, but not limited to, the Board of Governors, President, VP's, AVP's, Deans, Directors, employees, students, contractors, visitors, and volunteers.

**Validation** is the act of confirming that a method has achieved its objective and is suitable for its intended purpose through the provision of objective evidence. This can be achieved by observing that specific parameters have been met (e.g. using biological indicators, chemical integrators, or parametric monitoring devices placed in challenging locations within the load to confirm that a given autoclave cycle can decontaminate a representative load of waste).

**Verification** is the routine monitoring of equipment and processes to confirm continued efficacy between validations (e.g., testing the performance of an autoclave using biological indicators, viewing airflow gauges to confirm fan function in a BSC). Verification includes comparing the accuracy of a piece of equipment to an applicable standard or SOP.



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**Virulence** is the degree/severity of a disease caused by a pathogen.

**Virus** is a small infectious agent that can replicate only inside the cells of other organisms.

**Waste** is any solid or liquid material generated by a facility for disposal.

**Zoonoses** are diseases that are transmissible between living animals and humans. Zoonoses include anthroozoonoses (i.e. disease transmitted from animals to humans) and zooanthroposes, also known as reverse zoonoses (i.e., diseases transmitted from humans to animals).

**Zoonotic Pathogens** are pathogens 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.

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## Roles and Responsibilities

The roles and responsibilities outlined under the *Health and Safety Policy (GOV-100-005)* apply to this Program and include the following additions over and above the policy:

*Human Pathogen and License Holder*

*Biological Safety Officer*

## Biosafety Advisory Committee

### Terms of Reference

The Biosafety Advisory Committee (BSAC) is responsible for the approval, oversight, and administration of the University's Biosafety Program, which is designed to ensure the safe management of biological materials as it relates to education and research at the University of Regina. This includes the authority to establish and oversee a Biosafety Committee mandated to formulate and implement policies, regulations, and procedures governing the use of biological materials. The BSAC advises the Vice-President (Research) on all matters related to biosafety.

The BSAC consists of members who committed to the safe management of managing regulated materials. Committee members may represent various areas of expertise but will be concerned with regulations concerning all types of biological substances including biological substances that do not fall under Pathogen and Toxin License.

All members are voting members, except for the non-voting advisory members who provide expertise and additional resources on certain topics. Quorum will be met when half of the BSAC voting membership attends the meeting.

Membership will be decided at the beginning of each year and the membership list be updated and distributed by the BSO.

### Constitution of the BSAC

The BSAC may consist of the following members:

Voting Members:

- a) Academic Staff, Research Staff, and Staff Members chosen for their expertise in the safe use of biological materials or organisms
- b) Up to 3 members from the following: Post-Doctorate, Research Associate, and/or Research Assistant
- c) University administrative body representatives
- d) The Biosafety Officer (BSO)

Advisory Non-Voting Members (as required):

- e) Physician contracted with the University to provide medical expertise
- f) Representatives from Facilities Management

## Duties of BSAC

BSAC is authorized and responsible for:

- a) Approving, having oversight of, and administering the University's Biosafety Program;
- b) Establishing a Biosafety Committee (BSC) to implement and lead University of Regina day-to-day procedures governing the safe management of biological materials in accordance with the University's *Health and Safety Policy*;
- c) Advising on all matters related to laboratory biosafety that impact education and research;
- d) Ensuring the Public Health Agency of Canada *Human Pathogen and Toxin Act and Regulations* License Application and Administration Oversight Plan are sufficient, updated, and leading-practice;
- e) Ensuring the University of Regina Biosecurity Plan is sufficient for the dynamic research and teaching activities;
- f) Monitoring, reviewing, and if necessary, amending or rescinding the procedures and decisions made by the BSC or BSO if in non-compliance with the Pathogen and Toxin License; and
- g) Reviewing incident trends on a regular basis to make University recommendations.

## Frequency of Meetings

BSAC meets at least twice per year.

## Chair of BSAC

The Chair and Vice-Chair of the Committee are selected from Academic and Research staff members on the Committee. The Chair serves a one year term and is responsible for calling meetings and for correspondence with the committee members.

## Biosafety Committee

### Terms of Reference

The Biosafety Committee (BSC) implements and leads University of Regina day-to-day procedures governing the safe management of biological materials in laboratories that impact education and research in accordance with the University's *Health and Safety Policy*. Procedures and decisions made by the BSC or the BSO are subject to review and amendment by BSAC.

## Constitution of the Biosafety Committee

The Committee consists of the following members:

- a) The Chair of the Biosafety Advisory Committee (BSAC)
- b) The Biosafety Officer (BSO)

## Duties of the Biosafety Committee

The BSC is subject to the direction of BSAC, acts on behalf of, and is responsible for:

- a) Developing, formulating, implementing, and leading the University of Regina day-to-day procedures governing the use and management of biological materials in accordance with the University's *Health and Safety Policy*;
- b) Reports its activities to BSAC at such times and to such extent as BSAC directs;
- c) Annually assesses/ inspects biological activities and facilities;

- d) Reviews requests for and authorizes the commissioning of new Containment Level 2 laboratories in consultation with Facilities Management; and
- e) Responds to laboratory related biological substance safety situations which require immediate action.

### **Biosafety Officer**

The Biosafety Officer (BSO), reporting to the Manager, Health & Safety, is appointed by the Vice-President (Research) to give professional advice and coordinate all matters related to biological materials in education and research on campus. As according to the Public Health Agency of Canada's *Human Pathogen and Toxin Regulations BSO Minimum Qualifications* the BSO must have 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. The BSO is responsible for keeping procedures and practices for the use of regulated materials up to date, for identifying improvements and opportunities to keep biologically hazardous exposures minimal, and in assisting Academic Staff Members to meet regulatory compliance and University Policies.

#### **The duties of the BSO include:**

- a) Verifying the accuracy and completeness of license applications;
- b) Maintaining communication as necessary with the Public Health Agency of Canada (PHAC), Canadian Food Inspection Agency (CFIA), and the Occupational Health and Safety Division of the Government of Saskatchewan Ministry of Labour Relations and Workplace Safety (LRWS), and other regulators including preparation of annual reports and maintenance of required records;
- c) Promoting and monitoring compliance with the provisions of the HPTA and HPTR;
- d) Providing on-going advice and technical assistance to persons managing regulated materials;
- e) Reviewing biosafety aspects of plans, protocols, and operating procedures for research and teaching activities involving biologically hazardous substances prior to the implementation of these activities in consultation with the Biosafety Advisory Committee (BSAC);
- f) Leading investigations and supervising after incidents involving biologically hazardous substances;
- g) Coordinating with medical persons regarding possible laboratory-acquired infections;
- h) Ensuring proper waste management;
- i) Performing periodic internal biosafety audits on technical methods, procedures and protocols, biological agents, materials, and equipment;
- j) Discussing violations of biosafety protocols and procedures with the appropriate persons;
- k) Providing biosafety training for staff and students who wish to use biological materials or organisms, including animals;
- l) Providing a continuing education in biosafety;
- m) Assisting with the import/export of biologically hazardous materials or organisms to/from the laboratory, according to regulations;
- n) Assisting with the coordination of the receipt, shipment, and transport of biologically hazardous materials or organisms according Transportation of Dangerous Goods Regulations.



## Section 1 - Biosafety for Education and Research Activities

### Biological Education & Research Risk Assessment

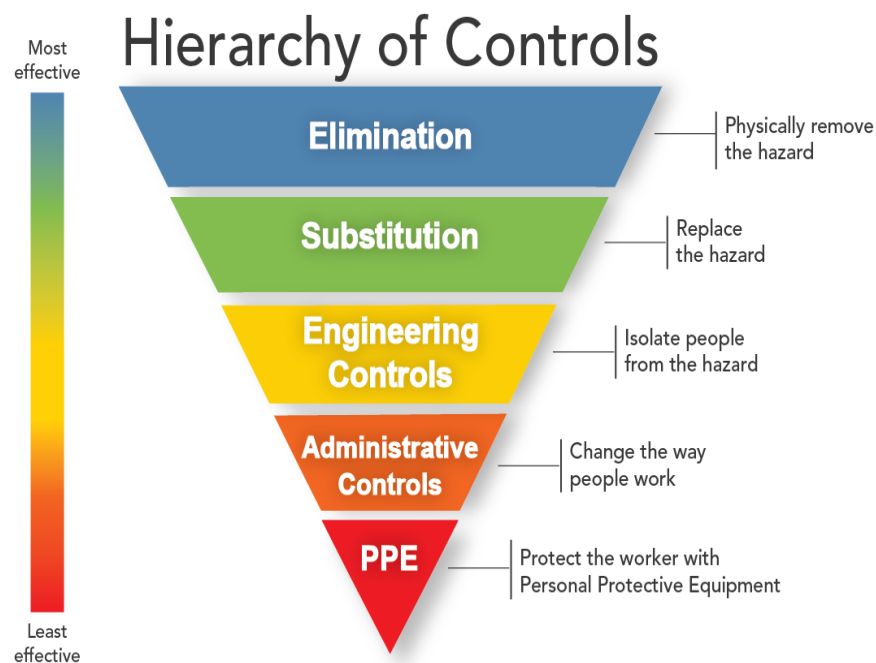
“Risk” is the probability of an undesirable event occurring and the consequences of the event (CBS, 2015). To ensure the safety of the community without making “blanket University statements or policies,” biological risk (in addition to all other types of risk (e.g. chemicals, mechanical, ergonomic, etc.) must be assessed and mitigated through various mechanisms.

Prior to starting a new project, activity, or experiment, you should take a step back and identify the hazards present. Once the hazards are identified, you use a risk assessment process to determine which risks are higher and require the greatest mitigation effort. To assist you in this process, see **Appendix 1 – Biological Education & Research Risk Assessment Instructions** for a comprehensive introduction into hazard identification and risk assessments and see **Appendix 2 – University of Regina Biosafety and Biosecurity Hazard Identification & Mitigation Strategies Tool** to help you formalize and document this process.

The BSO welcomes the opportunity to conduct this assessment process with you, please contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for assistance and guidance.

### Biological Education & Research Risk Management

Once you have identified hazards and determined the level of risk, the accepted mechanisms to control a hazard are:



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**Elimination (Substitution):** Is there a pathogen or process that poses less of a risk than the one selected that will provide the same result?

**Engineering Controls:** This includes the selection and use of primary containment devices (e.g. primary containment caging, biological safety equipment, closed vessel, HVAC systems, etc.) Another example includes handling materials in specialized Containment Labs that have increased physical infrastructure safety requirements (e.g. sealed benches).

**Administrative Controls:** These are the controls that can alter the way in which the tasks are done and can include procedures and practices. For example, detailed procedures and training regarding how infectious waste is transported to the autoclave.

**PPE:** The PPE selected and worn by individuals can reduce or minimize the potential exposure to infectious materials or toxins. This is the last and least reliable line of defense.

These strategies should be developed, implemented, regularly assessed, and updated. The following pages will identify mitigation controls for some of the higher-risk biological hazards known on campus. Please contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) for assistance and guidance.

## Biosecurity Risk Assessment and Plan (Risk Management)

While the concept of biosafety and biosecurity are closely located, the distinction between the two is important in the case of facilities where infectious material or toxins are handled or stored. *Biosafety* describes the containment principles, technologies, and practices that are implemented to prevent unintentional release. *Biosecurity* refers to the security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of infectious materials or toxins. These concepts are inherently complementary as the implementation of good biosafety practices serves to strengthen biosecurity programs.

The University of Regina (U of R) Biosecurity Plan has been divided into two basic levels to ensure the security of labs containing biological materials and organisms; Biosecurity Risk Level 1 and Biosecurity Risk Level 2 corresponding to the two levels of biological material containment at the University.

Principal Investigators (PIs), Lab Managers, Lab Instructors (LIs), and Supervisors are responsible for ensuring their lab and personnel under their guidance follow the level of biosecurity appropriate for the biological substances in use and programs in place for each individual lab.

Please contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) to incorporate and implement this over-arching institutional plan into your individual Lab Biosafety Programs. By integrating the elements of this U of R Biosecurity Plan into your Lab Biosafety Program, this will minimize the duplication and allow for a more efficient biosafety management system. If this Plan is not sufficient for your research and teaching projects, please add additional procedures and activities by conducting a biosecurity risk assessment in your

laboratory (see **Appendix 1 – Biological Research & Teaching Risk Assessment Instructions** and **Appendix 2 – University of Regina Biosafety and Biosecurity Hazard Identification & Mitigation Strategies Tool**) and/or contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) for assistance and guidance.

## Biological Research and Teaching (RG2) Procedures

All procurement, use, storage, transfer, and disposal of human pathogens and toxins under the auspices of the University are governed by the terms of U of R *Human Pathogen and Toxin License*. *HPTR* can be accessed [here](#).

### New Projects (Incoming Faculty)

New PIs, LIs, Lab Managers, and/or Supervisors of research and teaching activities and areas that procure, use, store, transfer, or dispose of Risk Group 2 biological materials in U of R facilities will require a detailed hazard identification and risk assessment conducted prior to any activities commencing. These assessments tools are available in **Appendix 1** and **Appendix 2**. The BSO is available to assist with the process and any activities necessary to meet any applicable commissioning and certification requirements. See **Appendix 3 – Assessed Biological Material Risk Group Guidance List** or contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) to determine if this process applies to your activities.

## Biological Education & Research Laboratory Commissioning & Certification Procedures

### General

At the U of R, building space design is developed, reviewed, and completed according to the National Building Code of Canada, National Fire Code of Canada, and other applicable codes and standards. Lab space can only be assigned by Facilities Management.

Some biological containment labs at the U of R must meet additional engineering, operational, technical, and physical requirements set by the U of R, PHAC, and CFIA.

### Biological Laboratory Containment Classification

Containment level (CL) refers to the minimum physical containment and operational practices required for a *containment zone* handling infectious materials, toxins, or plants safety in lab and animal work environments. A containment zone could be a single room (e.g. lab), a series of co-located rooms (e.g. several non-adjointing but lockable CL2 lab work areas), or it can be comprised of several adjoining rooms of the same CL.

Well characterized pathogens that have had a pathogen risk assessment completed by PHAC or CFIA have been assigned an appropriate risk group and CL. The risk group and CL are generally the same, but there are exceptions. As part of the risk assessments conducted, the CL may change when the pathogen has been modified or the original conditions of use have changed. These changes reflect the risk mitigation strategies to address the specific modification of the pathogen or conditions of use.



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See **Appendix 4 – Biological Laboratory Containment Level Classification** and/ or contact BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) to determine what containment level is appropriate for your activities.

## Biological Laboratory Decommissioning Procedures

All PIs, LIs, Lab Managers, and Supervisors who terminate or relocate their CL2 Lab activities at the U of R must contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) for assistance before starting the decommissioning process.

## Worker Authorization & Signage Procedures

Only authorized personnel are allowed to enter lab working areas. Visitors, maintenance staff, custodial staff and others, as deemed appropriate, must be provided with training and/or supervision commensurate with their anticipated activities in the containment area. All such individuals must have the permission of the PIs/LIs/Lab Managers to enter the containment area. Up-to-date campus-wide signage provides contact information for entry.

If entry into these areas is essential to maintain the building, H&S is available to provide the necessary orientation for staff or contractors required to enter these restricted laboratories. Contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) for more information.

## Health & Medical Surveillance Program Procedures

The purpose of a health and medical surveillance program is to help prevent and detect illness related to the exposure of personnel to infectious materials or toxins.

There are a number of ways in which biologically hazardous substances can enter the body and cause infection and disease, including ingestion, inhalation, puncture, or absorption. The types of lab events that can lead to an infection or disease include exposure to infectious aerosols, spills and splashes, accidental needle stick injuries, cuts from sharps, bites and scratches from animals, centrifuge accidents, and secondary spread of biologically hazardous substances to non-laboratory areas.

At the U of R, health and medical surveillance programs are determined on a project-by-project basis under the discretion of the PI/ LI/ Lab Manager in consultation with the BSO. Based on each individual project risk assessment, risk mitigation controls such as exposure control plans, immunizations, waivers, medical pre-screening, and SOP development may be required.

In general, all research personnel must understand the hazards and risks of their specific work projects and immuno-compromised and pregnant women must have the option of taking extra care and/or not working with certain biologically hazardous materials or organisms. See **Appendix 1, Appendix 2** or contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) for details on how to determine if your activities require a robust health and medical surveillance program.

## Pregnant Worker Notification

Students and workers who are pregnant should take steps to reduce their exposure to harmful biological substances by notifying their Supervisor immediately. PIs, LIs, and Lab Managers who have been notified that a lab user is pregnant must take steps to minimize the student/worker's exposure or assign the student/worker to less hazardous work if available. Contact BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) for assistance.

## Biological Material Emergency Response Procedures

### Emergency Contact Information

<b>24 Hour Emergency (Fire, Police, Medical):</b>	911
<b>24 Hour Saskatchewan Health Hotline:</b>	811
<b>Protective Services:</b>	306-585-4999

<b>Biosafety Officer (BSO):</b>	306-585-5198/ 306-527-4320
<b>Health &amp; Safety, Human Resources:</b>	306-585-4776 /306-585-5487
<b>Hazardous Material Response Team:</b>	306-585-4999

## Exposures, Suspected Exposures, and Post-Exposures

### Medical Emergency

1. Phone 911 – Direct them to the scene of the occurrence.
2. Call Protective Services: 585-4999
3. Give First Aid, if you are qualified to do so, or get help from Protective Services.
4. Stay with victim.

### Exposure or Suspected Exposure Procedures

#### Needle Stick Poke, Puncture Wound, or Percutaneous Injury

1. Remove gloves and allow the wound to bleed.
2. Immediately wash the affected area for 15 minutes with soap and warm water.
3. Notify Supervisor (if available) to obtain assistance.
4. Seek **medical assistance immediately** (within **1-2 hours**) from a health care professional. The cause of the wound and organisms involved should be reported.
5. Details of the incident must be documented using the **Incident Report Form** and forwarded to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca) or 306-585-4776. Please include the following details:
  - a) What was the method of contact (e.g. needle stick, splash)?
  - b) How did the exposure occur?
  - c) What known biological agents or body fluids were you in contact with?
  - d) What action was taken in response to the exposure to remove the contamination (e.g. hand washing)?
  - e) What personal protective equipment was being used at the time of exposure?
  - f) What is your immune status (e.g. Tetanus, Hepatitis A or B Virus)?

### Eyes or Mucous Membrane Exposure (e.g. Splash)

1. Immediately flush the affected area for 15 minutes using an eyewash or shower.
2. Notify Supervisor (if available) to obtain assistance.
3. Seek **medical assistance immediately** (within **1-2 hours**) from a health care professional. The organisms involved should be reported.
4. Details of the incident must be documented using the **Incident Report Form** and forwarded to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca) or 306-585-4776. Please include details as listed above.

### Ingestion

1. Protective clothing should be removed.
2. Notify Supervisor (if available) to obtain assistance.
3. Seek **medical assistance immediately** (within **1-2 hours**) from a health care professional.
4. Identification of the material ingested and circumstances of the incident should be reported.
5. Details of the incident must be documented using the **Incident Report Form** and forwarded to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca) or 306-585-4776. Please include details as listed above.

### Post-Exposure Procedures

If a student or employee has been exposed to biologically hazardous substances at the U of R, the University will, with the consent of the student/employee, during the student/employee's normal working hours, arrange for immediate medical evaluation, medical intervention, and confidential post-exposure counselling.

If a student/employee cannot receive medical evaluation, medical intervention, or post-exposure counselling during the student/employee's normal working hours, the U of R will credit the student/employee's attendance for evaluation, intervention, or counselling as time at work and shall ensure that the student/employee does not lose any pay or other benefits.

The U of R H&S Unit investigates and documents any occurrence of an occupationally transmitted infection and any occupational exposures to an infectious agent to identify the route of exposure and implement measures to prevent infection. All investigations and documentation concerning personal information of any work-related exposure incident, including the route of exposure and the circumstances in which the exposure occurred, are held in complete confidentiality.

### Biological Material Spill Procedures

The most immediate concern following a spill of infectious materials or toxins is to contain the spill and treat any exposed persons. See **Biological Material Emergency Response Procedures** above for step-by-step medical treatment procedures.

After this occurs, properly trained personnel can begin the clean-up and decontamination process. Use the detailed step-by-step biological material spill procedures outlined below.

### Small Non-Hazardous Biological Spill

(Spills that you are comfortable cleaning up)

1. All persons should inform other personnel in the affected area not to enter.
2. Review the MSDS and PSDS, to determine the protective equipment, spill cleanup, and disposal protocols that are necessary for all chemicals and biological materials involved.
3. Wear gloves, laboratory coat, shoes, pants, and other appropriate personal protective equipment (i.e. face and eye protection).
4. Cover the spill with cloth or paper towels to contain it.
5. Spray or pour an appropriate disinfectant over the paper towels and the immediate surrounding area (according to the specific biological PSDS; generally, 10% bleach or 70% ethanol solutions are appropriate).
6. Start applying the disinfectant from the outside and move inwards.
7. After the appropriate amount of time (5-10 minutes), clear away any materials like broken glass using forceps or another mechanical device and place in a sharps container/biohazard container.
8. Clean and disinfect the spillage area using paper towels and other appropriate cleaning materials.
9. Place contaminated materials into a labelled, leak-proof, puncture-resistant waste disposal container and dispose of waste appropriately. Contact Health & Safety (306-585-4776) for waste disposal assistance.
10. Complete an **Incident Report Form** and forward to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca).

### Large Non-Hazardous Biological Spill

(Spills you are not comfortable cleaning up by yourself)

1. All persons should inform other personnel in the affected area not to enter.
2. Review the MSDS and PSDS, to determine the protective equipment, spill cleanup, and disposal protocols that are necessary for all chemicals and biological materials involved.
3. The Laboratory Supervisor and UR Hazardous Material Spill Response Team (via Protective Services (306-585) 4999) should be informed for cleanup assistance.
4. Complete an **Incident Report Form** and forward to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca).

### Small Hazardous Biological Spill

(Spills you are comfortable cleaning up)

1. All persons should immediately leave the affected area and allow aerosols to settle (~30 minutes).
2. Signs should be posted indicating that entry into area is forbidden. Post a sign stating “**DO NOT ENTER, BIOHAZARD SPILL. Contact (name and phone #) for information.**”
3. Any exposed person should seek **medical assistance immediately** (within **1-2 hours**) from a health care professional.
4. The Laboratory Supervisor, Health & Safety (306-585-4776), or a “Spill Buddy” should be informed for cleanup assistance.
5. Wear gloves, laboratory coat, shoes, pants, and eye/face protection.
6. Cover the spill with cloth or paper towels to contain it.
7. Spray or pour an appropriate disinfectant over the paper towels and the immediate surrounding area (according to the specific biological PSDS; generally, 10% bleach solutions are appropriate).
8. Start applying the disinfectant from the outside and move inwards.

9. After the appropriate amount of time (see PSDS), clear away any materials like broken glass using forceps or another mechanical device and place in a sharps container/biohazard container.
10. Clean and disinfect the spillage area using paper towels and other appropriate cleaning materials.
11. Place contaminated cleaning materials into a labelled, leak-proof, puncture-resistant waste disposal container and dispose of waste appropriately. Contact Health & Safety (306-585-4776) for waste disposal assistance.
12. Complete an **Incident Report Form** and forward to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca).

### Large Hazardous Biological Spill

(Spills you are not comfortable cleaning up)

1. All persons should immediately leave the affected area and allow aerosols to settle (~30 minutes).
2. Signs should be posted indicating that entry into area is forbidden; post a sign stating “DO NOT ENTER, BIOHAZARD SPILL. Contact (name and phone #) for information.”
3. Any exposed person should seek **medical assistance immediately** (within **1-2 hours**) from a health care professional.
4. The Laboratory Supervisor and UR Hazardous Material Spill Response Team (via Protective Services (306-585) 4999) should be informed for cleanup assistance.
5. Supervised decontamination should proceed.
6. Complete an **Incident Report Form** and forward to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca).

### Potentially Hazardous Aerosol Release

1. All persons should immediately leave the affected area and no one should enter the room for an appropriate amount of time (e.g. 30 minutes), to allow for aerosols to be carried away and heavier particles to settle. If the laboratory does not have a central air exhaust system, entry should be delayed (e.g. for 24 hours).
2. Signs should be posted indicating that entry is forbidden. Post a sign stating “DO NOT ENTER, BIOHAZARD SPILL. Contact (name and phone #) for information.”
3. Any exposed person should seek medical assistance immediately (within 1-2 hours) from a health care professional.
4. The Laboratory Supervisor and UR Hazardous Material Spill Response Team (contacted via Protective Services (306-585) 4999) should be informed for cleanup assistance.
5. After the appropriate amount of time (~30 minutes – 24 hours), supervised decontamination should proceed.
6. Complete an **Incident Report Form** and forward to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca).

**Always contact Health & Safety (306-585-4776) prior to wearing a respirator for the first time. You MUST be fit-tested.**

### Spills inside a Biological Safety Cabinet

When a spill of biologically hazardous material occurs within a cabinet, cleanup should begin immediately, while the cabinet continues to operate. An effective disinfectant should be used and applied in a manner that minimizes the generation of aerosols. All items that come into contact with the spilled agent should be disinfected and/or autoclaved.

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Follow the above steps for a *Hazardous Biological Spill*.

### Spilled Hazardous Substances and Broken Containers

1. All persons should immediately leave the affected area.
2. Any exposed person should seek medical assistance immediately (within 1-2 hours) from a health care professional.
3. Determine if you are comfortable cleaning up the spill or require some assistance. Follow the above directions.

#### Additional Considerations:

1. Broken containers contaminated with infectious substances and spilled infectious substances should be covered with a cloth or paper towels. Care must be taken to avoid splashing or generating aerosols during the clean-up.
2. Glass fragments should be handled with forceps or another mechanical device and placed in a sharps container/biohazard container. NEVER with your hand.
3. If dustpans are used to clear away the broken material, they should be autoclaved or placed in an effective disinfectant for 30 minutes.
4. If laboratory forms or other printed or written material are contaminated, the information should be copied onto another form and the original discarded into the contaminated-waste container.

### Spills Kits

Every CL2 lab must have basic supplies to assist with biologically hazardous spill cleanup. The kit must contain:

- Personal protective equipment
- Forceps and sharps waste disposal container
- Concentrated disinfectant (effective against organism of use)
- Paper towels
- Autoclave/biohazard bags

The Hazardous Material Spill Response Team (contacted via Campus Security (4999)) can assist with biological material spill cleanup.

## Biological Material Decontamination Procedures

### General

Decontamination includes both the complete destruction of all microorganisms and any bacterial spores by **sterilization** and the chemical destruction and removal of specific types of microorganisms by chemical **disinfection**.

All contaminated materials including, but not limited to, laboratory cultures, stocks, animal tissues, laboratory equipment, tools, sharps, and personal and protective clothing that has been in contact with biologically hazardous substances must be decontaminated before disposal or reuse. A basic knowledge of how to properly decontaminate using chemical disinfectant and sterilization methods is important for biosafety in the laboratory.

Lab bench tops, biological safety cabinets, tools, and surfaces are to be decontaminated after all spills of biologically hazardous substances *and* at the end of the working day. Lab working rooms and large pieces of equipment may also require decontamination prior to servicing, maintenance, transfer and reassignment.

### **Sterilization**

Dry heat sterilization is a non-corrosive process used to sterilize lab glassware, lab waste, some plastics, metals, tools, etc. which can withstand temperatures of 160°C (320°F) or higher for 2-4 hours.

Moist heat sterilization is a process used to sterilize laboratory wares and wastes, and is most effective when used in the form of autoclaving. For more details, please see the online [U of R Autoclave Program](#). The process of boiling does not necessarily kill all biologically hazardous materials or organisms but it may be used as the minimum processing for decontamination where other methods such as chemical disinfection and autoclaving are not feasible.

### **Disinfection**

Dirt, soil, and organic material can shield microorganisms and interfere with the killing action of disinfectants; thus, pre-cleaning is required before properly decontaminating heavily soiled items with disinfectants. Cleaning is the removal of dirt, organic matter, and stains by brushing, vacuuming, dry dusting, washing, or damp mopping with water containing a soap or detergent.

Many types of chemicals can be used as disinfectants; therefore, the proper type of disinfectant must be carefully selected for each laboratory's specific needs. Refer to **Appendix 5 - Disinfectants** for a comprehensive list of disinfectant types and against which biological agents the disinfectant is effective.

### **Protective and Personal Clothing Decontamination**

All contaminated personal clothing items and non-disposable gowns, coveralls, and coats should be properly decontaminated to reduce risk of transmission and exposure. The risk of disease transmission from soiled linen is low, but soiled linens may carry organisms that may contaminate the air and immediate environment. See **Appendix 6 – Personal Protective Equipment** for step-by-step details.

## **Biological Material Laboratory Equipment Procedures**

### **Personal Protective Equipment**

Personal protective equipment (PPE) also known as barrier equipment is used to prevent biologically hazardous substances from making direct contact with an individual. In accordance with Universal Precautions, blood, body fluids, and tissues of all persons are considered potentially infectious.

The type and amount of PPE depends upon the task or activity performed. Remember, PPE is the least effective type of hazard control and the last resource on which to rely. Administrative and engineering controls are the most effective means of hazard control.

See **Appendix 6 - Personal Protective Equipment** for more information regarding types of PPE available for use with biological materials.



## Biological Safety Cabinets

Biological safety cabinets are specialized, vented cabinets, which use a variety of combinations of high efficiency particulate air (HEPA) filtration, laminar airflow, and containment to provide protection to personnel, laboratory materials, or the environment. *Biological safety cabinets are not chemical fume hoods and must not be used as such.*

A variety of types of cabinets exist, and the cabinet chosen must be suited to the work proposed:

- **Clean Air Bench (Laminar Flow Hood)** – These benches are used for product protection only, and do not protect the worker from aerosols or particulates from the work. HEPA-filtered air flows towards the worker. *This is not a biological safety cabinet and should not be used as such.*
- **Class I** – Laminar air flow is directed away from the user and through a HEPA filter. These cabinets provide partial protection to the user and protection of the environment, but do not protect the product. Class I cabinets are suitable for some work procedures at Containment Level 1 and 2.
- **Class II** – These cabinets provide protection to the worker, the work, and the environment.
- **Class III** – These cabinets are typically used in containment Level 4 facilities.

Please see **Appendix 7 – Guidelines for Biological Safety Cabinets Use** for more information, including procedures, training, and certification requirements.

## Centrifuges, Microtomes, Blenders/Sonicators/Homogenizer, Bunsen Burners, Vacuum Pumps and Systems, Electrophoresis

Please see the online [Hazardous Materials and Equipment Safety: Procedures, Forms & Guidelines](#) for more information, including procedures and training requirements.

## Biological Waste Disposal Procedures

All human, animal, and microorganism material that has been produced, used, or handled at the University must be disposed of properly. Biological material must never be poured down the drain or put into the regular garbage before inactivation and/or decontamination; this excludes whole water, soil, and plant samples that have not been manipulated.

See the online [Biological Waste Disposal](#) and **Appendix 8 – Biological Waste Disposal Procedures** for more details.

## Autoclaves

An autoclave is a specialized piece of equipment designed to deliver heat under pressure to a chamber, with the goal of decontaminating or sterilizing the contents of the chamber. Packaging materials to be autoclaved and using autoclave equipment properly ensures the integrity of research and teaching activities. Please see the online [U of R Autoclave Program](#) for a comprehensive manual detailing how to achieve these objectives.

## Incineration

Incineration is a useful method for disposing of laboratory waste, animal carcasses and tissues, and anatomical biomedical waste. Effective incineration depends on proper equipment design; modern



incinerators have two chambers with an ideal temperature in the primary chamber of at least 800°C and in the secondary chamber a temperature of at least 1,000°C.

The University has a contract with a waste disposal company to transport and incinerate all human, animal, and chemically-contaminated microbiological waste produced on and off campus. As most wastes need to be stored in fridges and freezers, a waste disposal pick-up is only scheduled as required. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) to schedule a waste disposal pick-up.

## Ordering and Receiving Biological Materials Procedures

For more information please see the online [Ordering and Receiving \(Importation\)](#) and/or contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)).

### Materials Transfer Agreements (MTA) Signing Authorization Policy

MTAs for Risk Group 1 and/or Risk Group 2 biological materials can affect the ownership and dissemination of research results. The *Delegation of Authority, Senior Executive Policy* (GOV-010-010; <http://www.uregina.ca/policy/browse-policy/policy-GOV-010-010.html>) governs this, so MTA's must be signed by the Vice President (Research) or designate. Please contact the Research Office for more information.

### Ordering Biological Materials

Additional importation, exportation, and transport permits may be required. To ensure no delays at Customs or receiving facilities on campus, please see the online [Ordering and Receiving \(Importation\)](#) and/or contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)).

Prior to any Risk Group 2 (or above) order being placed, the [Biologically Hazardous Agent Transfer Notification Form](#) must be submitted to the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)).

### Receiving Biological Materials

Biological materials can *only* be received through the University Science Stores by appropriately-trained personnel. Do not ever sign for and receive materials in your lab or office space. For more information, please see the online [Ordering and Receiving \(Importation\)](#) and/or contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)).

## Importing and Exporting Biological Materials Procedures

### Importing Biological Materials

The importation into and transfer within Canada of biological materials fall under various authorities to ensure that labs/ facilities have appropriate containment for the materials to be used and handled. To ensure no delays at Customs or receiving facilities on campus, please see the online [Ordering and Receiving \(Importation\)](#) and/or contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)).

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## Exporting Biological Materials

The exportation of biological materials outside Canada may require permits and paperwork to be completed prior to shipping. For more information, please see the online [Ordering and Receiving \(Importation\)](#) and/or contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)).

## Transporting Biological Materials within Canada Procedures

The transport of biological materials inside Canada may require a permits and paperwork to be completed prior to shipping. These forms can be found [online](#). For more information, please contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)).

## Human/Primary Specimen Procedures

Human/Primary/Clinical specimen or sample (e.g. blood, tissue, saliva, cells, etc.) may contain infectious material or toxins, and this should be considered when assessing the risks associated with working with this material. Handling blood in diagnostic laboratories is common practice, and even though some pathogens are not considered to be bloodborne, they can still be present in high concentrations in blood samples. Appropriate PPE and protocols that are proportional to the risks should always be in place to prevent exposure and to reduce the risk of accidental inoculation or cuts. See **Appendix 10 – Human/ Primary Specimen Guidelines** for guidance on what should be incorporated into your safety program and **Appendix 1 and Appendix 2** for more detailed information on how to conduct LRAs to determine required procedures to manipulate human specimens.

## Phlebotomy Procedures

By its nature, phlebotomy (the practice of drawing or collecting blood from a venous (venipuncture) or capillary blood source) has the potential to expose personnel to blood from other people, putting them at risk from bloodborne pathogens.

See the online [U of R Phlebotomy Guidelines](#) for more detailed guidelines that outline the required health and safety program for performing phlebotomy on human subjects at the U of R.

## Human Neurological Tissue Procedures

These procedures are intended for activities that use un-screened human neurological specimens, which are not suspected of containing prions but have not been definitively confirmed clear. There are no known effective treatments or vaccines for prions (also known as Transmissible Spongiform Encephalopathies or TSEs). Therefore, it is necessary to handle the neurological tissue with extreme caution, both for the researcher protection and for environmental protection.

Please contact the BSO ([health.safety@uregina.ca](mailto:health.safety@uregina.ca)) for more detailed guidelines that outline the required health and safety program for performing conducting activities with human neurological tissue.

## Viral Vector Procedures

See the online [Viral Vector Program](#).

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## Appendix 1 - Biological Education & Research Risk Assessment Guidance

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### Introduction to Risk Assessments

Each one of us encounters hazards on a daily basis, often without even recognizing that these things are hazards. A hazard is anything that has the potential to harm us. For example: a dog is a hazard. It can bite, scratch, carry disease, or cause allergic reactions. The risk is based on the probability, severity, and frequency with which we are exposed to that hazard. The probability of being bitten by a dog that is behind a fence is low, thus, the risk is low. The severity of the bite might depend on the size or aggressive nature of the dog, and the frequency of this hazard depends on how often you walk by the dog. We can easily ascertain that the risk of harm is high if the dog is unrestrained, aggressive, and one that we must walk near on a regular basis. In contrast, the risk is low for a restrained dog who is calm and even-tempered and that we only have to walk past once.

A variety of hazards exist at the University of Regina (U of R), and the risk to members of the University community can vary greatly depending on how the hazards are managed. Below is a list of the most common biological hazards, with reference to the Appendices or additional documents that provide further information on assessing and managing the risks associated with those hazards. This list is not exhaustive, and many additional examples can be added as this program progresses. Some things to think about when undertaking any activity involving the hazards listed below, are the severity, probability, and frequency of the activity. Your level of risk is based on the combination of these things.

**Probability** takes into account the different controls that are currently in place. For example, the probability of an inhalation of hazardous chemical is very low if these chemicals are only used in a fume hood, and very high if they are particularly hazardous and used outside a fume hood. An intermediate value would be given to lower hazard materials used outside the fume hood, because there is still a risk of inhalation, which we always want to avoid.

**Severity** looks at the “worst case scenario” for the given activity/hazard. For example, if students are commonly working alone after hours, the possibilities are almost endless for what could potentially happen. If the student spills hazardous material on themselves, is overwhelmed by the fumes and unable to get to a safety shower, they will be left there overnight. The results in this case could be fatal. However, if using the lone worker program, there is still the possibility of the student spilling material on themselves, but they are more likely to be found and assisted before serious damage occurs. To reduce the severity even less, a personal alarm system linked directly to security could be implemented. That way help will arrive almost immediately, as opposed to the once per hour walk by of the lone worker program. To eliminate this potential hazard entirely, lab rules could prohibit the use of particularly hazardous chemicals after hours, since a worker may not be able to activate a personal alarm if they are overtaken by the fumes immediately and faint.

Please note that this rating should also include the severity of the financial or environmental impact, or reputational damage that could occur if the worst was to happen. For example, if there was a large spill of chemical in a public hallway (but no one was hurt), there could still be reputational damage if the media was to discover this event and spin a headline like “toxic chemical spill at the

University of Regina, entire building evacuated while HAZMAT crews attend to the scene.” If a spill were to occur outside, there would be both environmental impact, and then additional costs associated with soil remediation.

**Frequency** takes into account both the frequency of the activity (working in an acid bath daily) and the number of people who perform the activity (only one student works in the acid bath vs. five students work in the acid bath on a daily basis).

When working with any hazardous materials, we should always be assessing our level of risk, and taking measures to reduce our risk whenever possible. Some guidance is provided in the appendices for each hazard, but these are not exhaustive/comprehensive risk assessments and it is therefore important to think critically about any activity/experiment you are about to perform.

### Biological-Specific Risk Assessments

Risk assessments are conducted for many components of a biosafety program, including the evaluation of community and environmental safety, biosecurity requirements, training needs, and regulatory compliance. The following paragraphs will lead you through details specific to certain biological-related hazards.

#### Human & Animal Pathogens

Classification of pathogens according to Public Health Agency of Canada’s (PHAC) and Canadian Food Inspection Agency’s (CFIA) four risk groups has traditionally been used to categorize the relative hazards. See **U of R Biosafety Program** and/or see [PHAC’s Pathogen Safety Data Sheets](#) for information about already assessed materials.

However, it is the responsibility of the PI and the U of R to conduct pathogen risk assessments on uncharacterized pathogens or pathogens that may have been modified. Individuals with varying expertise and responsibilities should be included in the pathogen risk assessment process (the Biosafety Advisory Committee (BSAC) can lead this process).

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

The pathogen risk assessment characterizes the risks associated with a pathogen based on the close examination of the following risk factors:

- **Pathogenicity/Virulence:** Is the pathogen able to infect and cause disease in humans and animals (i.e. pathogenicity)? What is the degree of disease severity in individuals (i.e. virulence)?
- **Route of Infection:** How does the pathogen gain entry into the host (i.e. ingestion, inhalation, mucous membranes, subcutaneous, genitourinary)?

- *Mode of Transmission:* How does the pathogen travel to the host (e.g. direct contact, indirect contact, aerosolized droplet or airborne transmission, vectors, zoonosis, etc.)?
- *Survival in Environment:* How stable is the pathogen outside the host? Under what environmental conditions can it survive and for how long?
- *Infectious Dose:* What amount of pathogen is required to cause an infection in the host (measured in number of organisms)?
- *Availability of Effective Preventative and Therapeutic Treatment:* Are effective preventative measures available (e.g. vaccines)? Are effective treatments available (e.g. antibiotics, antivirals)?
- *Host Range:* What are the primary, intermediate, and dead-end hosts? Does the pathogen cause infection in a wide range of species or is the host range more restricted?
- *Natural Distribution:* Is the pathogen present in Canada? Is it prevalent in a particular region, location, or human or animal population? Is the pathogen non-indigenous?
- *Impact of Introduction and/or Release into the Environment to the Canadian Public:* If the pathogen was introduced into the population or released into the environment (within Canada), what would be the economic, clinical, and biosecurity impact?

### **Human and Animal Pathogen Risk Group Categories**

Not all biological material will all perfectly into a given risk group following a risk assessment. This may be the case for biological material that may harbor pathogens (e.g. tissues), toxins, prions, or modified components of a pathogen. If this is the case, a Local Risk Assessment (LRA) must be performed to determine the appropriate level of precautions to be taken for infectious materials that is manipulated in a containment zone. A number of factors that should be considered when assessing the risks associated with activities involving these types of material or considerations are described below.

See the **Biosafety Program, Appendix 3 - Assessed Biological Material Risk Group Guidance List** for more information.

### **Security Sensitive Biological Agents (SSBAs)**

Security sensitive biological agents (SSBAs) are human pathogens and toxins that have been determined to pose an increased biosecurity risk due to their inherent dual-use potential for bioterrorism. Also known as “prescribed human pathogens and toxins.” For ease of reference, the PHAC maintains an exhaustive list of all SSBAs, including trigger quantities, which can be accessed [here](#).

### **Toxins**

Biological toxins are poisonous substances that are a natural product of the metabolic activities of certain microorganisms, plants, and animal species. Toxins are not considered to be infectious material, nor can they be classified as standard toxic chemicals; therefore, special considerations must be made when performing a risk assessment on this type of material. An exhaustive list of toxins governed under the Human Pathogen and Toxin Act (HPTA) is listed in the See the **Biosafety Program, Appendix 3 - Assessed Biological Material Risk Group Guidance List** for more information.

The principles of chemical and biosafety are both applicable when handling biological toxins, and Containment Level 2 Laboratory is the minimum requirement for laboratories where only biological toxins are handled (i.e. human or animal pathogens are not handled therein).

When handling toxins derived from biological microorganisms, a detailed risk assessment should include the following:

- Exposure Assessment to identify risks inherent to the procedure being performed (i.e. inoculation risk, aerosol generation, static buildup when handling powdered toxins, etc.)
- Routes of exposure (i.e. ingestion, inhalation, absorption (dermal and ocular), and injection)
- Concentration/amount of toxin being handled and units of activity
- Indicators of toxicity:
  - LD<sub>50</sub> (median lethal dose; amount of toxin that is lethal to 50% of the population)
  - ED<sub>50</sub> (median effective dose; amount of toxin that will cause a particular effect in 50% of the population)
- Rate of action (how long after exposure before effects are observed):
  - The effects of most neurotoxins are typically observed within minutes to hours after exposure
  - The effects of most cytotoxins are typically observed within hours to days after exposure
- Severity and duration of illness (acute vs chronic effects)
- Availability of vaccines or antitoxins; and
- Use of chemical safety practices appropriate to techniques used (i.e. solvents, acids).

## **Recombinant DNA (rDNA)**

### **Genetically Modified Organisms (GMOs)**

The use of rDNA technologies to create GMOs may change the risk group and/or containment level relative to the risk group and/or containment level of the parental organism, depending on factors such as the gene(s) in the recombination organism, the expression of the gene(s) in the recombinant organisms, the biological containment offered by the host organism, the interactions between the gene(s) being transferred and the host vector systems, and the viability of the host vector systems.

The containment requirements need to be assessment when genetic manipulations are performed that:

- Alter the pathogenicity or virulence of recombinant pathogens;
- Affect pharmacological activities (e.g. resistance to antibiotics) of recombinant pathogens;
- Delete genetic material or introduce genetic material with potentially adverse effects (e.g. insertion of an oncogene);
- Induce the production of toxins by recombinant microorganisms;
- Broaden the host range or cell tropism of recombinant pathogens;
- Create novel mechanisms or undesirable traits in transgenic animals;
- Produce attenuated strains of recombinant pathogens that have lost virulence factors; and
- Produce host bacterial or viral vector systems with limited ability to survive outside the containment zone

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Factors to consider when assessing GMOs should include the following:

- Containment level of the recipient organism(s);
- Containment level of the donor organism(s);
- Replication competency of the GMO;
- Property of the donor segment incorporated into the recombination particle;
- Potential pathogenic factors associated with the donor segment; and
- Novel hazards of the GMO that may not be well characterized.

### **Viral Vectors**

The risks associated with viral vector systems can be assessed by examining the considerations for GMOs outlined above, along with the choice of vector system, the safety features engineered into the system, and the nature of the transgene(s) in the vector. The use of retroviral vector systems, including lentiviral vectors derived from type human immunodeficiency virus (HIV-1), raises other possible risks that should be assessed. The major risks involving viral vectors include:

- Potential for generations and propagation of replications competent retrovirus (RC);
- Potential for oncogenesis;
- Potential for increased pathogenicity; and
- Potential for seroconversion, even with non-replication viruses.

### **Synthetic Biology**

The risks associated with synthetic biology and sDNA technologies are similar to the risks associated with GMOs and rDNA technologies. The principal difference is that synthetic biology seeks to design and construct novel biological functions and systems not found in nature; as such, assessing the potential risks associated with products of synthetic biology is somewhat more complex. The nature of the genetic materials being manipulated (e.g. where it encodes harmful characteristics, such as biological toxin) should be carefully considered. There may also be unexpected interactions as a result of the expression of the engineering genome which could have negative health impact on humans or animals.

### **Prions**

Prions are small, proteinaceous, infectious particles that are the cause of a number of fatal progressive neurodegenerative diseases in humans and animals known as transmissible spongiform encephalopathies (TSE). The most likely route of transmission of infectious prions is through inoculation or ingestion. Prions are resistant to decontamination procedures and processes commonly effective against other pathogens. Activities involving infectious prions are generally assessed to be safely conducted at CL2 with specific additional physical and operational requirements.

### **Human/ Primary Specimens**

Primary specimens (e.g. blood, tissue) may contain infectious material or toxins, and this should be considered when assessing the risks associated with working with this material. Handling blood in diagnostic laboratories is common practice, and even though some pathogens are not considered to be bloodborne, they can still be present in high concentrations in blood samples. Appropriate PPE and protocols that are



proportional to the risks should always be in place to prevent exposure and to reduce the risk of accidental inoculation.

Activities involving diagnostic specimens suspected of containing a pathogen that do not involve propagating the pathogen (e.g. extraction of genetic material from clinical samples, fixation of tissue samples for histology) are regularly carried out in hospitals and public health laboratories. In most, but not all cases, the risks associated with this type of work are considered lower than propagation and *in vivo* work. Based on the risk associated with the pathogen suspected of being within the diagnostic sample and the testing activity, the physical and/or operational requirements for activities with diagnostic specimens may sometimes be lower than the requirements for handling pure cultures.

Although agencies assign containment levels for pathogens, the *Canadian Biosafety Standards and Guidelines* is performance based, which allows personnel to use LRAs to determine the mitigation strategies for their activities. In situations where it is suspected that a sample contains a pathogen from a risk group higher than the containment level of the testing facility, additional operational practices or shipment to a facility with an appropriate containment level may be required.

### **Autologous Cells, Tissue, and Specimens**

Experimentally infecting cells or other specimens derived from the person conducting the experiment put the individual at risk and is strictly prohibited. Personnel should not conduct these types of experiments in lab areas where they work and they should never donate or collect their own specimens/ tissues, or those of any other personnel, within the containment zone.

### **Non-Indigenous Animal Pathogens (Pathogens Causing Foreign Animal and Emerging Animal Disease)**

Non-indigenous animal pathogens are exotic to Canada (i.e. foreign animal disease agents that are not present in Canada). For ease of reference, example lists of non-indigenous animal pathogens and emerging disease pathogens, sorted by risk group, are available through the CFIA's **Automated Import Reference System**, which can be accessed here:

<http://www.inspection.gc.ca/plants/imports/airs/eng/1300127512994/1300127627409>.

Also see, CFIA's **Animal Disease Fact Sheets**: <http://www.inspection.gc.ca/animals/biohazard-containment-and-safety/pathogen-imports/disease-agents/eng/1312495508549/1312497560331> to determine what category your animal pathogen falls in.

### **Plant Pathogens and Pests**

In order for a plant pest to survive and spread in an environment, the following conditions must be met: 1) the pest must be able to find a suitable host; 2) susceptible materials (e.g. plant tissues) must be available; and 3) the environment must be conducive to the pest's establishment and development. Natural limitations to any one of the three factors and/or human intervention, such as chemical or biological controls can influence pest establishment or spread. Plant pests can be contained by spatial and temporal isolation from their hosts, either in the natural environment or in containment facilities.



In order to prevent the escape and the establishment of plant pests in the environment, the facilities that work with such pests and their operating procedures must be appropriate to the biology of the specific pests under consideration. Containment precautions must also be appropriate to the proposed type of work (e.g. containing pests *in vitro* (petri dishes) is easier than containing pest *in vivo* (on infected or infested plants)).

Facilities that handle plant pests should be constructed and operated to achieve the containment levels required for the pests concerned. The level required depends on risk of the plant pest escaping and becoming established in the environment and on the environmental, economic, agricultural, forestry, and trade consequences of such an introduction.

The containment requirements for a particular organism are frequently project-specific and are determined after assessing pest risk factors such as:

- The known presence or absence of the organisms in Canada;
- Its host range and local presence of potential hosts;
- The existence of, or the potential for, significant organism biotypes or strains that are exotic to an area;
- The history of the organisms in other new environmental
- The virulence or aggressiveness of the organisms;
- The availability of pest risk information;
- The nature of the proposed work (*in vitro*, *in vivo*, or large scale *in vivo*);
- The location, proximity of suitable hosts and time of year of the proposed work;
- The mode of transmission or spread (e.g. active flight, passive airborne, contact soil-borne, water-borne);
- Its potential rate of local and long-distance spread;
- The presence of vectors in Canada (e.g. arthropods, fungi, nematodes);
- The presence of vectors in or near the containment facility;
- The persistence of the organism in the environment and its potential for overwintering;
- Environmental requirements for establishment and spread;
- The potential capacity to control or eradicate the organisms that escapes;
- The potential for economic or environmental loss from the organisms;
- The economic and environmental significance of potential pest organisms and their host plants; and
- Biosecurity-related risks (e.g. the potential of theft and misuse).

Based on a review of the above items, regulatory scientists make risk management recommendations aimed at reducing the risk of organism escape and establishment in Canada. The risk model (**Figure 1**) demonstrates the general principle of requiring increased levels of containment with increasing risk of pest escape, establishment, and consequences.

**Figure 1 – Conceptual Risk Model for Determining Containment Level**

 Taken from the Canadian Food Inspection Agency of Canada, *Containment Standards for Facilities Handling Plant Pests*, First Edition

Likelihood of Escape and Establishment	High	PPC-1	PPC-2	PPC-3	PPC-3
	Med	PPC-1	PPC-1	PPC-2	PPC-3
	Low	BASIC	BASIC	PPC-1	PPC-2
	Very Low	No containment required	BASIC	PPC-1	PPC-1
		Very Low	Low	Medium	High
		Consequence			

CFIA does not have an exhaustive plant pathogen/pest list available; but typically if you require an importation permit to acquire the pest, it most likely is restricted in Canada. See the following CFIA's **Pests Regulated by Canada** database, to determine if your material requires an *Importation Permit* and Containment Lab certification prior to importing: <http://www.inspection.gc.ca/plants/plant-protection/pests/regulated-pests/eng/1363317115207/1363317187811>.

### Aquatic Animal Pathogens

As aquatic animal pathogen import permits are received, the CFIA assess the risks associated with the pathogen and determines the appropriate risk group level (i.e. RG1-RG4) of the aquatic animal pathogen. Risk assessment of a pathogen considers severity of the disease caused, routes of infection, virulence, and infectivity. The containment level is then determined based on the risk group level and then associated work to be done with the pathogen (see above Human and Animal Pathogen Risk Assessment). See the CFIA's **Containment Standards for Facilities Handling Aquatic Animal Pathogens**, which can be accessed here: <http://www.inspection.gc.ca/animals/aquatic-animals/imports/pathogens/facilities/eng/1377962925061/1377963021283>.

As with other similar CFIA containment standards published for terrestrial animal pathogens, human pathogens, and plant pests, risk group level lists are not provided in published format. If you require information on the classification of a particular aquatic animal pathogen, please do not hesitate to contact [importzoopath@inspection.gc.ca](mailto:importzoopath@inspection.gc.ca) for assistance.

### Large Scale Work

The PHAC and CFIA generally consider activities involving volumes of toxins or the *in vitro* culture of infectious material on a scale of 10 litres or greater to be large scale; this could be a single vessel with a volume of 10 litres or greater or multiple vessels with a total volume of 10 liters or greater. Other requirements and additional considerations will need to be determined on a case-by-case basis.

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## Biosecurity Risk Assessment

The preliminary step in developing a biosecurity plan is a biosecurity risk assessment. The complexity and detail of the plan should be consistent with the level of risk posed of the infectious material or toxins in questions.

The following elements are commonly included in a biosecurity risk assessment:

### 1. Identify and Prioritize Assets

Infectious material or toxins present within the facility should be identified with the location and state of the material noted. An evaluation should be considered to determine the potential for misuse of the infectious material or toxins and to prioritize the material based on the consequences of release. The consequences may include the number of people or animals that could become infected, intoxicated, or killed; the social, economic, and environmental impact; and the impact on research due to the loss of material. Specific threats associated with the possession of other assets may also affect the security of the infectious material or toxins within the facility. Assets that should also be identified and assessed include people, equipment, non-infectious materials, and animals. It is helpful to identify the individuals who have access to the asset when carrying out this portion of the assessment, as it will be useful for developing the biosecurity plan.

### 2. Define Threats

Individuals, organizations, or groups that may pose a threat to the infectious material or toxins present within the facility should be identified. Determination of the motive, means, and opportunity of these potential threats should be carefully considered. This includes the potential of internal threats such as disgruntled employees and animal rights activists.

### 3. Determine Risks and Mitigation Strategies

A list of potential biosecurity scenarios should be created based on the infectious material or toxins that are present, persons involved, and actions required (e.g. emergency response). The probability of each scenarios occurring and the associated consequences should be evaluated. Possible mitigation strategies for vulnerabilities identified in the scenarios should be identified and used when developing the biosecurity plan.

## Elements of a Biosecurity Plan

Once the initial biosecurity risk assessment is complete (above), a biosecurity plan tailored to the facility can be developed and implemented. Please see **Biosafety Program, Section 1, Appendix 3 – University of Regina Biosecurity Plan** to incorporate and implement this over-arching plan into your specialized Lab Biosafety Program. By integrating the elements of this U of R Biosecurity Plan within your Lab Biosafety Program, this will minimize the duplication and allow for a more efficient biosafety management system. If this Plan is not sufficient for your duties, please add additional procedures and activities and contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca).

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## Health and Medical Surveillance Assessment

The basic purpose of a medical surveillance program is to help prevent and detect illness related to the exposure of personnel to infectious material or toxins. The focus of this program is primarily preventative, although it also provides response mechanisms through which a potential infection can be identified and treated before serious injury or disease occurs.

The medical surveillance program, which is based on an overarching risk assessment and local risk assessments (LRAs), must be developed and implemented, and covered in the Laboratory Biosafety Manual. When changes are made to a laboratory program (e.g. change in the infectious materials or toxins used or the kinds of activities carried out), the medical surveillance program must be updated accordingly. It may be appropriate to involve an occupational health and safety professional or a local health care provider (e.g. physician, nurse) as well as emergency responders, in the process of developing the medical surveillance program.

### Laboratory Acquired Infections (LAI)

Individuals who work with infectious material in a laboratory are at risk of exposure to the material they handle and may develop LAIs. These infections, whether symptomatic or asymptomatic in nature, can be transmitted to others within or outside the laboratory setting. Although it may be difficult to determine the root cause in all cases, LAIs are not uncommon.

### Pre-Placement Medical Surveillance

A pre-placement medical surveillance may be conducted for new personnel prior to commencing activities with human pathogens, toxins, or zoonotic pathogens. The primary purpose of such surveillance is to assess the initial health status of the individual and identify if there are any underlying medical conditions that may increase the risk of harm associated with anticipated job activities.

The evaluation may include an interview with the institutional occupational health care provider and/or a personal medical history questionnaire to document the individuals' previous and current medical problems; current medications; known allergies to medications, animals, or environmental allergens; and prior immunizations. Personnel who are immuno-compromised (e.g. through radiation therapy or chemotherapy, pregnancy, diabetes, etc.) may be particularly susceptible to infections or experience more severe illness if they contracted an infection following exposure to a pathogen. A complete physical examination is rarely necessary as part of this process but may be appropriate.

Before commencing work, the individual should be informed of any preventative measures available against the infectious material or toxins, such as vaccinations and/or other treatments, along with the risks and benefits of these vaccinations and treatments. They should also be informed of the steps to follow in the event of potential exposure, including appropriate first aid measures, incident reporting, and medical treatments.

Personnel with a considerable risk of exposure to pathogens may be encouraged to provide a blood sample for serum testing and storage prior to the initiation of work with the pathogen.

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### **Vaccinations**

Vaccines are highly regulated, complex biological products designed to induce a protective immune response both effectively and safely. The availability of vaccines or other prophylaxis should be evaluated, and these should be offered to personnel, as required, prior to work commencing. Periodic testing of antibody titers may be conducted post-vaccination to determine if the required level of protective immunity has been achieved and if a booster vaccination is necessary. Should an individual decline or not respond immunologically to a vaccination that is deemed a pre-requisite for working in a containment zone, a re-evaluation of placement may be required.

### **Ongoing Medical Surveillance**

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

## Appendix 2 –University of Regina Biosafety and Biosecurity Hazard Identification & Mitigation Strategies Tool

### Instructions

This tool is designed to assist faculty, staff, and students in identifying potential hazards associated with research activities. Once hazards have been identified, mitigation strategies should be implemented to reduce the hazard risk. If you require assistance in assessing the safety hazards and risks associated with your research, please contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca).

Name:	
Date Assessment is Complete:	
Date Assessment is Reviewed/Updated:	

### Section 1 Non-Biological Hazard Identification and Management

Please indicate what non-biological hazards/factors apply to your project and how you will mitigate/manage these hazards:

Experimental Hazard	Mitigation Strategy
Training or directing the work of others	
Leaving the City of Regina for travel and/or fieldwork	
working alone during evenings and weekends?	
lifting or transferring heavy loads?	
handling, storing, or working near WHMIS controlled chemicals?	
work unsupervised with chemicals and equipment (e.g. gas cylinders) in a wet laboratory?	
receiving, shipping, and/or transporting chemicals, biological, radioisotopes and/or other dangerous goods?	
risk of fire,	
Potential for self-inoculations	

handling, using, or caring for live animals?	
Use of rotating equipment, power tools or pressurized equipment (i.e. gas cylinder, hydraulic press, table saw, drill press, hydrostatic (pump), equipment with stored energy (i.e. compressed springs, suspended loads), robotics	
handle or use radioisotopes, lasers, or x-ray equipment?	
Entry or working in confined spaces? A confined space is defined as any space not normally intended for human occupancy.	
working at heights greater than 3 meters, or using ladders?	
Exposed to extreme temperatures, noise, or vibration?	

## Section 2 Biological Material Classification/Identification

Does or will your laboratory group use, handle, manipulate, store, etc.:

- Bacteria
- Virus
- Fungi
- Protozoa
- Viral Vectors
- Recombinant DNA
- Toxin (see U of R Biosafety Program Appendix 6)
- Security Sensitive Biological Agents (<http://phac-aspc.gc.ca/lab-bio/regul/ssba-abcse-eng.php>)

- Biohazardous material handled in large volumes/ scale (>10L)
- Human Cells/ Culture
- Human Tissue/ Organs
- Human Blood or Body Fluids
- Animal Cells/Culture
- Animal Blood or Body Fluids
- Animals
- Prions
- Dual-Use Research

### Section 3 Biological Material Safety

#### Section 2a Risk Assessment

**Biological Material Name:** e.g. *Staphylococcus aureus*, *Microcystis sp*, mouse serum, human artery.

If material is from cell lines please include species and tissue origin (e.g. mouse mammary gland) and any additional known information (i.e. chemical, oncogene, etc.)

**Risk Group:** According to the American Biological Safety Association **Risk Group Database** (<http://www.absa.org/riskgroups/index.html>) and **Biosafety Program Appendix 6** for a guidance list. If unknown, indicate “unknown.”

**Host Ranges:** Is this material a suspected or actual human, animal, or plant pathogen?

**Hazard Classification Method:** The process used to determine the risk group of the material:

Method	Example
Supplier Information	Enter code “ <b>S</b> ” if a HELA cells were purchased from ATCC and listed in their catalogue as Risk Group II material
Other Researcher	Enter code “ <b>R</b> ” if a cell line was received from another researcher. Attach name and institution
Guides	Enter Guide name. Various guides by CDC or Public Health Agency of Canada list organisms in risk groups.
Internal Review	Enter code “ <b>I</b> ” if the researcher has completed their own internal review process using Public Health Agency of Canada’s <i>Canadian Biosafety Standards &amp; Guidelines</i> . Attach documentation
Needs to be Reviewed	Enter code “ <b>N</b> ” if the risk group needs to be determined in conjunction with the U of R BSO
Other	Enter code “ <b>O</b> ” and attach documentation



PHAC Pathogen Safety Data Sheets are available from the following web page: <http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php>

Please assess the risk of your biological material and complete the following table, using the above information as a guide.

Biological Material Name	Risk Group	Host Ranges	Hazard Classification Method	PHAC PSDS Available (y/n)

*\* Please attach additional pages if necessary*

### Section 3b Health and Medical Surveillance

Based on the material safety risk assessment completed above, does a Health and Medical Surveillance Program need to be implemented? (See **Biosafety Program Appendix 1**)

If **YES**, please attach your Laboratory Health & Medical Surveillance Plan to this application.

If **NO**, please indicate why below:

### Section 3c Biosecurity Risks

The University has a comprehensive Biosecurity Plan (available from BSO). Please review this Plan and determine if the Biosecurity Plan is sufficient for your proposed activities.

If **YES**, no further action is required.

If **NO**, indicate below what additional mitigation strategies are required to manage your additional biosecurity risks:

Biosecurity Risk	Examples	Additional Mitigation Strategies Required
Physical Security	Access by public, Visitors, Trades Personnel, Custodians, etc to containment zones and storage	

Personnel Suitability and Reliability	Employment pre-appointment screening and requirements	
Infectious Material and Toxin Accountability	Track and document infectious materials to identify missing items	
Incident and Emergency Response	Unauthorized entry, missing materials, etc.	
Information Security	To protect sensitive information from unauthorized access and ensure confidentiality	

\* Please attach additional pages if necessary

#### Section 4 Project Locations (Including Storage & Shared Equipment Rooms, etc.)

Please indicate where the project activities will be located; please include storage (e.g. fridges and freezer locations), shared equipment rooms (e.g. incubators, centrifuges, biological safety cabinets, etc.) inside and outside containment area, and if appropriate how security will be maintained:

Building	Room	Room Use (e.g. storage, manipulations, waste disposal, etc.)	Security Considerations

\* Please attach additional pages if necessary

#### Section 5 Biological Safety Cabinets & Other Primary Device Equipment

Please indicate what primary containment devices you need or are providing:

Make/ Model	Serial #	Class	Location	Certificate Date

Will you be providing funding for the maintenance and annual certification of equipment?

---

If you do **NOT** require primary containment devices, please indicate why not here:

Please attach appropriate equipment SOPs to this application. Please include operation, training requirements, preventative maintenance, emergency response, etc.

### **Section 6      Biological Waste Disposal**

Please indicate biological material waste disposal methods your research program will require:

- Autoclave & Landfill (see **Section 6a**)
- Incineration & Waste Services (see **Section 6b**)

### **Section 6a      Autoclave Specific Requirements**

What type of autoclave cycle, quality control testing methods, and autoclave equipment/accessories are required for your research waste? Will you require additional tests or autoclave cycle options? See UR Autoclave Manual or contact Autoclave Technician for assistance in completing this section.

### **Section 6b      Incineration & Waste Services Requirements**

What type of waste will require incineration and what kind of waste disposal containers will you require? *i.e.* animal, human, microbiological, sharps containers, broken glass, etc. See UR Autoclave Manual or contact BSO for assistance in completing this section.

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**Section 6      Decontamination**

What type of chemical disinfectant is appropriate for your research materials and how often will the disinfectant be made? e.g. 1/10 dilution of fresh bleach daily, 70% ethanol, Virex256, etc.

## Appendix 3 - Assessed Biological Material Risk Group Guidance List

Compiled from the Public Health Agency of Canada's (PHAC) *Human Pathogens and Toxins Act*, 2009 and the Saskatchewan Ministry of Advanced Education, Employment and Labour (AEEL).

### Toxins (Schedule 1 - Human Pathogens and Toxins Act)

Aerolysin	Enterococcal Shiga-like toxin 1 (EAST)
Alpha toxin	Exfoliative toxin (also called Exfoliatin)
<b>Anthrax toxins:</b>	Exotoxin A
Lethal Toxin and Oedema Toxin	Hemolysin
<i>Bordetella pertussis</i> Adenylate cyclase toxin	Listeriolysin O
Botulinum neurotoxin	<i>Pasteurella multocida</i> toxin
Cholera toxin	Perfringolysin O
<i>Clostridium botulinum</i> C2 and C3 toxins	Pertussis toxin
<i>Clostridium difficile</i> toxins A and B	Pneumolysin
<i>Clostridium perfringens</i> Epsilon toxin	Pyrogenic exotoxin
Dermonecrotic toxin	Shiga-like toxin (verotoxin)
Diphtheria toxin	Shigatoxin
<b><i>Escherichia coli</i> toxins:</b>	Staphylococcal enterotoxins
<i>E. coli</i> Cytotoxic Necrotizing Factor (CNF)	<i>Staphylococcus aureus</i> Toxic shock syndrome toxin
Heat-labile <i>E. coli</i> enterotoxin (LT)	Streptolysin O
Heat-stable <i>E. coli</i> enterotoxin (ST)	Tetanolysin
Cytolethal distending toxin (CLDT)	Tetanospasmin (Tetanus toxin)

### Risk Group 2 (Schedule 2 - Human Pathogens and Toxins Act)

#### Bacteria

<i>Actinobacillus pleuropneumoniae</i>	<i>Clostridium perfringens</i>
<i>Actinobacillus ureae</i>	<i>Clostridium tetani</i>
<i>Actinomyces israelii</i>	<i>Corynebacterium diphtheriae</i>
<i>Aerococcus ureinae</i>	<i>Enterococcus faecium</i>
<i>Aeromonas hydrophila</i>	<i>Escherichia coli</i>
<i>Aggregatibacter actinomycetemcomitans</i>	<i>Francisella novicida</i>
<i>Arcanobacterium bernardiae</i>	<i>Haemophilus influenzae</i>
<i>Bordetella bronchiseptica</i>	<i>Haemophilus parainfluenzae</i>
<i>Bordetella parapertussis</i>	<i>Helicobacter pylori</i>
<i>Bordetella pertussis</i>	<i>Klebsiella pneumoniae</i>
<i>Borrelia burgdorferi</i>	<i>Legionella pneumophila</i>
<i>Campylobacter jejuni</i>	<i>Leptospira interrogans</i>
<i>Chlamydia trachomatis</i>	<i>Listeria monocytogenes</i>
<i>Chlamydophila pneumoniae</i>	<i>Moraxella catarrhalis</i>
<i>Citrobacter freundii</i>	<i>Mycobacterium avium</i>
<i>Clostridium botulinum</i>	<i>Mycobacterium leprae</i>
<i>Clostridium difficile</i>	<i>Mycobacterium smegmatis</i>
<i>Mycoplasma genitalium</i>	<i>Mycoplasma pneumoniae</i>

**Bacteria (continued)**

*Neisseria gonorrhoeae*  
*Neisseria meningitidis*  
*Pasteurella multocida*  
*Porphyromonas gingivalis*  
*Proteus mirabilis*  
*Proteus vulgaris*  
*Pseudomonas aeruginosa*  
*Salmonella*  
*Serratia marcescens*  
*Shigella dysenteriae*

*Shigella sonnei*  
*Sphingobacterium faecium*  
*Staphylococcus aureus*  
*Staphylococcus saprophyticus*  
*Streptococcus agalactiae*  
*Streptococcus pyogenes*  
*Streptococcus salivarius*  
*Treponema pallidum*  
*Ureaplasma urealyticum*  
*Vibrio cholerae*  
*Yersinia pseudotuberculosis*

**Viruses**

Adenovirus  
 Avian influenza virus  
 (excluding highly pathogenic strains)  
 Colorado tick fever viruses  
 Cowpox virus  
 Cocksackievirus  
 Epstein Barr virus  
 Hepatitis A virus  
 Hepatitis B virus  
 Hepatitis C virus  
 Hepatitis D virus  
 Hepatitis E virus  
 Herpes simplex viruses  
 Human coronavirus (excluding SARS-CoV)  
 Human herpesvirus 5 (cytomegalovirus)  
 Human herpesvirus 6 (roseolovirus)  
 Human herpesvirus 8  
 (Kaposi's sarcoma-associated herpesvirus)

Human parvovirus  
 Human rotavirus  
 Influenza virus, types A-C  
 (excluding Type A 1918 Spanish Flu and H2N2 strains)  
 Measles virus  
*Molluscum contagiosum* virus  
 Mumps virus  
 Newcastle disease virus  
 Norwalk virus  
 Papillomaviruses  
 Parainfluenza virus (types 1-4)  
 Reoviruses  
 Respiratory syncytial virus  
 Rhinovirus  
 Semliki Forest virus  
 Sendai virus  
 Simian virus 40  
 Vaccinia virus

**Fungi**

*Aspergillus fumigates*  
*Aspergillus niger*  
*Aspergillus oryzae*  
*Candida albicans*  
*Cryptococcus neoformans*  
*Microsporium audouinii*

*Microsporium ferrugineum*  
*Sporothrix schenkii*  
*Trichophyton concentricum*  
*Trichophyton rubrum*  
*Trichophyton schoenleinii*  
*Trichophyton tonsurans*

**Protozoa**

*Acanthamoeba castellanii*  
*Giardia lamblia* (**AEEL**)  
*Leishmania aethiopica*  
*Leishmania braziliensis*  
*Leishmania chagasi*  
*Leishmania donovani*  
*Leishmania guyanensis*  
*Leishmania infantum*

*Leishmania panamensis*  
*Plasmodium falciparum*  
*Toxoplasma gondii*  
 (**AEEL** - where work involves routine handling of or exposure to the excreta or materials contaminated with the excreta, of carrier animal species)  
*Trypanosoma brucei gambiense*  
*Trypanosoma brucei rhodiense*  
*Trypanosoma cruzi*

**Prions**

Chronic wasting disease agent

**Parasites**

*Echinococcus* (AEEL- gravid segments)

**Risk Group 3 (Schedule 3- Human Pathogens and Toxins Act)****Bacteria**

*Bacillus anthracis*

*Brucella abortus*

*Brucella canis*

*Brucella melitensis*

*Brucella ovis*

*Brucella suis*

*Burkholderia mallei*

*Burkholderia pseudomallei*

*Chlamydia psittaci*

*Coxiella burnetii*

*Francisella tularensis*

*Mycobacterium africanum*

*Mycobacterium avium* (AEEL)

*Mycobacterium bovis*

*Mycobacterium canettii*

*Mycobacterium microti*

*Mycobacterium tuberculosis*

*Neorickettsia sennetsu*

*Pasteurella multocida* (AEEL)

*Pseudomonas mallei* (AEEL)

*Rickettsia akari*

*Rickettsia australis*

*Rickettsia conorii*

*Rickettsia japonicum*

*Rickettsia prowazekii*

*Rickettsia rickettsii*

*Rickettsia siberica*

*Rickettsia typhi*

*Yersinia pseudotuberculosis* (AEEL)

*Yersinia pestis*

**Viruses**

African Horse Sickness virus

Água Preta virus

Akabane virus

Allpahuayo virus

Andes virus

Araguari virus

Batken virus

Bayou virus

Bear Canyon virus

Bermejo virus

Bhanja virus

Bijou Bridge virus

Black Creek Canal virus

Cabassou virus

Cano Delgadito virus

Chikungunya virus

Dhori virus

Dobrava-Belgrade virus

Douglas virus

Dugbe virus

Duvenhage virus

Eastern equine encephalitis virus

Enseada virus

Maporal virus

Mapuera virus

Mayaro virus

Mobala virus

Monkeypox virus

Monongahela virus

Mopeia virus

Mucambo virus

Murray Valley encephalitis virus

Negishi virus

New York virus

Ngari virus

Oliveros virus

O'Nyong-nyong virus

Oran virus

Oropouche virus

Pergamino virus

Piritral virus

Piry virus

Powassan virus

Puumala virus

Rabies virus

Rift Valley fever virus

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Everglades virus	Rocio virus
Flexal virus	Saaremaa virus
Garissa virus	Sakpa virus
Germiston virus	SARS coronavirus (SARS-CoV)
Hantaan virus	Seoul virus
Herpesvirus ateles	Sin nombre virus
Herpesvirus saimiri	Slovakia virus
Highly pathogenic avian influenza virus	Somone virus
Human immunodeficiency virus	Sripur virus
Human T-cell lymphotropic virus	St. Louis encephalitis virus
Influenza A H2N2	Thogoto virus
Israel Turkey meningoencephalitis virus	Tonate virus
Issyk-Kul virus	Topografov virus
Japanese encephalitis virus	Venezuelan equine encephalitis virus
Juquitiba virus	Vesicular stomatitis virus
Khabarovsk virus	Wesselsbron virus
Koutango virus	Western equine encephalitis virus
Kunjin virus	West Nile fever virus
Laguna Negra virus	Whitewater Arroyo virus
Lechiguanas virus	Xingu virus
Louping ill virus	Yellow fever virus
Lymphocytic choriomeningitis virus	

**Fungi**

*Blastomyces dermatitidis*  
*Cladophialophora bantiana*  
*Coccidioides immitis*  
*Coccidioides posadasii*  
*Histoplasma capsulatum*  
*Paracoccidioides brasiliensis*  
*Penicillium marneffeii*

**Prions**

Bovine spongiform encephalopathy agent and other related animal transmissible spongiform encephalopathies agents  
Creutzfeldt-Jakob disease agent  
Fatal Familial Insomnia agent  
Gerstmann-Sträussler-Scheinker syndrome agent  
Kuru agent  
Variant Creutzfeldt-Jakob disease agent

**Risk Group 4 (Schedule 4- Human Pathogens and Toxins Act)****Viruses**

Absettarov virus  
Alkhumra virus  
Crimean Congo haemorrhagic fever virus  
Ebola virus  
Guanarito virus  
Hanzalova virus  
Hendra virus  
Herpes B virus



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Hypr virus  
Junin virus  
Kumlinge virus  
Kyasanur Forest virus  
Lassa fever virus  
Machupo virus  
Marburg virus  
Nipah virus  
Omsk haemorrhagic fever virus  
Russian spring-summer encephalitis virus

**Prohibited Human Pathogens and Toxins (Schedule 5 - Human Pathogens and Toxins Act)**

Variola virus

**Plant Pests**

See <http://www.inspection.gc.ca/plants/plant-protection/pests/regulated-pests/eng/1363317115207/1363317187811#p> for a list of the pests regulated under the authority of the Canadian Food Inspection Agency *Plant Protection Act*.

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## Appendix 4 – Biological Laboratory Containment Level Classification

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Containment level refers to the minimum physical/infrastructure containment and operational practices required for a *containment zone* handling infectious materials, toxins, or plants safety in laboratory and animal work environments. A containment zone could be a single room (e.g. laboratory), a series of co-located rooms (e.g. several non-adjointing but lockable CL2 lab work areas), or it can be comprised of several adjoining rooms of the same containment level.

### Human and/or Animal Pathogens

The following factors are considered when determining the specific physical and operational requirements for handling a human and/or animal pathogen:

- **Aerosol Generation** – Are equipment or procedures that may generate aerosols being used (e.g. pipetting, centrifugation, homogenization)? Personnel can be exposed to infectious aerosols by direct inhalation of aerosolized droplets or by ingestion of droplets that settle on surfaces or hands.
- **Quantity** – What quantity of pathogen is being manipulated, and in what format (e.g. one large vessel, multiple vessels)? Large scale processes (e.g. industrial fermentation, vaccine product) may have different containment requirements than laboratory work using the same pathogen.
- **Concentration the Pathogen** – The concentration of the pathogen may vary depending on the work being performed (e.g. diagnostic specimens may contain a lower concentration of pathogen than pure cultures).
- **Type of Proposed Work** – What is the nature of the work (e.g. *in vitro*, *in vivo*, large scale)? For example, for *in vivo* work, the type of animal and the inherent risks associated with that animal need to be considered when determine the appropriate containment level.
- **Shedding (Specific to Animals)** – The shedding of pathogens should be considered when working with infected animals. Pathogens may be present in the saliva, urine, feces, and may also be exhaled by the animal.

### Human or Animal Pathogen or Toxin Containment Level Categories

#### Containment Level 1

Containment Level 1 (CL1) is a basic laboratory with features that provide the foundation for all containment laboratories. Biosafety is primary achieved through a basic level of operational practices (i.e. good microbiological lab practices) and physical design features (e.g. well-designed laboratory).

Some of the key physical and operational biosafety elements are:

- Well-designed and functional space;
- Cleanable work surfaces;
- Use good microbiological practices;
- Conduct local risk-assessments on activities to identify risks, and to develop safe work practices;
- Provide training;
- Use PPE appropriate to work being done;

- Keep laboratory and animal work areas clean;
- Maintain an effective rodent and insect control program;
- Employ proper animal work practices; and
- Decontaminate work surfaces appropriately, in accordance with biological material in use.

### **Containment Level 2**

Containment Level 2 (CL2) builds upon the basic laboratory foundation established for CL1. Biosafety and biosecurity at CL2 are achieved through operational practices and a core subset of physical containment requirements that are proportional to the risks associated with the agents handled therein.

See **Biosafety Program, Research & Teaching, Appendix 9** for a detailed **Containment Level 2 Lab Safety Commissioning Physical and Operational** requirement checklist. Additional operational practices and physical containment requirements can be applied proportionally to handle agents that may require extra care in handling/use. See **Biosafety Program, Research & Teaching, Appendix 10** for further detail

### **Containment Level 3**

Biosafety and biosecurity at Containment Level 3 (CL3) are achieved through comprehensive operational practices and physical containment requirements. CL3 requires stringent facility design and engineering controls (e.g. inward directional airflow, HEPA filtration of exhaust air), as well as specialized biosafety equipment (e.g. BSCs, centrifuges with sealed rotors), to minimize the release of infectious agents into the surrounding lab work area, animal rooms/cubicles, and the environment. CL3 requires a high level of operational practices that build on those required at CL2 (e.g. PPE use, work practices). Presently, the University of Regina does not have the infrastructure for certified-CL3 laboratories. If you require the use of CL3 laboratories, contact the BSO.

### **Containment Level 4**

Containment Level 4 (CL4) is the highest level of containment available. CL4 requires a highly complex facility design (i.e. isolated unit that is functionally, and when necessary, structurally independent of all other areas), a maximum engineering controls (e.g. HEPA filtration of exhaust and supply air), specialized biosafety equipment (e.g., BSC, effluent treatment systems), and redundant biosafety features (e.g., two stage HEPA filtration of exhaust air). CL4 requires the maximum level of operational practices that build on those required at CL3 (e.g. PPE use, work practices, medical surveillance). CL4 zone necessitate the use do positive-pressure suits for personnel or, as an alternative, use of a Class III BSC. At minimum, Class II BSCs are located within a certified CL3 lab for work with RG4 pathogens, in consultation with PHAC and CFIA. Presently, the University of Regina does not have the infrastructure for certified- CL4 laboratories. To date the only CL4 lab in Canada is the National Microbiology Laboratory (NML) in Winnipeg, MB. If you require the use of CL4 laboratories, contact the BSO.

### **Plant Pest/ Pathogens**

See <http://www.inspection.gc.ca/plants/plant-protection/pests/regulated-pests/eng/1363317115207/1363317187811#p> for a list of the pests regulated under the authority of the Canadian Food Inspection Agency *Plant Protection Act*.

### **Plant Pest/Pathogen Containment Levels Categories**

Regardless of the containment Levels (CL) of the facility, physical attributes of the facility and the operational procedures must be suitable for containing the pests under consideration and should be tailored to that purpose.

The concept of biological containment is usually applied to work done in buildings, growth chambers, or greenhouses which have, or present, physical barriers to prevent the escape of pests. It does not apply to soil, genetically modified plants, or biological control insects.

On request, the Canadian Food Inspection Agency (CFIA) will review your project intent to determine the required Plant Pest Containment Level and provide recommendations on how to attain the desired level. See: <http://www.inspection.gc.ca/plants/plant-protection/biocontainment/form-a-pp/eng/1392510539063/1392510598721> or contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for more information.

To aid in the development of your standard operating procedures for a PPC-2, PPC-2A, PPC-3, and PP-3A facilities, see the CFIA **Biosafety Manual Requirements Checklist for Facilities Handling Plant Pests**: <http://www.inspection.gc.ca/plants/plant-protection/biocontainment/biosafety-manual-requirements-checklist/eng/1359696391388/1363630455327>

### **Basic Containment**

Basic Containment (BC) is the lowest containment level for plant pests and it provides simple, but adequate, barriers to pest escape. Facilities may consist of field plots, basic labs, or simple glass, plastic, screen houses which may have dirt or gravel flows and unscreened vents.

BC is applicable for work with low to very low plant pests for scientific, research, educational, processing, industrial, or exhibition purposes. The following are examples of the type of work that could be appropriately conducted in BC: 1) establishing a field plot using plants infected with a virus that can only be transmitted by grafting; 2) using lyophilized virus-infected plant tissue as a control in an ELISA test; or 3) using plant tissues infected with a common strain of tobacco mosaic virus to inoculate tobacco plants for a high school biology project.

Containment of plant pests is achieved through:

- Sanitation;
- Spatial isolation from susceptible hosts;
- Physical security;
- Signage;
- Destruction of waste;
- Destruction of all viable pests at the end of the experiment or the testing period.

### **Plant Pest Containment Level 1**

Plant Pest Containment Level 1 (PPC-1) is the next highest containment level for plant pests. Examples include 1) inoculating host plants with isolated plum pox or other plant virus in the absence of the vectors of those virus; 2) importing low-risk tropical insects into butterfly houses for study, display or rearing; 3)

studying and rearing nematodes of quarantine concern in Canada that have low spread potential (e.g. *Globodera rostochiensis* and *Ditylenchus destructor*).

Facilities include permanent structures such as labs, greenhouses, and screenhouses. Windows that can be opened must be fitted with appropriate screens, and greenhouses must be fully screened and caulked to both contain and exclude arthropods. An autoclave must be available to treat waste and waste water must be treated to kill pests where appropriate.

See the CFIA **Plant Pest Containment Level 1 Self-Assessment Checklist** here:

<http://www.inspection.gc.ca/plants/plant-protection/biocontainment/self-assessment-checklist/eng/1359612120660/1359612242816> to help you evaluate the physical and operational components of your facility.

### **Plant Pest Containment Level 2**

Plant Pest Containment Level 2 (PPC-2) facilities include permanent structures such as labs and greenhouses but not screenhouses. Containment is achieved through facility design, operational procedures, and use of specialized equipment. All PPC-1 physical and operational requirements also apply to this CL. Examples include 1) conducting plant inoculations with an isolate of *Ralstonia solanacearum* Biovar 2, Race 3 (the causal agent of potato brown rot disease; 2) morphological examination and DNA extraction of sporangia of *Synchytrium endobioticum* (the causal agent of Potato Wart) and their use as diagnostic controls; 3) rearing the arthropod pest *Anophlophora glabripennis* (the Asian long-horned beetle); 4) conducting plant inoculations with specific races of corn pathogen *Helminthosporium turcicu*.

#### **Key Operational Practices include:**

- Using if primary containment devices;
- Use of dedicated or disposal laboratory clothing;
- Appropriate decontamination of solid and liquid waste;
- Pest monitoring and regular inspections of screens, filters, and caulking for defects;
- Clear documentation of standard operating procedures (SOPs);
- Mandatory personnel training; and
- The availability of suitable emergency response plans.

#### **Key Physical Practices include:**

- Restricted access via an anteroom;
- An on-site autoclave; and
- Greenhouse that are mechanically ventilated with screened or filtered inlet and exhaust air.

#### **Key Physical Practices for PPC-2 Arthropod (PPC-2A) Facilities include:**

- Sealing or screening all penetration into the work area;
- Inward directional airflow; and
- Access via dedicated anteroom.

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See the CFIA **Plant Pest Containment Level 2 Self-Assessment Checklist** here:

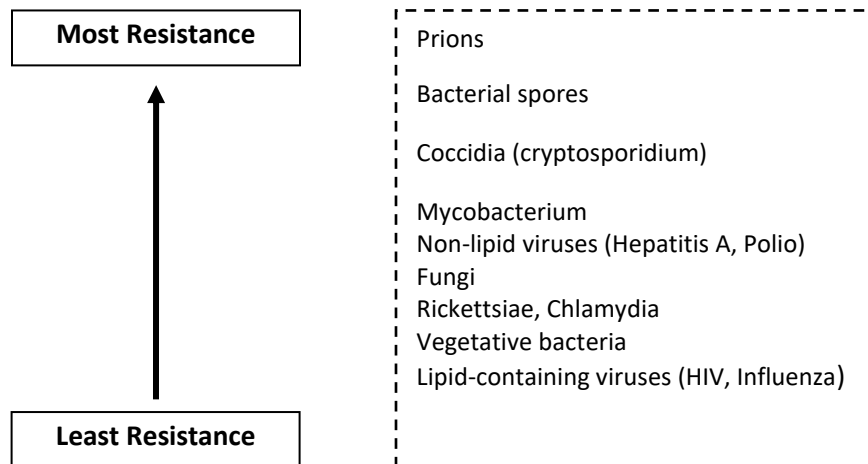
<http://www.inspection.gc.ca/plants/plant-protection/biocontainment/plant-pest-containment-level-2/eng/1359694755601/1359694733741> to help you evaluate the physical and operational components of your facility.

### **Aquatic Animal Pathogens**

See <http://www.inspection.gc.ca/animals/aquatic-animals/imports/pathogens/facilities/eng/1377962925061/1377963021283> and the **U of R Biosafety Program, Section 2** for more information.

## Appendix 5 – Disinfectants

Many disinfectants can be harmful to humans or the environment; therefore, they should be selected, stored, handled, used and disposed of with care, following manufacturers' instructions. For personal safety, appropriate personal protective equipment (gloves, laboratory coats, closed-foot shoes, and eye protection) is recommended when preparing dilutions of the disinfectant.



\* Figure modified from University of Saskatchewan's Biosafety Manual, 2006

## Comparison of Common Chemical Disinfectants

**Legend:** ✓ Effective    ● Variable    X Not Effective

### Chlorine (sodium hypochlorite; household bleach)

General Info/ Used For	Effective Against	Directions for Use
<ul style="list-style-type: none"> <li>Usually sold as household bleach (e.g. Clorox)</li> <li>Fast-acting oxidant</li> <li>General all-purpose disinfectant: <u>1 g/l available chlorine</u> concentration (WHO, 2004)</li> <li>Cleaning biohazardous spills and in the presence of large amounts of organic matter: <u>5 g/l available chlorine</u> concentration</li> <li>Highly alkaline and can be corrosive to metal</li> </ul>	<ul style="list-style-type: none"> <li>Vegetative Bacteria ✓</li> <li>Lipid Viruses ✓</li> <li>Nonlipid Viruses ✓</li> <li>Mycobacteria ✓</li> <li>Fungi ✓</li> <li>Bacterial Spores ●</li> </ul>	<ul style="list-style-type: none"> <li>Chlorine gas is toxic, so bleach must be stored and used in well-ventilated areas</li> <li>Bleach must not be mixed with acids or other chemicals to prevent the release of harmful chlorine by-products</li> <li>Activity is reduced by organic matter and a freshly (daily-weekly) made dilution is required</li> <li>Household bleach contains approximately 50 g/l available chlorine so should be diluted 1:50 or 1:10 (to obtain a working concentration of 1 g/l and 5 g/l, respectively)</li> </ul>

**Alcohol (ethanol, isopropanol)**

General Info/ Used For	Effective Against	Directions for Use												
<ul style="list-style-type: none"> <li>Does not leave residue on items</li> <li>70 % (v/v) of ethanol can be used on skin, lab work surfaces, and to soak small pieces of surgical instruments</li> <li>Alcohol-based hand rubs can be used for the decontamination of lightly soiled hands where hand washing is not possible or inconvenient</li> </ul>	<table border="0"> <tr><td>Vegetative Bacteria</td><td>✓</td></tr> <tr><td>Lipid Viruses</td><td>✓</td></tr> <tr><td>Nonlipid Viruses</td><td>○</td></tr> <tr><td>Mycobacteria</td><td>✓</td></tr> <tr><td>Fungi</td><td>✓</td></tr> <tr><td>Bacterial Spores</td><td>X</td></tr> </table>	Vegetative Bacteria	✓	Lipid Viruses	✓	Nonlipid Viruses	○	Mycobacteria	✓	Fungi	✓	Bacterial Spores	X	<ul style="list-style-type: none"> <li>Highest effectiveness is used at ~70% (v/v) in water</li> <li>Alcohols are volatile and flammable and must not be used near open flames</li> <li>Alcohol will evaporate so alcohols need to be properly stored</li> <li>Alcohol may harden rubber and some glue types</li> <li>Mixtures with other agents (formaldehyde (100 g/l), chlorine (2 g/l)) are more effective than alcohol alone</li> </ul>
Vegetative Bacteria	✓													
Lipid Viruses	✓													
Nonlipid Viruses	○													
Mycobacteria	✓													
Fungi	✓													
Bacterial Spores	X													

**Phenolic compounds (Triclosan and chloroxylenol)**

General Info/ Used For	Effective Against	Directions for Use												
<ul style="list-style-type: none"> <li>Safe for skin and mucous membranes</li> <li>Safety concerns: In lab studies, bacteria show resistance to certain types of antibiotics</li> <li>Used for the decontamination of environmental surfaces and some are among the more commonly used antiseptics (e.g. triclosan and chloroxylenol)</li> <li>Triclosan is common in hand-washing products</li> <li>Not recommended for use of food contact surfaces and in areas with young children</li> </ul>	<table border="0"> <tr><td>Vegetative Bacteria</td><td>✓</td></tr> <tr><td>Lipid Viruses</td><td>✓</td></tr> <tr><td>Nonlipid Viruses</td><td>○</td></tr> <tr><td>Mycobacteria</td><td>○</td></tr> <tr><td>Fungi</td><td>○</td></tr> <tr><td>Bacterial Spores</td><td>X</td></tr> </table>	Vegetative Bacteria	✓	Lipid Viruses	✓	Nonlipid Viruses	○	Mycobacteria	○	Fungi	○	Bacterial Spores	X	<ul style="list-style-type: none"> <li>Some phenolic compounds could be inactivated by water hardness and therefore must be diluted with distilled or deionized water</li> <li>May be absorbed by rubber</li> </ul>
Vegetative Bacteria	✓													
Lipid Viruses	✓													
Nonlipid Viruses	○													
Mycobacteria	○													
Fungi	○													
Bacterial Spores	X													

**Quaternary ammonium compounds (benzalkonium chloride; Lysol)**

General Info/ Used For	Effective Against	Directions for Use												
<ul style="list-style-type: none"> <li>Often used as mixtures in combination with other germicides, such as alcohols</li> <li>Low biodegradability- may accumulate in the environment</li> <li>Benzalkonium chloride is used as an antiseptic</li> </ul>	<table border="0"> <tr><td>Vegetative Bacteria</td><td>✓</td></tr> <tr><td>Lipid Viruses</td><td>✓</td></tr> <tr><td>Nonlipid Viruses</td><td>○</td></tr> <tr><td>Mycobacteria</td><td>X</td></tr> <tr><td>Fungi</td><td>○</td></tr> <tr><td>Bacterial Spores</td><td>X</td></tr> </table>	Vegetative Bacteria	✓	Lipid Viruses	✓	Nonlipid Viruses	○	Mycobacteria	X	Fungi	○	Bacterial Spores	X	<ul style="list-style-type: none"> <li>Germicidal activity reduced by organic matter, water hardness, and anionic detergents (soaps)</li> <li>Potentially harmful bacteria can grow in quaternary ammonium compound solutions</li> </ul>
Vegetative Bacteria	✓													
Lipid Viruses	✓													
Nonlipid Viruses	○													
Mycobacteria	X													
Fungi	○													
Bacterial Spores	X													



### Hydrogen peroxide and peroxy acid (peracids)

General Info/ Used For	Effective Against	Directions for Use
<ul style="list-style-type: none"> <li>• Like chlorine, hydrogen peroxide and peracids are strong oxidants</li> <li>• Safer to humans and the environment</li> <li>• Hydrogen peroxide can be corrosive to metals such as aluminum, copper, brass and zinc</li> <li>• Can decolourize fabrics, hair, skin, and mucous membranes</li> <li>• Potent broad-spectrum germicide</li> <li>• Hydrogen peroxide can be used for the decontamination of work surfaces</li> </ul>	<ul style="list-style-type: none"> <li>Vegetative Bacteria ✓</li> <li>Lipid Viruses ✓</li> <li>Nonlipid Viruses ✓</li> <li>Mycobacteria ✓</li> <li>Fungi ✓</li> <li>Bacterial Spores ✓</li> </ul>	<ul style="list-style-type: none"> <li>• Hydrogen peroxide is supplied as a ready-to-use 3% or as an aqueous 30% solution that needs to be diluted 5-10 times its volume with sterilized water</li> <li>• Articles treated must be thoroughly rinsed</li> <li>• Should be stored away from heat and protected from light</li> <li>• 3-6% solutions are relatively slow and limited</li> <li>• Stronger concentrations may be suitable for disinfecting heat-sensitive devices</li> </ul>

### Formaldehyde

General Info/ Used For	Effective Against	Directions for Use
<ul style="list-style-type: none"> <li>• A gas which is slow-acting and needs a humidity level of ~70%</li> <li>• A suspected carcinogen and is a dangerous, irritating gas with a strong smell</li> <li>• Decontamination &amp; disinfection</li> </ul>	<ul style="list-style-type: none"> <li>Vegetative Bacteria ✓</li> <li>Lipid Viruses ✓</li> <li>Nonlipid Viruses ✓</li> <li>Mycobacteria ✓</li> <li>Fungi ✓</li> <li>Bacterial Spores ✓</li> </ul>	<ul style="list-style-type: none"> <li>• Supplied as paraformaldehyde or formalin which is heated to liberate the gas</li> <li>• Must be stored and used in a fume-hood or well-ventilated area</li> <li>• Chemical safety regulations must be followed</li> <li>• May be used as a liquid disinfectant</li> </ul>

### Glutaraldehyde

General Info/ Used For	Effective Against	Directions for Use
<ul style="list-style-type: none"> <li>• Non-corrosive</li> <li>• Fast-acting but takes several hours to kill bacterial spores</li> <li>• Supplied as a solution with a concentration of 20 g/l (2%)</li> <li>• Toxic and an irritant so contact must be avoided</li> <li>• Not recommended as a spray or solution for the decontamination of environmental surfaces</li> </ul>	<ul style="list-style-type: none"> <li>Vegetative Bacteria ✓</li> <li>Lipid Viruses ✓</li> <li>Nonlipid Viruses ✓</li> <li>Mycobacteria ✓</li> <li>Fungi ✓</li> <li>Bacterial Spores ✓</li> </ul>	<ul style="list-style-type: none"> <li>• Activated solution (by addition of a bicarbonate compound supplied with the product) can be reused for 1-4 weeks depending on the type and frequency of use</li> <li>• Should be discarded if it becomes turbid</li> <li>• Must be used in a fume-hood or well-ventilated area</li> <li>• Chemical safety regulations must be followed</li> <li>• Some products may need to be activated before use</li> </ul>

## Iodine and Iodophors

General Info/ Used For	Effective Against		Directions for Use
<ul style="list-style-type: none"> <li>• Iodine can stain fabrics and environmental surfaces</li> <li>• Iodine can be toxic</li> <li>• Iodine is generally unsuitable for use for lab disinfectant</li> <li>• Iodophors are good antiseptics</li> <li>• Action similar to chlorine, but slightly less inhibited by organic matter</li> </ul>	Vegetative Bacteria Lipid Viruses Nonlipid Viruses Mycobacteria Fungi Bacterial Spores	✓ ✓ ✓ ○ ○ ○	<ul style="list-style-type: none"> <li>• Action similar to chlorine, but slightly less inhibited by organic matter</li> <li>• Iodine should not be used on aluminum or copper</li> <li>• Organic iodine-based products must be stored at 4-10C to avoid the growth of potentially harmful bacteria</li> <li>• Polyvidone-iodine is a reliable and safe surgical scrub and preoperative skin antiseptic</li> </ul>

\* Data compiled from numerous sources including the World Health Organization's *Laboratory biosafety guidelines*, 2004, University of Saskatchewan's *Biosafety Manual*, 2006, and Arizona State's *Biosafety Manual*, 2010.

## Appendix 6 – Personal Protective Equipment

### Gloves

- Gloves reduce the possibility that personnel will become exposed to infectious substances and contract infectious diseases.
- Gloves should always be worn when touching blood, body fluids, fecal matter, saliva, contaminated objects, pathogens, toxins, microorganisms, animal droppings, and wild animals. When in doubt, wear a pair of gloves.
- When gloves are required, disposable, single-use gloves should be worn.
- No glove can provide protection against all hazards, so the gloves selected must be appropriate for the duty/activity they are used for. Gloves available for protection against biologically hazardous materials or organisms are latex, nitrile, vinyl, or rubber.

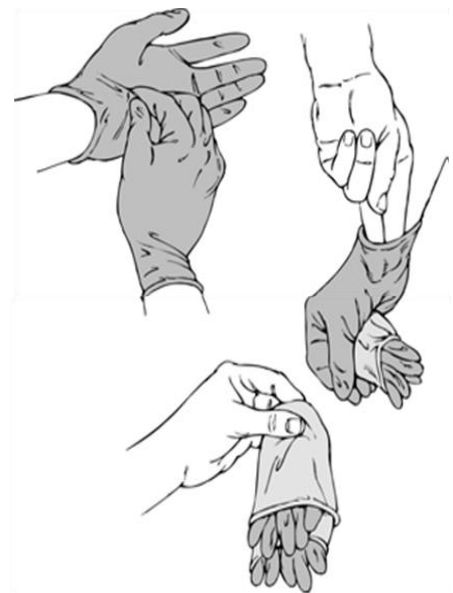
Along with the increasing usage of latex gloves, there have been increasing reports of irritations or allergic reactions to latex, including some severe, immediate reactions. If you detect a reaction to latex, notify your supervisor immediately.

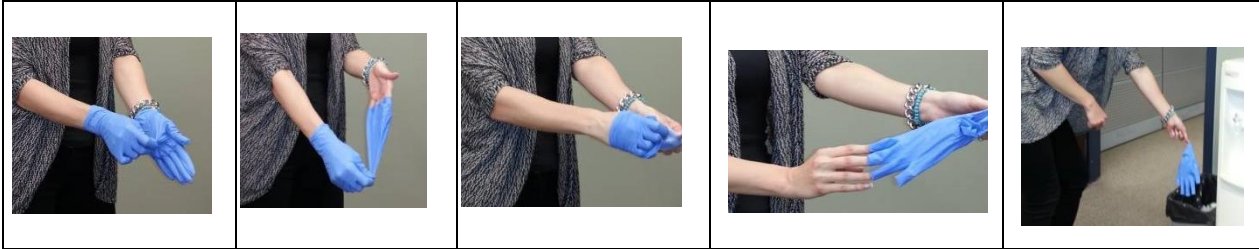
### Steps for Putting on Gloves

1. Place hand through opening of first glove and pull the glove up to the wrist.
2. Repeat with second glove.
3. Adjust gloves to cover wrists or cuffs of gown. Caution: Do not touch any part of your body with gloved hands.
4. Complete duty.

### Steps for Removing Gloves

1. Grasp one glove on the inside of wrist at ½ inch below band of dirty side of glove without touching the skin.
2. Pull down glove, turning it inside out, and pull hand out. Hold the glove with the still-gloved hand.
3. Insert fingers of ungloved hand under the cuff of the glove on the other hand (on inside of cuff).
4. Pull down glove until it is inside out, drawing it over the first glove.
5. Discard both gloves by dropping them in appropriate trash container.
6. Wash hands well.

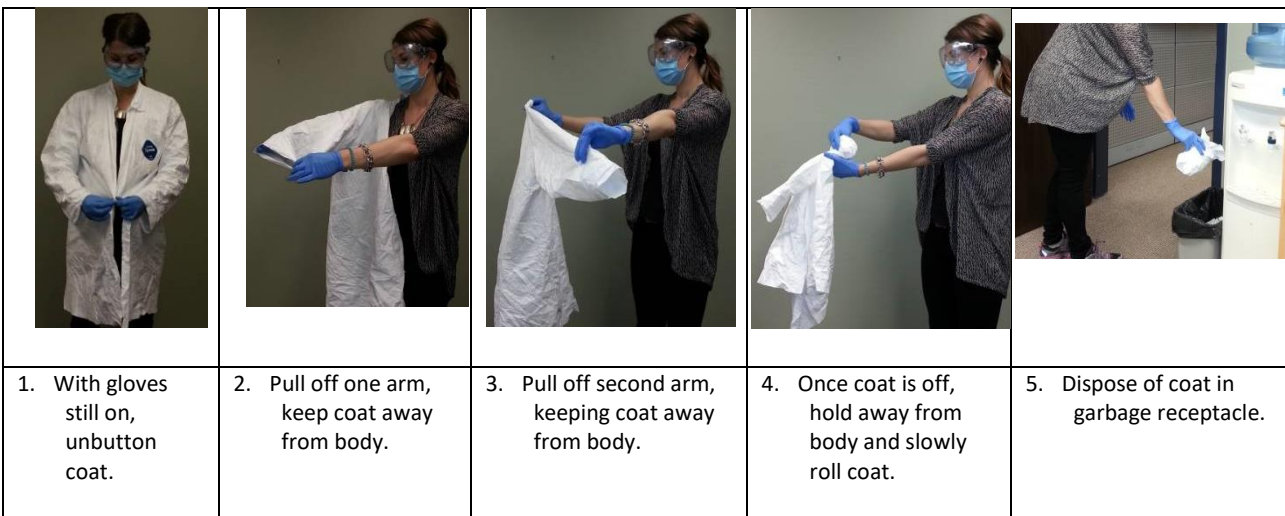




### Laboratory Coats, Gowns, Coveralls, and Aprons

- U of R employee uniforms/clothing are not considered appropriate PPE.
- Lab coats, gowns, coveralls, and aprons are used to prevent skin and clothing from being splashed or soiled with biologically hazardous substances.
- If the protective clothing is disposable, these must be properly disposed of in a plastic-lined garbage receptacle after use and before leaving area of use. If the protective clothing is non-disposable and soiled, the coat must be laundered.

### Steps for Removing Laboratory Coat:



### Protective and Personal Clothing Decontamination

All contaminated personal clothing items and non-disposable gowns, coveralls, and coats should be properly decontaminated to reduce risk of transmission and exposure. The risk of disease transmission from soiled linen is low, but soiled linens may carry organisms that may contaminate the air and immediate environment. It is recommended that decontamination via the University Laundry Service (Science Stores) be performed every 6 months, but this will vary with the type and intensity of research activity.





1. Do not walk into public areas with contaminated clothing.
2. Promptly don the appropriate PPE for removing contaminated clothing (i.e. gloves).
3. If soiled clothing cleaning and disinfecting procedures cannot be completed in the room that the clothing was soiled, the items must be removed and transported in strong biohazard/plastic bags.
4. Soiled clothing should be handled as little as possible and with minimum agitation.

5. Hold the soiled clothing away from your unsoiled clothing.
6. Bring the soiled clothing sealed in strong biohazard/plastic bag down to Science Stores for Laundry Servicing.

### Face and Eye Protection

- Face and eye protection must be worn whenever there is potential for the generation of splashes, spray, splatter, or droplets of biologically hazardous substances in the face, especially eyes, nose and mouth.
- Eye protection may be provided by safety glasses, goggles, or chin length face shields. Nose and mouth protection may be provided by surgical masks and face shields. Some face shields may provide protection against impact injuries.
- Surgical masks may protect the mucous membranes of the mouth and nose against sprays, splashes and droplets, but do not offer protection from infectious aerosols.

### Steps for Removing Mask:

			
<p>1. Without touching face, grasp mask strap behind one ear with a clean hand.</p>	<p>2. Pull mask to the front and away from the face, taking care not to touch the outer surface of the mask.</p>	<p>3. Keep pulling mask around to the other side of face until the last ear strap comes away from head.</p>	<p>4. Dispose of mask in the garbage receptacle.</p>

### Respiratory Protection

- Respirators offer levels of protection against different contaminants by varying their aerosol filter or cartridge efficiency (95, 99, & 99.7%).
- National Institute of Safety and Health (NIOSH)-approved masks and respirators for airborne protection against infectious aerosols are the N95, N99 or N100 rated respirators.
- All respirator wearers must be properly Fit Tested before they can use a respirator! If the respirator does not fit properly on the user's face, it will not offer any protection against infectious aerosols.
- Please contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for more information.

## Appendix 7 - Guidelines for Biological Safety Cabinet Use

Biological safety cabinets (BSCs) are vented cabinets which use a variety of combinations of high-efficiency particulate air (HEPA) filtration, laminar air flow, and containment to provide protection to personnel, laboratory materials, or the environment. They differ from chemical fume hoods due to the presence of HEPA filters and the laminar flow of air. BSCs must not be used as chemical fume hoods.

The World Health Organization's (WHO) *Laboratory Biosafety Manual*, 2004, states that HEPA filters trap 99.97% of particles 0.3 µm in diameter and 99.99% of particles of greater size, so the use of biological safety ensures that microbe free exhaust air is discharged from the cabinet.

### Choice of Cabinets

A variety of types of cabinets exist, and the cabinet chosen must be suited to the work proposed:

- **Clean Air Bench (Laminar Flow Hood)** – These benches are used for product protection only, and do not protect the worker from aerosols or particulates from the work. HEPA-filtered air flows towards the worker. This is not a biological safety cabinet and should not be used as such.
- **Class I** – Laminar air flow is directed away from the user and through a HEPA filter. These cabinets provide partial protection to the user and protection of the environment, but do not protect the product. Class I cabinets are suitable for some work procedures at Containment Level 1 and 2.
- **Class II** – These cabinets provide protection to the worker, the work and the environment. There are different variations of Class II cabinets allowing for specialized purposes.

e.g. **Class II type A1** – The air drawn into the cabinet is passed through a HEPA filter before flowing downwards towards the work surface. Additionally, the downward air captures the aerosol particles generated at the work surface, thereby providing the highest level of product protection.

- **Class III** – These cabinets provide the highest level of personal protection and are typically used in Containment Level 4 facilities. Supply air is filtered through two HEPA filters and the cabinet interior is kept under negative pressure. Access to the work area is through heavy duty rubber gloves.

The following table provided by the WHO's *Laboratory Biosafety Manual*, 2004, summarizes the selection of a BSC by type of protection needed:

Type of Protection	Biological Safety Cabinet Selection
Personnel protection, biological substances in Risk Groups 1-3	Class I, Class II, Class III
Personnel protection, biological substances in Risk Group 1, glovebox laboratory	Class III
Personnel protection, biological substances in Risk Group 4, suit	Class I, Class II
Product protection	Class II, Class III only if laminar flow
Volatile radionuclide/chemical protection, small amounts	Class IIB1, Class IIA2 vented to the
Volatile radionuclide/chemical protection	Class I, Class IIB2, Class III

## Location of Cabinets

The following factors should be taken into account when locating BSCs:

- The correct location of the cabinet will improve the efficiency of its operation. The cabinet should be located away from doors, windows, air supply registers and main traffic areas in the lab – air currents can disrupt the laminar flow characteristics inside the cabinet.
- Allow at least 30 cm of space on either side and behind the cabinet.
- A minimum of 40 cm should be available between the top exhaust filter and the ceiling to allow access for certification.
- Do not locate a cabinet directly under or adjacent to the room air supply.

## Personal Protective Equipment

Personal protective equipment should be worn whenever using a BSC:

- Laboratory coats
- Gloves pulled over the wrists of the coat rather than worn inside; double-gloves should be considered
- Masks and safety glasses may be required for some procedures

## Use of Cabinets

If BSCs are not used properly, their protective benefits may be greatly reduced. The following rules must be considered and followed when using a biological safety cabinet:

### 1) Before Using the Cabinet

- Allow the blower to run at least five minutes.
- Turn off UV lamp; turn on fluorescent lamp.
- The number of movements across the front opening should be minimized by placing all necessary items into the cabinet prior to beginning manipulations.
- Do not block or cover the front intake grille with paper, equipment or other items.
- Disinfect work surfaces.
- Materials to be placed inside cabinet should be disinfected with 70% alcohol (WHO, 2004).
- All materials should be placed as far back in the cabinet as practical without blocking the rear grille.
- Aerosol generating equipment (e.g. mixers, centrifuges) should be placed towards the rear of the cabinet.
- Bulky items such biohazard bags and discard pipette containers should be placed inside and to one side of the interior cabinet.

### 2) Using the Cabinet

- Operators' arms should be moved in and out of the cabinet slowly, perpendicular to the front opening.
- Manipulations of materials within the cabinets should be delayed for about 1 minute after placing hands and arms inside.
- Do not use gas burners inside a Class II Biological Safety Cabinet – the flame will disrupt the laminar air flow.
- When a spill of biologically hazardous material occurs with a cabinet, cleanup should begin immediately, while the cabinet continues to operate.



### 3) After Completing Work

- Leave blower on at least five minutes.
- All items within the cabinet, including equipment, should be surface-decontaminated and removed.
- Decontaminate the cabinet with a disinfectant that will kill any microorganism that might be found inside the cabinet.
- Turn off the blower and fluorescent lamp; turn on UV lamp.

#### Ultraviolet Lights Inside of Cabinets

If UV lights are used to decontaminate the work surfaces inside a cabinet, the following points must be taken into consideration:

- The 253.7 $\mu\text{m}$  wavelength has limited penetrating power and is only effective against microbes in the air or on the work surface.
- The intensity of the lamp, and therefore, the ability of the lamp to sterilize, decreases with time.
- The intensity of the radiation decreases as the square of the distance of the lamp; therefore, exposure time required is related to the distance from the lamp.
- The lamp must be cleaned regularly.
- The UV light reflects off the cabinet surfaces and is a risk to persons working in or near the hood. Never operate the lamp if a worker is near the hood.

The use of UV light for the purpose of decontamination is only allowed as a secondary means of decontamination. **UV light is NOT sufficient on it's own** and must be pair with other decontamination methods such as 70% ethanol.

#### Spills Inside a Biological Safety Cabinet

When a spill of biologically hazardous material occurs within a cabinet, cleanup should begin immediately, while the cabinet continues to operate. An effective disinfectant should be used and applied in a manner that minimizes the generation of aerosols. All items that come into contact with the spilled agent should be disinfected and/or autoclaved.

#### Small Non-Hazardous Biological Spill

(Spills that you are comfortable cleaning up)

1. All persons should inform other personnel in the affected area not to enter.
2. Review the MSDS and PSDS, to determine the protective equipment, spill cleanup, and disposal protocols that are necessary for all chemicals and biological materials involved.
3. Wear gloves, laboratory coat, shoes, pants, and other appropriate personal protective equipment (i.e. face and eye protection).
4. Cover the spill with cloth or paper towels to contain it.
5. Spray or pour an appropriate disinfectant over the paper towels and the immediate surrounding area (according to the specific biological PSDS; generally, 10% bleach or 70% ethanol solutions are appropriate).
6. Start applying the disinfectant from the outside and move inwards.
7. After the appropriate amount of time (5-10 minutes), clear away any materials like broken glass using forceps or another mechanical device and place in a sharps container/biohazard container.
8. Clean and disinfect the spillage area using paper towels and other appropriate cleaning materials.



9. Place contaminated materials into a labelled, leak-proof, puncture-resistant waste disposal container and dispose of waste appropriately. Contact Health & Safety (306-585-4776) for waste disposal assistance.
10. Complete an **Incident Report Form** and forward to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca).

### Large Non-Hazardous Biological Spill

(Spills you are not comfortable cleaning up by yourself)

1. All persons should inform other personnel in the affected area not to enter.
2. Review the MSDS and PSDS, to determine the protective equipment, spill cleanup, and disposal protocols that are necessary for all chemicals and biological materials involved.
3. The Laboratory Supervisor and UR Hazardous Material Spill Response Team (via Protective Services (306-585) 4999) should be informed for cleanup assistance.

### Small Hazardous Biological Spill

(Spills you are comfortable cleaning up)

1. All persons should immediately leave the affected area and allow aerosols to settle (~30 minutes).
2. Signs should be posted indicating that entry into area is forbidden. Post a sign stating “DO NOT ENTER, BIOHAZARD SPILL. Contact (name and phone #) for information.”
3. Any exposed person should seek **medical assistance immediately** (within **1-2 hours**) from a health care professional.
4. The Laboratory Supervisor, Health & Safety (306-585-4776), or a “Spill Buddy” should be informed for cleanup assistance.
5. Wear gloves, laboratory coat, shoes, pants, and eye/face protection.
6. Cover the spill with cloth or paper towels to contain it.
7. Spray or pour an appropriate disinfectant over the paper towels and the immediate surrounding area (according to the specific biological PSDS; generally, 10% bleach solutions are appropriate).
8. Start applying the disinfectant from the outside and move inwards.
9. After the appropriate amount of time (see PSDS), clear away any materials like broken glass using forceps or another mechanical device and place in a sharps container/biohazard container.
10. Clean and disinfect the spillage area using paper towels and other appropriate cleaning materials.
11. Place contaminated cleaning materials into a labelled, leak-proof, puncture-resistant waste disposal container and dispose of waste appropriately. Contact Health & Safety (306-585-4776) for waste disposal assistance.
12. Complete an **Incident Report Form** and forward to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca).

### Large Hazardous Biological Spill

(Spills you are not comfortable cleaning up)

1. All persons should immediately leave the affected area and allow aerosols to settle (~30 minutes).
2. Signs should be posted indicating that entry into area is forbidden; post a sign stating “DO NOT ENTER, BIOHAZARD SPILL. Contact (name and phone #) for information.”
3. Any exposed person should seek **medical assistance immediately** (within **1-2 hours**) from a health care professional.
4. The Laboratory Supervisor and UR Hazardous Material Spill Response Team (via Protective Services (306-585) 4999) should be informed for cleanup assistance.
5. Supervised decontamination should proceed.

### Potentially Hazardous Aerosol Release

1. All persons should immediately leave the affected area and no one should enter the room for an appropriate amount of time (e.g. 30 minutes), to allow for aerosols to be carried away and heavier particles to settle. If the laboratory does not have a central air exhaust system, entry should be delayed (e.g. for 24 hours).
2. Signs should be posted indicating that entry is forbidden. Post a sign stating “DO NOT ENTER, BIOHAZARD SPILL. Contact (name and phone #) for information.”
3. Any exposed person should seek medical assistance immediately (within 1-2 hours) from a health care professional.
4. The Laboratory Supervisor and UR Hazardous Material Spill Response Team (contacted via Protective Services (306-585) 4999) should be informed for cleanup assistance.
5. After the appropriate amount of time (~30 minutes – 24 hours), supervised decontamination should proceed.

**Always contact Health & Safety (306-585-4776) prior to wearing a respirator for the first time. You MUST be fit-tested.**

### Spilled Hazardous Substances and Broken Containers

1. All persons should immediately leave the affected area.
2. Any exposed person should seek medical assistance immediately (within 1-2 hours) from a health care professional.
3. Determine if you are comfortable cleaning up the spill or require some assistance. Follow the above directions.

#### Additional Considerations:

1. Broken containers contaminated with infectious substances and spilled infectious substances should be covered with a cloth or paper towels. Care must be taken to avoid splashing or generating aerosols during the clean-up.
2. Glass fragments should be handled with forceps or another mechanical device and placed in a sharps container/biohazard container. NEVER with your hand.
3. If dustpans are used to clear away the broken material, they should be autoclaved or placed in an effective disinfectant for 30 minutes.
4. If laboratory forms or other printed or written material are contaminated, the information should be copied onto another form and the original discarded into the contaminated-waste container.

### Operation and Maintenance of Cabinets

- BSCs must be certified annually to CSA standards by a qualified technician
- All repairs made on biological safety cabinets must be made by a qualified technician
- Any malfunction in the operation of a cabinet should be reported to the Biosafety Officer and repaired before the cabinet is to be used again
- The biological safety cabinet must be decontaminated before filter changes and before being moved
- Biological safety cabinets can be equipped with one of two kinds of alarms:
  - **Sash alarms** are found only on cabinets with sliding sashes. This alarm signifies that the operator has moved the sash to an improper position. Corrective action for this type of alarm is returning the sash to the proper position.

- 
- **Airflow alarms** indicate a disruption in the cabinet's normal airflow pattern. This alarm represents an immediate danger to the operator or product and when an airflow alarm sounds, work should cease immediately and the Laboratory Supervisor is notified.

### **Training**

Training is absolutely required prior to using a BSC. Not only will this minimize the risk of personnel being exposed to biologically hazardous substances but is also essential for ensuring that the product is not contaminated. Training will also help minimize the risk of damage to the equipment. This guideline is one tool to assist in training. You must receive training specific to the BSC you will be using.

Training will help promote:

- safety,
- research quality, and
- optimal use and care of equipment.

All PIs, LIs, Lab Managers, and Supervisors should ensure that their staff and students receive adequate training. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for more information.

## Appendix 8 - Biological Waste Disposal Procedures

### Human Waste Disposal

#### Human Blood & Body Fluids

##### Autoclave\*

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items should be mixed with liquid waste.
3. Place waste in an autoclavable container.
4. Inactivate waste by autoclave. Inactivated waste can be treated as decontaminated and can be slowly poured down sewer with plenty of water.

\*Items that cannot be autoclaved: oil; waxes; materials containing solvents, >3% chlorinated compounds (i.e. HCl, bleach), corrosive chemicals (i.e. phenol, ether, chloroform), flammable materials, radioisotopes.

Plastic Type	Autoclave Compatible?	Number on Plastic
PETE or PET – Polyethylene Terephthalate	no	1
HDPE – High-density polyethylene	no	2
PVC or Vinyl – Polyvinyl Chloride	no	3
LDPE – Low-density polyethylene	no	4
<b>PP - Polypropylene</b>	<b>yes</b>	<b>5</b>
PS - Polystyrene	no	6
<b>PC - Polycarbonate</b>	<b>yes</b>	<b>7</b>
PE - Polyethylene	no	-
<b>PMP - Polymethylpentene</b>	<b>yes</b>	-
<b>PTFE Resin</b>	<b>yes</b>	-

##### Chemically Inactivate

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. Inactivate waste by fresh 10% bleach. Allow waste to sit for 30 minutes.
3. Inactivated waste can be treated as decontaminated and can be slowly poured down sewer with plenty of water.

##### Third-Party Disposal

1. If waste cannot go in autoclave or be mixed with bleach, waste can be collected and disposed of by third-party.
2. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
3. No other items (i.e. solid) should be mixed with liquid waste.
4. Place waste in properly labeled, leak-proof waste container (available from Science Stores). Fill container no more than 75% full.
5. Put chemical waste label on container - label all chemicals and biologicals.
6. Disinfect outside of waste container with 70% ethanol.
7. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

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### Human Tissues, Solids, and Items Saturated with Blood and Body Fluids

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids) should be mixed with solid waste.
3. Place waste in a red biohazard pail available from Science Stores. Fill container no more than 75% full.
4. Put chemical waste label on container - label all chemicals and biologicals.
5. Disinfect outside of waste container with 70% ethanol.
6. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

### Sharps Contaminated with Human Materials (i.e. Needles, razor blade, scalpels, etc.)

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids, solids) should be mixed with sharps waste.
3. Place waste in a biohazard sharps waste container available from Science Stores. Fill container no more than 75% full.
4. If applicable, put on chemical waste label and label all chemicals.
5. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

### Broken Glass Contaminated with Human Materials

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids, solids, needled, intact glass) should be mixed with broken glass waste.
3. Place waste in a white "broken glass" waste container available from Science Stores. Fill container no more than 75% full.
4. If applicable, put on chemical waste label and label all chemicals.
5. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

## Animal Waste Disposal

All animal materials ***must*** be incinerated to abide by Provincial and Municipal regulations.

### Animal Blood & Body Fluids

#### Autoclave\*

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items should be mixed with liquid waste.
3. Place waste in an autoclavable container.
4. Inactivate waste by autoclave. Inactivated waste can be treated as decontaminated and can be slowly poured down sewer with plenty of water.

\*Items that cannot be autoclaved: oil; waxes; materials containing solvents, >3% chlorinated compounds (i.e. HCl, bleach), corrosive chemicals (i.e. phenol, ether, chloroform), flammable materials, radioisotopes.

Plastic Type	Autoclave Compatible?	Number on Plastic
PETE or PET – Polyethylene Terephthalate	no	1
HDPE – High-density polyethylene	no	2
PVC or Vinyl – Polyvinyl Chloride	no	3
LDPE – Low-density polyethylene	no	4
<b>PP - Polypropylene</b>	<b>yes</b>	<b>5</b>
PS - Polystyrene	no	6
<b>PC - Polycarbonate</b>	<b>yes</b>	<b>7</b>
PE - Polyethylene	no	-
<b>PMP - Polymethylpentene</b>	<b>yes</b>	-
<b>PTFE Resin</b>	<b>yes</b>	-

#### Chemically Inactivate

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. Inactivate waste by fresh 10% bleach. Allow waste to sit for 30 minutes.
3. Inactivated waste can be treated as decontaminated and can be slowly poured down sewer with plenty of water.

#### Third-Party Disposal

1. If waste cannot go in autoclave or be mixed with bleach, waste can be collected and disposed of by third-party.
2. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
3. No other items (i.e. solid) should be mixed with liquid waste.
4. Place waste in properly labeled, leak-proof waste container (available from Science Stores). Fill container no more than 75% full.
5. Put chemical waste label on container - label all chemicals and biologicals.
6. Disinfect outside of waste container with 70% ethanol.
7. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

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**Animal Tissues, Carcasses, Solids, and Items Saturated with Blood and Body Fluids**

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids) should be mixed with solid waste.
3. Place waste in a red biohazard pail available from Science Stores. Fill container no more than 75% full.
4. Put chemical waste label on container - label all chemicals and biologicals.
5. Disinfect outside of waste container with 70% ethanol.
6. Store container in a secure fridge or freezer until waste disposal.
7. Disposals are only coordinated based on need. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

**Animal Husbandry** (e.g. bedding, waste feed, litter, etc.)

1. Waste that is not contaminated with radioactivity, chemicals, or biologically hazardous substances can be directly disposed of into a regular garbage bin.
2. Double-bag materials.

**Sharps Contaminated with Animal Materials** (i.e. needles, razor blade, scalpels, etc.)

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids, solids) should be mixed with sharps waste.
3. Place waste in a biohazard sharps waste container available from Science Stores. Fill container no more than 75% full.
4. If applicable, put on chemical waste label and label all chemicals.
5. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

**Broken Glass Contaminated with Animal Materials**

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids, solids, needled, intact glass) should be mixed with broken glass waste.
3. Place waste in a white “broken glass” waste container available from Science Stores. Fill container no more than 75% full.
4. If applicable, put on chemical waste label and label all chemicals.
5. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

## Microbiological Laboratory Waste Disposal (Risk Group 1 and 2)

### Liquids

#### Autoclave\*

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items should be mixed with liquid waste.
3. Place waste in an autoclavable container.
4. Inactivate waste by autoclave. Inactivated waste can be treated as decontaminated and can be slowly poured down sewer with plenty of water.

\*Items that cannot be autoclaved: oil; waxes; materials containing solvents, >3% chlorinated compounds (i.e. HCl, bleach), corrosive chemicals (i.e. phenol, ether, chloroform), flammable materials, radioisotopes.

Plastic Type	Autoclave Compatible?	Number on Plastic
PETE or PET – Polyethylene Terephthalate	no	1
HDPE – High-density polyethylene	no	2
PVC or Vinyl – Polyvinyl Chloride	no	3
LDPE – Low-density polyethylene	no	4
<b>PP - Polypropylene</b>	<b>yes</b>	<b>5</b>
PS - Polystyrene	no	6
<b>PC - Polycarbonate</b>	<b>yes</b>	<b>7</b>
PE - Polyethylene	no	-
<b>PMP - Polymethylpentene</b>	<b>yes</b>	-
<b>PTFE Resin</b>	<b>yes</b>	-

#### Chemically Inactivate

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. Inactivate waste by fresh 10% bleach. Allow waste to sit for 30 minutes.
3. Inactivated waste can be treated as decontaminated and can be slowly poured down sewer with plenty of water.

#### Third-Party Disposal

1. If waste cannot go in autoclave or be mixed with bleach, waste can be collected and disposed of by third-party.
2. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
3. No other items (i.e. solid) should be mixed with liquid waste.
4. Place waste in properly labeled, leak-proof waste container (available from Science Stores). Fill container no more than 75% full.
5. Put chemical waste label on container - label all chemicals and biologicals.
6. Disinfect outside of waste container with 70% ethanol.
7. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.



### Solids and Items Saturated with Microorganisms

(e.g. laboratory cultures, weigh boats, gloves, paper towels, absorbent pads, bench top covers, plastic products (tubes, flasks, petri dishes), etc.

#### Autoclave\*

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items should be mixed with liquid waste.
3. Place waste in an autoclave/ biohazard bag.
4. Inactivate waste by autoclave. Inactivated waste can be treated as decontaminated and can be disposed of in regular garbage. Deface biohazard symbols before placing in garbage (if applicable).
5. Only place autoclaved waste in autoclave room garbage receptacles.

\*Items that cannot be autoclaved: oil; waxes; materials containing solvents, >3% chlorinated compounds (i.e. HCl, bleach), corrosive chemicals (i.e. phenol, ether, chloroform), flammable materials, radioisotopes.

Plastic Type	Autoclave Compatible?	Number on Plastic
PETE or PET – Polyethylene Terephthalate	no	1
HDPE – High-density polyethylene	no	2
PVC or Vinyl – Polyvinyl Chloride	no	3
LDPE – Low-density polyethylene	no	4
<b>PP - Polypropylene</b>	<b>yes</b>	<b>5</b>
PS - Polystyrene	no	6
<b>PC - Polycarbonate</b>	<b>yes</b>	<b>7</b>
PE - Polyethylene	no	-
<b>PMP - Polymethylpentene</b>	<b>yes</b>	-
<b>PTFE Resin</b>	<b>yes</b>	-

#### Third-Party Disposal

1. If waste cannot go in autoclave, be mixed with bleach, or is higher-risk (i.e. lentivirus) waste can be collected and disposed of by third-party.
2. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
3. No other items (i.e. solid) should be mixed with liquid waste.
4. Place waste in properly labeled red waste container (available from Science Stores). Fill container no more than 75% full.
5. Put chemical waste label on container - label all chemicals and biologicals.
6. Disinfect outside of waste container with 70% ethanol.
7. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

#### Sharps Contaminated with Biological Materials (i.e. needles, razor blade, scalpels, etc.)

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids, solids) should be mixed with sharps waste.
3. Place waste in a biohazard sharps waste container available from Science Stores. Fill container no more than 75% full.
4. If applicable, put on chemical waste label and label all chemicals.
5. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

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**Broken Glass Contaminated with Biological Materials**

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids, solids, needled, intact glass) should be mixed with broken glass waste.
3. Place waste in a white “broken glass” waste container available from Science Stores. Fill container no more than 75% full.
4. If applicable, put on chemical waste label and label all chemicals.
5. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

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## Appendix 9 - Ordering and Receiving Biological Materials

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Principle Investigators (PIs), Lab Managers, and Supervisors may order any permitted biological material from any supplier and/or institution, if the requirements, outlined below, for ordering and receiving biological substances are followed.

### Materials Transfer Agreements (MTA) Signing Authorization Policy

MTAs for Risk Group 1 and/or Risk Group 2 biological materials can affect the ownership and dissemination of research results. The *Delegation of Authority, Senior Executive Policy* (GOV-010-010; <http://www.uregina.ca/policy/browse-policy/policy-GOV-010-010.html>) governs this, so MTA's **must be signed by the Vice President (Research) or designate**.

Please contact Ara Steininger by email: [Ara.Steininger@uregina.ca](mailto:Ara.Steininger@uregina.ca) or phone: 337-3238 for assistance.

### Ordering Biological Materials

Importation of hazardous and non-hazardous **plants, plant-products**, plant-pests, **animals**, animal by-products, and **soil** require obtaining a **Canadian Food Inspection Agency (CFIA) Importation Permit** prior to ordering (see **Appendix 21**). Importation of human and/or animal pathogens (Risk Group 2 and above) and toxins require obtaining a Public Health Agency of Canada (PHAC) *Importation Permit* prior to ordering (see **Appendix 21**).

To ensure no delays at Customs or receiving on campus, please contact the BSO at [health.safety@uregina.ca](mailto:health.safety@uregina.ca) as soon as possible before ordering.

### Risk Group 1

Biological substances can be ordered by PIs and research personnel, through the University Science Stores.

The delivery address on the Purchase Order/Requisition Order/Importation **must be**:

[Academic Staff Member Name]  
c/o Science Stores, Research and Innovation Centre 110  
University of Regina  
3737 Wascana Parkway  
Regina SK S4S 0A2

### Risk Group 2

Biologically hazardous substances (Risk Group 2) may only be ordered and received by authorized personnel through Science Stores, unless written approval from the Biosafety Committee (BSC) has been provided. Prior to any order being placed, **Biologically Hazardous Agent Transfer Notification Form (Appendix 20)** must be sent to [health.safety@uregina.ca](mailto:health.safety@uregina.ca). Biologically hazardous substances can **only** be ordered through the University Science Stores.

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The delivery address on the Purchase Order/Requisition Order/Importation **must** be:

[Academic Staff Member Name]  
c/o Science Stores, Research and Innovation Centre 110  
University of Regina  
3737 Wascana Parkway  
Regina SK S4S 0A2

### **Receiving Biological Substances**

Biological materials (Risk Group 1 & Risk Group 2) can **only** be received through the **University Science Stores** by TDG-trained personnel. Do not sign for and receive materials in your lab or office space. HSE personnel are available to receive packages for you, at any time.

### **Risk Group 2**

Packages must only be opened and verified by the PI, or designate, in a PHAC- and/or CFIA- certified CL2 Lab after being received by Science Stores. The PI will keep the packing slip with other receipt documents and the BSO will update the University's Biological Inventory.

## Appendix 10 - Human/ Primary Specimen Guidelines

Human/primary/clinical specimen or sample is defined as all tissue and body fluid specimens obtained from a human patient or donor. This includes cell cultures and unprocessed waste derived from human tissue or body fluid specimens.

### 1) Laboratory Containment and Training

First and foremost, a hazard identification and risk assessment should be conducted for each project to determine what containment level lab and training is required. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) to start the process.

### 2) Health and Medical Surveillance

U of R researchers are to treat all human specimens as containing infectious pathogens regardless of the source or case history (Universal Precautions).

Anyone handling human specimens should be immunologically protected against appropriate pathogens (see **Table 1** below). Research personnel may formally decline immunization. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for more information.

**Table 1**

<b>Recommended immunizations for U of R lab faculty and staff working with human/ primary specimens</b>	
<b>Vaccine</b>	<b>Recommendation(s)</b>
<b>Diphtheria Tetanus</b>	All Researchers or lab staff should be immune. Primary series if no previous immunization. Booster doses of Td vaccine every 10 years. <i>(Available as Td or Tdap or Tdap-IPV. Tdap is indicated if an adult pertussis dose is needed. Tdap-IPV is indicated if both pertussis and polio vaccinations are needed.)</i>
<b>Hepatitis A &amp; B</b>	If no evidence of immunity. <i>(Post-immunization serologic testing within 1 to 6 months of completion of primary series.)</i>
<b>Measles</b>	If no evidence of immunity, regardless of age - 2 doses.
<b>Mumps</b>	If no evidence of immunity, regardless of age - 2 doses.
<b>Pertussis</b>	A single dose of Tdap vaccine if not previously received in adulthood.
<b>Polio</b>	Primary series if no previous immunization – 3 doses. Unvaccinated Researchers and Lab staff at highest risk of exposure should be particularly targeted for primary immunization. A single lifetime booster dose for Researchers and Lab staff at highest risk of exposure.
<b>Rubella</b>	If no evidence of immunity – 1 dose.
<b>Varicella</b>	If no evidence of immunity - 2 doses. <i>(Self-reported history of varicella or herpes zoster is not reliable for a Researcher or Lab staff to be considered immune.)</i>

Research personnel working with human specimens shall self-monitor their health and should not conduct work with these materials if their immune system is compromised either due to illness or immunosuppressive medications. Personnel who are uncertain about an illness or medication should consult with their family physician prior to resuming work. When discussing health issues with medical personnel, research personnel shall make it clear they work in a biomedical laboratory and identify what biohazardous materials they handle.

People who have had surgical or cosmetic procedures (including, but not limited to tattoos and piercings) or physical injuries (i.e., cuts, abrasions, burns, etc.) involving significant alteration to the normal integrity of the skin shall not handle human specimens until healed. This is especially important where the area involved is the face, head, neck, hands, or arms. Personnel who are uncertain about a wound should consult with their Supervisor prior to resuming work.

### 3) Personal Protective Equipment

Anyone directly handling human specimens shall wear the standard minimum biohazard personal protective equipment of a fully-fastened lab coat or gown, disposable gloves, safety glasses, closed-foot shoes, and floor-length pants.

### 4) Procedures

**Biological safety cabinet:** All manipulations of human specimens that could potentially generate aerosols shall be conducted inside a biological safety cabinet, or in other equipment outfitted with aerosol-containment feature (e.g., a centrifuge outfitted with a sealed rotor).

**Sharps:** All sharp instruments and needle-spring assemblies shall be disposed of immediately after use into a sharps waste disposal container, without attempting to cap or clip the instrument. If possible, needled-locking hypodermic syringes should be used.

Sharps waste disposal containers must be sealable, leak-proof and puncture-resistant. Containers are available from Science Stores.

When working with sharps, the sharps waste disposal container shall be kept within arm's reach of the workspace. Personnel should not have to walk across the room from their work area to access a sharps container.

#### Sharps Disposal (i.e. needles, razor blade, scalpels, etc.)

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids, solids) should be mixed with sharps waste.
3. Place waste in a biohazard sharps waste container available from Science Stores. Fill container no more than 75% full.
4. If applicable, put on chemical waste label and label all chemicals.
5. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

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### **Needle Stick Poke, Puncture Wound, or Percutaneous Injury**

1. Remove gloves and allow the wound to bleed.
2. Immediately wash the affected area for 15 minutes with soap and warm water.
3. Notify Supervisor (if available) to obtain assistance.
4. Seek **medical assistance immediately** (within **1-2 hours**) from a health care professional. The cause of the wound and organisms involved should be reported.
5. Details of the incident must be documented using the **Incident Report Form** and forwarded to Health & Safety within 24 hours. Forms can be found [online](#) or by contacting [health.safety@uregina.ca](mailto:health.safety@uregina.ca) or 306-585-4776. Please include the following details:
  - a) What was the method of contact (e.g. needle stick, splash)?
  - b) How did the exposure occur?
  - c) What known biological agents or body fluids were you in contact with?
  - d) What action was taken in response to the exposure to remove the contamination (e.g. hand washing)?
  - e) What personal protective equipment was being used at the time of exposure?
  - f) What is your immune status (e.g. Tetanus, Hepatitis A or B Virus)?

**Decontamination:** All work surfaces and equipment used with human specimens shall be regularly decontaminated during work, and at the end of work, with a disinfectant effective against both viruses and bacteria (e.g., 10% (v/v) household bleach, Oxivir TB, etc.)

**Biological Spills:** The most immediate concern following a spill of infectious materials or toxins is to contain the spill and treat any exposed persons. After this occurs, properly trained personnel can begin the clean-up and decontamination process. Use the detailed step-by-step biological material spill procedures outlined in **Appendix 9 – Biological Material Spills.**

Every CL2 lab must have basic supplies to assist with biologically hazardous spill cleanup. This kit must contain:

- Personal protective equipment
- Forceps and sharps waste disposal container
- Concentrated disinfectant (effective against organism of use)
- Paper towels
- Autoclave/biohazard bags

The Hazardous Material Spill Response Team (contacted via Campus Security (4999)) can assist with biological material spill cleanup.

### **Waste Disposal:**

#### **Human Blood & Body Fluids**

##### **Autoclave\***

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items should be mixed with liquid waste.
3. Place waste in an autoclavable container.
4. Inactivate waste by autoclave. Inactivated waste can be treated as decontaminated and can be slowly poured down sewer with plenty of water.

\*Items that cannot be autoclaved: oil; waxes; materials containing solvents, >3% chlorinated compounds (i.e. HCl, bleach), corrosive chemicals (i.e. phenol, ether, chloroform), flammable materials, radioisotopes.

Plastic Type	Autoclave Compatible?	Number on Plastic
PETE or PET – Polyethylene Terephthalate	no	1
HDPE – High-density polyethylene	no	2
PVC or Vinyl – Polyvinyl Chloride	no	3
LDPE – Low-density polyethylene	no	4
<b>PP - Polypropylene</b>	<b>yes</b>	<b>5</b>
PS - Polystyrene	no	6
<b>PC - Polycarbonate</b>	<b>yes</b>	<b>7</b>
PE - Polyethylene	no	-
<b>PMP - Polymethylpentene</b>	<b>yes</b>	<b>-</b>
<b>PTFE Resin</b>	<b>yes</b>	<b>-</b>

### Chemically Inactivate

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. Inactivate waste by fresh 10% bleach. Allow waste to sit for 30 minutes.
3. Inactivated waste can be treated as decontaminated and can be slowly poured down sewer with plenty of water.

### Third-Party Disposal

1. If waste cannot go in autoclave or be mixed with bleach, waste can be collected and disposed of by third-party.
2. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
3. No other items (i.e. solid) should be mixed with liquid waste.
4. Place waste in properly labeled, leak-proof waste container (available from Science Stores). Fill container no more than 75% full.
5. Put chemical waste label on container - label all chemicals and biologicals.
6. Disinfect outside of waste container with 70% ethanol.
7. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

### Human Tissues, Solids, and Items Saturated with Blood and Body Fluids

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids) should be mixed with solid waste.
3. Place waste in a red biohazard pail available from Science Stores. Fill container no more than 75% full.
4. Put chemical waste label on container - label all chemicals and biologicals.
5. Disinfect outside of waste container with 70% ethanol.
6. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

### Sharps Contaminated with Human Materials (i.e. Needles, razor blade, scalpels, etc.)

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.



2. No other items (i.e. liquids, solids) should be mixed with sharps waste.
3. Place waste in a biohazard sharps waste container available from Science Stores. Fill container no more than 75% full.
4. If applicable, put on chemical waste label and label all chemicals.
5. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

#### **Broken Glass Contaminated with Human Materials**

1. Wear gloves, laboratory coat, closed-toe shoes, and other appropriate personal protective equipment, including face and eye protection.
2. No other items (i.e. liquids, solids, needled, intact glass) should be mixed with broken glass waste.
3. Place waste in a white “broken glass” waste container available from Science Stores. Fill container no more than 75% full.
4. If applicable, put on chemical waste label and label all chemicals.
5. Contact [health.safety@uregina.ca](mailto:health.safety@uregina.ca) for disposal.

#### **Phlebotomy:**

By its nature, phlebotomy (the practice of drawing or collecting blood from a venous (venipuncture) or capillary blood source) has the potential to expose personnel to blood from other people, putting them at risk from bloodborne pathogens.

See the **U of R Phlebotomy Guidelines** for more detailed guidelines that outline the recommended health and safety program for performing phlebotomy on human subjects at the U of R.