UNIVERSITY OF THE FRASER VALLEY

# Biosafety

Reference Manual

March 2022

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**University of the Fraser Valley Biosafety Manual 2019**

## 1.0 Introduction

The intent of the Biosafety Program at UFV, and the purpose of the UFV's Biosafety Manual (BSM), is to inform UFV faculty, staff and students how to safely handle biological agents that can be hazardous to people, animals and the environment. Its goal is to provide information to safeguard UFV personnel from any accidental exposure and to explain how to reduce the risks of such exposure. This manual has been edited by the Office of Risk & Safety, the UFV Institutional Biosafety Officer (IBO) and the UFV Institutional Biosafety Committee (IBC). UFV is committed to adhere to the most current version of the Canadian Biosafety Standards and Guidelines. UFV adopts the UFV Biosafety Manual as its policy and procedures for biosafety on all campuses.

The UFV BSM will guide you in how to fulfill the legislative requirements as outlined in the Canadian Biosafety Standard (CBS) 2nd Edition, 2015, the Canadian Biosafety Handbook (CBH) 2nd Edition, 2016 , the Public Health Agency of Canada (PHAC), the Canadian Food Inspection Agency (CFIA), the BC Occupational Health and Safety Regulations (OH&S Regulations), the Human Pathogen and Toxin Act (HPTA) and the Human Pathogen and Toxin Regulations (HPTR). Much of the information presented in the UFV BSM has been reproduced directly from the CBS or the CBH and is summarized for your convenience. To be fully aware of all aspects of Biosafety, it is recommended that you review the CBS and the CBH.

UFV defines biohazardous agents as biological material that poses a potential health risk to people or animals or is a potential threat to the environment. Biohazardous agents may include but are not limited to; bacterial pathogens and their toxins, viruses, mammalian blood, blood products and other mammalian body fluids possibly contaminated with infectious agents, fungus, cell lines, prions, animal carcases and body parts, mycoplasms and parasites. In addition, materials such as DNA or RNA used to produce genetically altered organisms or other genetic manipulations are considered potentially biohazardous.

Principal investigators, faculty, staff, or students working with any biohazardous material as define above are required to contact the UFV Biosafety Officer (IBO) or the Institutional Biosafety Committee (IBC) to obtain a biosafety permit. The commencement of any work with biohazardous material is not permitted without a valid biosafety permit.

## 1.1 Roles and Responsibilities

### 1.1.1 Human Pathogen and Toxin Act (HPTA) License Holder

The HPTA requires all facilities working with biohazardous agents to appoint a licence holder. At UFV, the Director of Safety and Security acts as the license holder on behalf of the university. It is the license holder's responsibility to ensure that implementation of UFV's Biosafety Policies and Procedures are in compliance with the HPTA and is ultimately accountable for any activities carried out with the pathogens and toxins in a licensed facility.

### 1.1.2 Institutional Biosafety Officer (IBO)

The IBO is part of UFVs Safety and Security Office and is the Manager Environmental Health & Safety. The IBO is the license holder's representative and is responsible to develop and implement UFVs Biosafety Policies and Procedures and is charged with the oversight of all biosafety and biosecurity practices, including the overall management of UFVs biosafety program. As outline in the CBG the IBO primary responsibilities include, but are not limited to:

- Consult with the Institutional Biosafety Committee (IBC) to develop and implement specific policies and procedures that promote compliance with the applicable legislation and requirements of the PHAC and CFIA
- Provide any reports or documentation as required by the regulatory agencies of Canada
- Develop, maintain and update UFVs Biosafety Manual
- Provide support and advice on safe work practices within UFV facilities handling biohazardous agents
- Advise researchers and faculty on the regulations and guidelines found within UFVs Biosafety manual
- Review applications for biosafety permits, verifying the accuracy and completeness of license applications or renewals and conducting local risk assessments
- Oversee and document biosafety-related training as required
- Conduct facility site visits and promote compliance of all regulations found within UFVs biosafety manual
- Act as the contact person for any incidents involving biosafety or biosecurity

### 1.1.3 Institutional Biosafety Committee (IBC)

The IBC is responsible to oversee UFVs Biosafety Program and Procedures, provide policy direction, recommend changes and any other measures relevant to the administration of this program. Members of the committee may hold positions of Biosafety administration in their faculty departments. IBC members are appointed by senior management, and jointly with the IBO, act in an advisory role reporting to the license holder on matters pertaining to biosafety and biosecurity. The primary responsibilities of the IBC include but are not limited to:

- To develop and implement specific policies and procedures that promote compliance with the applicable legislation and requirements of the PHAC and CFIA
- Meet on a regular basis to review updates on biosafety and biosecurity issues
- In instances of non-compliance advise and recommend corrective measures

### 1.1.4 Principal Investigator or Laboratory Supervisor

The PI or laboratory instructors are the supervisory individuals working most closely with any biohazardous agents in their area. As such, they shoulder a heavy responsibility to protect all UFV personnel and prevent damage to the environment. Their duties include, but are not limited to:

- Be familiar with the contents of the UFV BSM and ensure that it is followed in their work area
- Identify any biohazardous agents and keep an inventory of all such material stored or used within their work area.
- Obtain and maintain a valid Biosafety Permit
- Maintain and keep up to date any required biosafety training
- Ensure personnel under their supervision are adequately trained to the required level. This will include an online Biosafety Quiz and any other training deemed appropriate in the local risk assessment (LRA)
- Maintain documentation of training for any personnel under their supervision
- Ensure that all individuals under their supervision receive any necessary immunizations and any other medical surveillance that may be required

- Ensure that UFV's Emergency Procedures are in place, posted in a visible area and that personnel know the location
- Report all exposure incidents to the IBO as soon as possible (within 24 hours).
- Report any spills, release from containment, or stolen or missing RG2 biohazardous agents to the IBO as soon as possible (within 24 hours)

### 1.1.5 UFV Personnel and Students Working with Biosafety Permit Holder

All UFV personnel and students have an obligation to keep themselves, others around them, and the environment safe from accidental exposure to biohazardous agents. Working in a restricted area requires diligent observance of all safety related procedures and regulations. Failure to do so may have serious health implications for lab personnel or the public and as such anyone not adhering to all biosafety guidelines may be removed from the containment zone. In general, personnel and students under the jurisdiction of a UFV biosafety permit are required to:

- Take the UFV biosafety training appropriate to the containment zone and the type of infectious material they are working with which includes taking an online Biosafety quiz and any other training material deemed necessary by the IBO.
- Strictly follow all work area specific SOPs identified within the Biosafety permit
- Know UFV's Emergency Response procedures for their work area
- Inform the PI or lab supervisor if they may be immunocompromised so that any mitigation strategies can be reviewed.
- Inform the PI or lab supervisor if their health status changes and may require a reassessment of any working conditions
- Immediately inform the PI or lab supervisor of any exposure to biohazardous agents
- Report any spills or release of containment of any biohazardous materials

UFV adheres to the most current version of the Canadian Biosafety Standards and Guidelines. For further information on Biosafety, contact the UFV Institutional Biosafety Officer (IBO@ufv.ca)

## 2.0 Requirements for Working with Biohazardous Material at UFV

You must have a valid Biosafety permit to handle or work with any biohazardous material at UFV. The process of obtaining a valid biosafety permit will involve the following.

- Contacting the UFV biosafety officer (IBO) (IBO@ufv.ca)
- Completing a local risk assessment (LRA) (UFV BSM 3.1)
- Establishing standard operating procedures (SOPs) for the safe handling of all biohazardous materials (UFV BSM 4.3) in the work area
- Implementing an effective training program for all personnel (UFV BSM 5.1)
- Ensuring all biohazardous material is safely stored and inventoried (UFV BSM 5.2.1)
- Employing the appropriate decontamination and waste disposal protocols (UFV BSM 6.0)
- Ensuring proper signage is in place (UFV BSM 4.7)
- Ensuring Biosafety measures are in place (UFV BSM 5.2)
- Applying UFV's Emergency Response Plan if necessary (UFV BSM 4.8)

## 2.1 Biosafety Permit Applications

All UFV faculty, staff and students working with any biohazardous agents or biomedical material are required to be under the administration of an approved biosafety permit. Commencement of any research, laboratory teaching, medical practice training or student projects may not start without the written approval of the UFV Institutional Biosafety Officer (IBO), their designate or the Institutional Biosafety Committee (IBC). Note: Depending on the project, you may also require permits from the Human Research Ethics Board (HREB) or the Animal Care Committee (ACC).

### 2.1.1 When to Apply

A biosafety permit must receive written approval from the UFV Institutional Biosafety Officer (IBO), their designate or the Institutional Biosafety Committee (IBC) prior to the start of any work involving biohazardous material. It is the role of the IBO, or their designate, to review and approve biosafety permits. There are numerous requirements necessary to obtain a valid permit, therefore, it is strongly recommended that you apply as early as possible.

### 2.1.2 Who Can Apply

Program Coordinators, Department Heads, Principal Investigators, Faculty members and Laboratory Instructors may apply. Students may not apply. Student projects require the oversight of a principal investigator or faculty member who may apply for them.

Researchers from institutions other than UFV, but who are working in conjunction with UFV personnel, may be included as co-researchers on a UFV biosafety permit providing the research is conducted at UFV. A joint research project conducted at both UFV and another institution, requires biosafety approval from both institutions. Projects involving UFV members working in collaboration with co-researchers from other institutions, and where the research is exclusively conducted at another institution, will require a copy of the other institution's biosafety permit. A UFV biosafety permit is not required.

### 2.1.3 Application Process and Permit Duration

Once an application has been completed, it should be submitted electronically to the UFV IBO or the co-chair of the IBC where it will be quickly reviewed for completeness. Incomplete applications will be returned to the applicant which may delay approval. Applications will be reviewed by the IBO and co-chair of the IBC. Approved permits will be signed, and a copy sent to the applicant.

Permit expiry dates can be found on the signed permit approval document. Unless noted on the permit, biosafety permits for course-based applications are valid for 3 years providing no changes have been made. Permits for research applications are valid for one year after the approval date. The IBO must be immediately informed if any changes or additions are made to the original application. The IBO or their designate will determine if a new biosafety application is needed.

### 2.1.4 After Submission

After a review of the application, either by the IBO or the IBC, a local risk assessment (LRA) must be completed. The IBO, or their designate, will contact the applicant to arrange an LRA. In general, the LRA will assess the following:

- the risk group (RG) of any pathogens or potential infectious agents
- is the workspace suitable for the level of containment required
- is proper signage in place

- have all workers been trained on the appropriate SOPs
- are all biohazardous materials securely stored and inventoried
- have biosecurity measures been considered and put into place
- is the waste management plan appropriate for the biohazardous materials being used

For more detailed information on the LRA see BSM 3.0

## 3.0 Risk Assessment

Risk assessment is the cornerstone of a Biosafety program. Risk, as an element of biosafety, is the chance that an unwanted event will happen, and risk assessment evaluates the likelihood and consequences of such an event. As much as possible, a risk assessment tries to predict risks and then mitigate those risks through safe working conditions. An overarching risk assessment is multi-faceted and evaluates several factors such as:

- Identification of biohazardous agents and reducing the risk of adverse effects from these materials
- Protecting workers, the environment, and animal resources from harm
- Preventing the release of infectious materials or toxins
- Promoting safe work practices and improving safety performance
- Maintaining regulatory compliance through a combination of training, documentation, inspections, evaluations, and communication
- Evaluating Biosecurity requirements

Biosafety and Biosecurity risk assessments aim to identify potential hazards to determine the associated risks with the goal of mitigating the identified risks. Risk assessments also determine whether existing mitigation measures are appropriate and meet the requirements of the Canadian Biosafety Standards (CBS).

### 3.1 Local Risk Assessment (LRA)

The first step of your LRA is to contact the IBO. After an initial consultation you will be asked to submit a biosafety permit application (UFV BSM Appendix 1). Information on how to apply, and what is required can be found in section 2.0 of the UFV BSM.

The IBO, or their designate, will help you evaluate the degree of risk associated with your activities and help you determine the appropriate containment level required (see BSM 4.2). In addition, the IBO will help establish a suitable training program for all individuals involved and will help with other components of biosafety such as biosecurity measures, selection or development of SOPs, evaluation of any medical surveillance requirements, and identification of proper waste management practices. In general, your LRA should assess the following:

- the risk group (RG) of any pathogens or potential infectious agents
- is the work space suitable for the level of containment required
- is proper signage in place
- have all workers been trained on the appropriate SOPs
- are all biohazardous materials securely stored and inventoried
- have biosecurity measures been considered and put into place
- is the waste management plan appropriate for the biohazardous materials being used
- is a medical surveillance program necessary

There is a systematic approach to conducting risk assessments, regardless of the type of risk. A good risk assessments strategy follows a plan that allows for continual improvement of processes to improve the risk assessment and to evaluate any incidents that have occurred since the implementation of the risk mitigation strategies. Additionally, it is essential that the mitigation strategies implemented have not introduced new hazards.

Various types of risk assessment are used to evaluate the risk associated with the handling and storing of infectious materials and toxins, including the risks related to the pathogen, to the specific work activities or tasks, to biosecurity and to the scientific program as a whole. The key concepts and approaches to risk assessment and risk management can be universally applied to each type of risk assessment.

The IBO, or their designate, will perform a LRA based on the information provided in the application and will evaluate the different categories of risk as outlined below. Depending on

the nature of the activities, the IBO may consult with the IBC co-chair, members of the IBC, or local UFV experts to determine the appropriate containment level. For applications considered as CL1, the IBO and the IBC co-chair will undertake the LRA. For applications deemed CL2, the IBO, IBC co-chair and a departmental biosafety representative will conduct the LRA.

### 3.1.1 What to expect during a LRA

Your LRA can vary dramatically depending on the information provided in the application. For example, a LRA for a student teaching lab that has received prior biosafety approval, but now is relocating to a different lab space, will be less time consuming compared to a newly proposed research program. The former will already have in place approved pathogen risk assessments, developed SOPs, waste management protocols, and biosecurity measures. As such, the LRA will focus more on the new facilities to ensure they are appropriate to the biosafety work and then modify the existing protocols as deemed necessary. On the other hand, a new research program may need to freshly develop all protocols and documentation associated with their biosafety work. Below are some key considerations of an LRA.

**Step 1: Development and Implementation of Standard Operating Procedures (SOPs)**

First, identified and characterized the activity-specific hazards. If possible, break down the activities into steps, which can possibly reduce the amount of work needed for each LRA. If a step is ever modified, only that step needs to be reassessed, not the entire procedure. An analysis of the hazardous materials and activities performed will allow the PI to develop standard operating procedures (SOPs) appropriate to the work being conducted (see UFV BSM 4.3). To aid in SOP development the following should be considered:

- What is the quantity and concentration of infectious material or toxin handled or stored?
- What is the potential of aerosol generation by equipment or activities?
- What is the form or state of the infectious material or toxin (e.g., liquid, solid, powder)?
- Does the work involve animals?
- Are sharps or glassware used? Are sharps handled and disposed of properly?
- Who will be performing the activity? (e.g., experienced investigator, junior technician, or student).

While the pathogen's risk group and the containment level at which it must be handled or stored will be determined by the pathogen risk assessment, certain pathogen-specific characteristics may need to be considered in the LRA, such as:

- How the pathogen gains entry into hosts (i.e., ingestion, inhalation, inoculation, contact with skin or mucous membranes, or genitourinary)
- The host range; and
- The stability of the pathogen outside the host. That is, the environmental conditions in which it can survive and for how long.

**Step 2: Assess Risk**

Assess the potential risks associated with each activity-specific hazard. When assessing risk, for each step in the procedure, the likelihood of exposure to, or release or loss of the pathogen or toxin, and the severity of the consequences (e.g., infection, illness, outbreak etc.) in the event of an exposure, should be considered. During this process each hazard that poses an unacceptable risk will be evaluated to see if mitigations steps are available. Guides from the BC Workmen's Compensation Board and the BC Municipal Safety Association may prove useful in developing a numerical approach to assigning risk.

The LRA will consider all potential risks that could occur at each step or task in an activity. By assessing the potential risks of each task, the circumstances and the likelihood of an incident leading to exposure, release, or loss of infectious material or toxins will be identified.

Those performing the activity may also need to be considered. The likelihood of an incident occurring can depend on the individual performing the activity. For example, the likelihood of an incident occurring when a student is performing a laboratory activity for the first time is much higher than when an experienced technician is performing the same activity. More oversight and mitigation controls may be required for the student.

**Step 3: Develop and Implement Risk Mitigation Strategies**

After the risks associated with each step or task have been assessed, mitigation strategies that address any unacceptable risk (i.e., over the risk tolerance threshold) can be implemented. It may be found that existing mitigation measures reduce the identified risks to acceptable levels and that no additional measures are needed. On the other hand, if mitigation strategies cannot reduce the risk to acceptable levels, the activity will have to be modified or the work terminated.

Whenever possible, it is best to implement controls to prevent the incident from occurring altogether. However, having a mechanism in place to contain biohazardous materials to prevent an exposure (e.g., PPE, sealed secondary container, biological safety cabinet) will reduce the consequences of the incident, should it occur.

For example, a student lab exercise requiring students to streak a culture plate with a bacterial sample should have the following mitigation strategies in place

- Bench top surfaces should be cleaned with disinfectant at the start of the lab period and again at the end.
- To prevent possible exposure to the student, PPE such as a lab coat and disposable gloves must be worn
- To prevent aerosol formation, single use disposable loops should be used
- To prevent contamination of the working environment, containers containing an appropriate chemical disinfectant should be at hand to immediately collect contaminated disposable loops and biohazard bags should be readily available to collect contaminated gloves.
- To aid in waste removal, leak proof containers should be available to transport any contaminated waste to site of decontamination (e.g., central autoclave)

### 3.1.2 Pathogen Risk Assessment

A pathogen risk assessment characterizes the risks associated with a pathogen based on the inherent characteristics of the pathogen that contribute to the risk it poses to humans and animals. It is used to determine how likely a pathogen is to cause negative health effects and the severity of those health effects. The pathogen risk assessment process will determine the pathogen's risk group and the appropriate containment level needed for the safe and secure handling of the pathogen.

The Human Pathogens and Toxins Act (HPTA) website maintains a Pathogen Safety Data Sheet (PSDS) data base assigning risk group levels to many human and animal pathogens. This resource is a good starting place for information helpful in developing a pathogen risk assessment profile for a specific pathogen.

The pathogen risk assessment characterizes the risks associated with a pathogen based on the close examination of the following risk factors, which are the inherent characteristics of a pathogen that contribute to the risk it poses to humans and different animal species.

- **Pathogenicity and Virulence**: Is the pathogen able to infect and cause disease in humans or animals (i.e., pathogenicity)? What is the severity of disease in individuals or in different animal species (i.e., virulence; the degree of disease)?
- **Route of Infection**: How does the pathogen gain entry into hosts (i.e., ingestion, inhalation, inoculation, contact with skin or mucous membranes, or genitourinary)?
- **Mode of Transmission**: How does the pathogen travel to hosts? Is the pathogen transmissible by direct contact (e.g., close intimate contact or casual contact) or indirect contact (e.g., fomites, aerosolized droplets or airborne transmission)? Can the pathogen be transmitted by vectors or zoonosis?
- **Survival in the Environment**: How stable is the pathogen outside the host? Under which 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 Preventive and Therapeutic Treatments**: Are effective preventive 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 or is it exotic to Canada (i.e., non-indigenous)? Is it prevalent in a particular location, region, or human or animal population?
- **Impact of Introduction and/or Release into the Environment or the Canadian Public**: If the pathogen were introduced into the human or animal population or released into the environment (within Canada), what would be the economic, clinical, and biosecurity impact?

While most infectious material will clearly fall into one of the four risk groups (see BSM 3.1), 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 category. For example, if a pathogen is unlikely to cause disease in humans or animals, it may be irrelevant that it can survive in the environment for a long period of time.

### 3.1.3 Biosecurity Risk Assessment

A biosecurity risk assessment is used to identify, prioritize, and mitigate the biosecurity risks associated with biological and other related assets in a facility. It is an evaluation of the probability of the loss of a biological asset (e.g., pathogen, toxin, infectious material, equipment, animals, information) or of an intentional event, such as the theft, misuse, diversion, or unauthorized release of biological and related assets (e.g., personnel, equipment, non-infectious material, and animals), and the consequences of that event (e.g., community health impact resulting from unauthorized release of a pathogen, theft of proprietary information). The biosecurity risk assessment differs from biosafety risk assessments (i.e., overarching, pathogen and toxin, and LRAs), in that the individuals or groups that may have malicious interest in the asset (i.e., threats) also need to be considered.

In addition, a biosecurity risk assessment needs to consider the increased security requirements of assets with dual-use potential (i.e., assets that can be used for legitimate scientific applications, but also pose an increased biosecurity risk due to an inherent potential for development and use as a biological weapon). Assets with dual-use potential not only include security sensitive biological agents (SSBAs) but can also include assets related to their handling and storing (e.g., equipment, information).

## 3.2 Definition of Biohazardous Agents

### 3.2.1 Bacteria

Bacteria are single-celled prokaryotic organisms lacking a nucleus and other membrane-enclosed organelles. There are microscopic in size and appear as spherical (cocci) or appear as rods (bacilli) that may be straight, curved, spiraled, or tightly coiled. Some bacteria can induce an extreme immune response, secrete exotoxins, produce surface-associated endotoxins, or form spores that enhance survival and transmission outside the host for extended periods of time.

Bacteria that can infect and cause disease in humans and/or animals are referred to as pathogenic bacteria. Many pathogenic bacteria that colonize the body do not cause disease unless a disruption occurs in the host's immune system or natural barriers to infection, or the host is exposed to an excessively high dose of the pathogen, as may occur through activities conducted in a laboratory or an animal facility. Infections with certain pathogenic bacteria almost always result in illness. Examples of pathogenic bacteria include Bacillus anthracis, certain strains of Escherichia coli, Mycobacterium tuberculosis, and Salmonella species (spp.).

### 3.2.2 Viruses

Viruses are the smallest of replicating organisms. Their small size (20-300 nm) allows them to pass through filters that typically capture the smallest bacteria. Viruses have no metabolism of their own and, once inside a host cell, they redirect existing host machinery and metabolic functions to replicate. Structurally, the simplest viruses consist of nucleic acid enclosed in a protein capsid (nucleocapsid). Enveloped viruses have a more complex structure in which the nucleocapsid is enclosed inside a lipid bilayer membrane. This membrane facilitates the virus's interaction with the host cells, but also increases susceptibility to decontamination.

There are many families of viruses that are able to infect human and animal hosts. Some are species-specific while others infect a wide range of host species. Some viruses are able to produce a persistent infection (i.e., host cell remains alive and continues to produce virus over a long period of time) or a latent infection (i.e., there is a delay of months or years between viral infection of the host and the appearance of symptoms), or they may be carcinogenic (e.g., integration of an oncogene-carrying retrovirus into host genome). Examples of pathogenic viruses include influenza viruses, HIV, herpes viruses, rabies virus, and Ebola virus.

### 3.2.3 Human Blood, Blood Products and other Human Body Fluids

Primary specimens are samples taken directly from a person. The HPTA and HPTR don't apply to human pathogens and toxins that are in an environment in which they naturally occur. However, human body fluids can contain infectious pathogens that are classified as RG2 or higher. Most of these pathogens cause diseases with visible symptoms, but not always. Often individuals in an early stage of an infection or those who are asymptomatic carriers, will not exhibit any visible signs. These individuals can be highly contagious capable of transmitting disease to those around them through their body fluids

### 3.2.4 Fungi

Fungi are eukaryotic microorganisms that can be easily distinguished from bacteria and other prokaryotes by their greater size and the presence of organelles. Of the 1.5 million estimated fungal species, approximately 300 are known to cause disease in human and/or animal hosts. Several species of yeast, which normally grow as single cells, and of moulds, which grows in branching chains, are known to be pathogenic to animals and humans. Differences in the virulence of these fungal species are used to categorize them into two main categories: frank pathogens, which can cause disease in healthy hosts, and opportunistic pathogens, which can cause disease in immunocompromised hosts.

The main risk associated with fungi is the exposure to spores that can be transmitted via the airborne route, inoculation, or casual contact, depending on the species. In addition, some fungal species may produce and disperse mycotoxins, which can be toxic. In general, human and animal tissue and blood samples are not considered a risk for the airborne dispersal of fungal spores. Examples of pathogenic fungi include Aspergillus niger, Candida albicans, and Histoplasma capsulatum.

### 3.2.5 Prions

Prions are small, proteinaceous infectious particles that are generally accepted to be the cause of a group of progressive neurodegenerative diseases in humans and animals known as Transmissible Spongiform Encephalopathies (TSEs). When an infectious prion enters a healthy host, it induces the normally folded prion protein to convert to the disease-associated, misfolded prion isoforms. The pathogenic isoform acts as a template that guides the misfolding of more prion proteins, which eventually leads to an accumulation of large amounts of the extremely stable, misfolded protein in infected tissue, causing tissue damage and cell death. There are no treatments and no vaccines available for TSEs.

The most likely route of transmission to personnel handling infectious prions is through accidental inoculation or ingestion of infected tissues. Appropriate procedures and the use of PPE to avoid cuts and punctures are the best approaches for protecting personnel. Although there is insufficient information to completely assess the risk associated with TSE disease-causing prions transmitted by inhalation, it is prudent to mitigate personnel exposure when aerosol- or splash-generating procedures are being conducted. The short-and long-term consequences of gross contamination of mucosa in the nasal, olfactory, and oral cavities, as well as possible ingestion, are not known.

### 3.2.6 Toxins

Biological toxins are poisonous substances that are a natural product of the metabolic activities of certain microorganisms, plants, and animal species. Toxins can cause adverse health effects, severe incapacitation, or death in a human or animal. Toxins can often cause severe health effects even when present at relatively low levels in host tissues. Some toxins can be artificially produced by chemical synthesis or by genetic engineering and rDNA technology. Toxins are classified according to the organism from which the toxin is derived (e.g., bacterial, fungal, plant, animal), although toxins are typically associated with bacterial disease.

Two types of bacterial toxins exist: exotoxins and endotoxins. Exotoxins are often heat-labile proteins and polypeptides that are produced and secreted or released by a variety of species, including both Gram-negative and Gram-positive bacteria. Bacterial exotoxins can be classified in five main groups based on their effect on the host, as follows: damage to cell membranes, inhibition of protein synthesis, inhibition of release of neurotransmitters, activation of secondary messenger pathways, or activation of host immune responses. Examples of exotoxins include tetanus toxin, produced by the Gram-positive bacterium Clostridium tetani, and cholera toxin, produced by the Gram-negative bacterium Vibrio cholerae. Additionally, a family of heat-stable exotoxins exists, called enterotoxins, that exert their primary effects on the digestive tract. They include Staphylococcus Enterotoxin Type B produced by Staphylococcus aureus, heat-stable enterotoxins produced by enterotoxigenic Escherichia coli (ETEC), and cereulide produced by Bacillus cereus.

Endotoxins are structural molecules that are embedded in the outer layer of the cell wall of certain Gram-negative bacteria, such as Escherichia coli and Shigella dysenteriae. They are generally less toxic than exotoxins and are heat stable. When compared to microbiological pathogens, it is easy to control the spread of toxins. Toxins do not replicate, are not infectious, and are not transmitted from person to person. The most likely route of transmission to personnel handling toxins is through accidental inoculation or by the exposure of mucous membranes to aerosols.

Note: There is no specific research being conducted on toxins within UFV, however, the production of a toxin (exotoxin) or the presence of endotoxins is possible from bacteria used in a student laboratory.

### 3.2.7 Recombinant DNA

Genetic material from more than one source, either natural or synthetic, can be combined to construct novel recombinant DNA (rDNA). rDNA technologies are widely used in modem-day research and have many applications, including the production of transgenic animals, the cloning of microbial toxin genes or other genes in expression vectors, and the production of full-length infectious viral clones.

### 3.2.8 Cell Lines

Cell lines (or cell cultures) are commonly used in diagnostic, research, and industrial microbiology laboratories. Many cell lines do not inherently pose a risk to the individuals manipulating them in the laboratory; however, they have the potential to contain pathogenic

organisms such as bacteria, fungi, mycoplasmas, viruses, prions, or recombinant virions. This can occur either naturally or through contamination by adventitious organisms, transformation or recombination. Cell lines that are known or potentially contaminated should be manipulated at the containment level appropriate for the contaminating organism of the highest risk.

Bacterial and fungal contamination in cell lines can be readily identified; however, viruses are not as easily identified and can pose a significant hazard. Growth conditions (e.g., pH, temperature, medium supplements) may cause altered expression of oncogenes, expression of latent viruses, interactions between recombinant genomic segments, or altered expression of cell surface proteins. One of the primary hazards of manipulating any cell line relates to the expression of latent viruses. Endogenous viral sequences have been found in a variety of cell lines derived from mammalian species, including humans.

### 3.3 Risk Groups

Biohazardous agents are assigned to specific risk groups. This statement is not as simple as it sounds as new uncharacterized pathogens are constantly being discovered and because microorganisms are adept at evolving and changing their characteristics. However, most infectious material can be categorized into one of four risk groups. The Human Pathogens and Toxins Act (HPTA) website maintains a Pathogen Safety Data Sheet (PSDS) resource assigning risk group levels to many human and animal pathogens**. Note:** working with biohazardous agents requiring containment level 3 or higher is strictly prohibited at UFV. UFV has no laboratories compliant with CL3 regulations.

#### 3.3.1 Risk Group 1 (low individual and community risk)

A microorganism, nucleic acid, or protein that is either a) not capable of causing human or animal disease; or b) capable of causing human or animal disease, but unlikely to do so. Those capable of causing disease are considered pathogens that pose a low risk to the health of individuals or animals, and a low risk to public health or animal population. RG1 pathogens can be opportunistic and may pose a threat to immunocompromised individuals resulting in serious health issues. Therefore, due care should be exercised when handling these materials.

Because there is a low risk to public health and animal population associated with RG1 material, the CBS has no mandatory physical or operational requirements for handling CL1 biohazardous agents. However, the PHAC has recently publish a companion guide of recommendations for CL1 physical design and operational practices and highly recommends the use of Good Microbiological Laboratory Practices for all activities involving RG1 pathogens and toxins. In

addition, the waste from some RG1 biohazardous material is classified as biomedical waste (waste from human blood or other body fluids) and must be decontaminated prior to disposal. Non-decontaminated biomedical waste cannot be disposed in a normal waste disposal system (see BSM 6.3.1).

Due to the potential serious health issues of exposure to opportunistic pathogens and the nature of biomedical waste, the UFV IBC requires all UFV personnel and students handling CL1 biohazardous material to be under the jurisdiction of a valid CL1 biosafety permit.

### 3.3.2 Risk Group 2 (moderate individual risk, low community risk)

A pathogen or toxin that poses a moderate risk to the health of individuals or animals, and a low risk to public health and the animal population. These pathogens can cause serious disease in a human or animal but are unlikely to do so. Effective treatment and preventive measures are available and the risk of spread of diseases caused by these pathogens is low.

### 3.3.3 Containment Areas

Once the risk group has been determined by a LRA, there are several key factors to determine the appropriate level of containment at which the identified pathogen or toxin can be safely handled. Well-characterized pathogens that have had a pathogen risk assessment completed by the PHAC or the CFIA have already been assigned an appropriate risk group and containment level. In general, the containment level and risk group of the pathogen are the same (e.g., RG2 pathogens are handled at CL2); however, there are some exceptions. If the pathogen has been modified, the containment requirements may need to be revised accordingly. These containment level changes reflect the risk mitigation strategies to address the specific modification of the pathogen.

The following factors are considered when conducting a containment assessment (i.e., determining the specific physical containment requirements, operational practice requirements, and performance and verification testing requirements) for a pathogen:

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

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

Some factors considered when determining the risk group may also be evaluated in the context of the containment assessment. For example, the concentration of the pathogen being handled may have less importance if the infectious dose is very high. On the other hand, aerosol generation becomes more important for pathogens transmitted via the inhalation route.

## 4.0 Biosafety Practices and Procedures

### 4.1 General UFV Biosafety Practices Overview

I. The UFV Institutional Biosafety Committee has adopted the UFV BSM, the CBS, the CBH, and the UFV Biosafety Standard Operating Procedures (SOP's) as its policy and procedures governing all aspects of activities, either research (faculty or student based), teaching laboratories, or medical training programs that are handling biohazardous materials.

II. It is the responsibility of the Principal Investigator or Laboratory Instructor to identify potential biohazards and to specify safe practices and procedures. All laboratory personnel must be informed of the potential hazards and trained in safe handling techniques as defined within the UFV BSM. Service personnel and cleaning staff that enter the facility must be informed of the hazards that might be encountered.

III. Prior to the commencement of any biosafety work involving infectious materials, all UFV employees and students handling RG1 biohazardous material must be trained in SOP UFV BS01. Employees or students handling RG2 biohazardous materials must be trained on SOP UFV BS03. In addition, personnel must be trained according to requirements identified during the LRA review.

IV. Issues of non-compliance will be reported to the IBO and an incident report form will be generated (see BSM Appendix 6). All incident report forms are reviewed by the IBO and the IBC. An offending laboratory may be shut down according to CBS compliance requirements.

V. All students enrolled in a UFV Biology laboratory handling microorganisms must be trained and tested to ensure that they are competent to safely work with infectious materials. Under the direction of the IBO, training is the responsibility of the PI or the laboratory supervisor. Testing will be accomplished using a biosafety quiz and a record of the testing results must be maintained.

VI. The recommendations for containment levels assume a population of immunocompetent individuals. Individuals with altered immunocompetence may be at increased risk for the hazards associated with manipulating a particular pathogen or combinations of pathogens in the laboratory environment. The IBO must take immunocompetence into consideration in individual cases when containment levels are being determined. All students involved in a student laboratory involving biological material are requested to inform their instructor, supervisor, or IBO if they consider themselves to be immunocompromised. Possible reasons for a student to be immunocompromised include, but are not limited to certain illnesses, pregnancy, malnutrition, or drug use.

## 4.2 Containment Levels

Classification of organisms according to risk group may not be entirely appropriate for the handling of biological hazards in the laboratory setting. For example, the risk group system does not consider the procedures that are to be employed during the manipulation of a particular organism. Containment levels are more appropriate and give the end-user an indication of the containment required for handling the organism safely. A LRA is required to assign an appropriate containment level for the safe handling of the biohazardous material in use. The LRA will evaluate all aspects of the work involved; the inherent nature of the pathogen or toxin; the types of manipulations and procedures used; the engineering and physical attributes of the working area. In some instances, this may mean a CL2 facility is required when working with an RG1 pathogen. Likewise, a LRA may determine that potential RG2 material (e.g., human body fluids) that undergo clinical diagnostic procedures may only require a CL1 biosafety permit.

The containment level required for work with a particular agent is based on the manipulations generally associated with laboratory-scale research and clinical procedures. If a particular procedure, such as the preliminary identification of an infectious agent, poses a lower hazard than manipulating a live culture, then a lower containment level may be appropriate.

Both physical containment and good laboratory practices are important for reducing the risk of laboratory acquired infections. Note that laboratory technique can significantly alter the risk of exposure to biohazards. Good microbiological practices include the use of PPE, hand washing, disinfecting work areas, the use of procedures that minimize the creation of aerosols, and proper decontamination and disposal of materials.

### 4.2.1 Requirements When Working with CLI Biohazardous Material

CLI requires no special design features beyond those suitable for a well-designed and functional laboratory. Biological safety cabinets are not required. Work may be done on an open bench top, and containment is achieved using practices normally employed in a basic microbiology laboratory.

In general, manipulating RG1 biological material requires a CL1 working area. RG1 biological or biomedical material is unlikely to cause human or animal disease, and as such, is not considered pathogenic. Nevertheless, RG1 material can be harmful to individuals under certain conditions. Many RG1 infectious agents are opportunistic pathogens capable of harming

immunocompromised or immunosuppressed individuals. While many individuals susceptible to these pathogens are aware of their condition (e.g., diabetics or other chronic medical conditions) others may not be (e.g., early pregnancy or in an early stage of infectious disorders such as mononucleosis). Therefore, as recommended in the CBS, the UFV IBC require the manipulation of CL1 biohazardous agents be carried out in a laboratory or area that incorporates basic laboratory design using CL1 safe operational practices (see SOP UFV BS01) and that all UFV personnel and students handling CL1 biohazardous material be under the jurisdiction of a valid CL1 biosafety permit.

Both physical containment and safe laboratory practices are important for reducing the risk of laboratory acquired infections. PI and lab supervisors should consider that laboratory technique can significantly alter the risk of exposure to biohazards. If possible, techniques that are likely to increase the risk of aerosols or increase the chances of direct skin contact should be avoided. If this is not possible, informing students of the potential risk when using these procedures should be emphasized. In addition, the use of mitigation strategies such as wearing PPE, hand washing, disinfecting work areas, should be closely monitored.

### 4.2.2 Requirements When Working with CL2 Biohazardous Material

This level applies to the laboratory handling agents requiring containment level 2. The primary exposure hazards associated with organisms requiring CL2 are through the ingestion, inoculation, and mucous membrane route. Agents requiring CL2 facilities at UFV are not generally transmitted by the airborne route, but care must be taken to avoid the generation of aerosols (aerosols can settle on bench tops and become an ingestion hazard by contamination of the hands) or splashes. CL2 requirements are achieved through standard operational practices and through a set of containment requirements listed below. Required operational practices include, but are not limited to:

- Biosafety program management
- Implementation of SOP UFV BS03
- The use of PPE (gloves, lab coat, protective eye wear)
- Hand washing
- Disinfection of work areas
- Collection and disposal of contaminated waste
- UFV's Emergency Response Plan posted and in place

Due to the potential serious health issues of exposure and the nature of biomedical waste, the UFV IBC requires all UFV personnel and students handling RG2 biohazardous material to be under the jurisdiction of a valid CL2 biosafety permit.

### 4.2.3 Requirements when Working with Human Tissues, Cell Lines and Body Fluids

Primary specimens are samples taken directly from a person. The HPTA and HPTR do not apply to human pathogens and toxins that are in an environment in which they naturally occur. However, human body fluids can contain infectious pathogens that are classified as RG2 or higher. Most of these pathogens cause diseases with visible symptoms, but not always. Often individuals in an early stage of an infection or those who are asymptomatic carriers, will not exhibit any visible signs. These individuals can be highly contagious capable of transmitting disease to those around them through their body fluids. A small sampling of contagious human pathogens found in body fluids that potentially exist in the UFV population or in individuals from the Fraser Valley population are listed below.

- RG2 Influenza virus
- RG2 Epstein Barr Virus
- RG2 Hepatitis A or B
- RG3 Mycobacterium tuberculosis
- RG2 Parvo Virus
- RG2 Norwalk Virus
- RG3 Human Immunodeficiency Virus
- RG2 Enteroinvasive Escherichia coli
- RG2 Rubeola Virus
- RG2 Cytomegalovirus (CMV)

The dichotomous nature of human body fluids (free of infectious agents versus potentially pathogenic) poses unique challenges for the PI, lab supervisor and IBO. During a LRA, the IBO (in consultation with stakeholders) will carefully exam all procedures involving the collection or manipulation of primary human biohazardous materials to develop the appropriate mitigation strategies.

At UFV and most Canadian universities, human tissues, cell lines, blood, and body fluids are classified as RG2 biohazardous materials and require CL2 level facilities and practices. The UFV IBC requires that a Biosafety permit be obtained prior to the commencement of any work involving human tissues, human cell lines, blood, or body fluids. Laboratory practices should assume that human materials are potentially infectious.

Diagnostic activities involving primary specimens that do not involve propagating, concentrating, or purifying the pathogen (e.g., enzyme-linked immunosorbent assay [ELISA], extraction of genetic material, fixation of tissue samples for histology) are regularly carried out in hospitals, public health laboratories, and veterinary diagnostic laboratories. In most cases,

the risks associated with this type of work are considered lower than propagation and in vivo work. Based on the risks associated with the pathogen suspected of being within the primary specimen and the laboratory procedures, the physical containment, and operational requirements for activities with primary specimens may sometimes be lower than the requirements for handling pure cultures.

Due to the diverse nature of the programs offered at UFV, personnel from the Health Sciences might be more familiar with, and may have received infection control training, using the safety practices referred to as "Universal Precautions and Routine Practices". Routine practices and good microbiological laboratory practices are similar in scope, and both are suitable training methods. During the LRA the IBO will review all pertinent SOPs to ensure the Biosafety permit holder and any workers under their supervision have been adequately trained regardless of their educational program.

During the LRA the IBO will evaluate the likelihood of risk by assessing the following factors:

- The nature of the sample population. Is the population generally healthy or likely to be infected?
- Is the sample population screened for transmittable infections (e.g., HIV, Hepatitis) and are infected samples excluded?
- The means of sample collection (e.g., saliva in a microfuge tube, sharps such as a retractable lancet or a needle and syringe) and the volume collected (e.g., microlitres or millilitres)

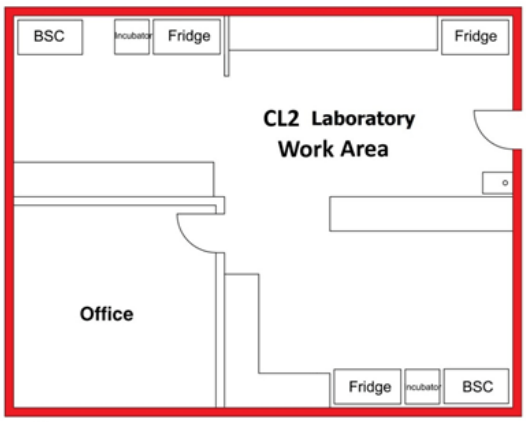
The collection and manipulation of samples should follow the general safe work practices listed below:

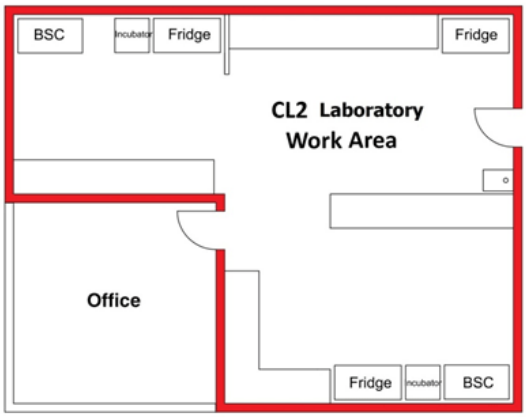
- Training on the appropriate SOP
- Wearing the appropriate PPE such as lab coats, gloves, appropriate footwear, long pants/skirts and protective eyewear when there is a risk of exposure to splashes
- Waste to be disposed of in biohazardous waste bags
- Waste requiring transport to the waste disposal site (e.g., autoclave) should be double bagged and transported in a leak proof container
- Wastes to decontaminated either through autoclaving, chemical disinfection or other means deemed appropriate through the LRA
- After removing gloves, hands should be washed

- Appropriate vaccinations as deemed appropriate
- Are appropriate sharp containers needed and readily accessible

### 4.3 CL 2 Working Area

A CL2 laboratory work area includes physical containment features within a containment zone as shown below. Prior to setting up a containment zone, special considerations should be given to the placement of office space. Office space within the containment zone cannot be used to store personal items (e.g., street cloths, lunches etc.). On the other hand, lab personnel must remove their lab coats and wash their hands prior to entering office space located outside of the containment zone.




CL2 laboratory designs include features such as:

- Location of the lab work area, support areas and offices
- Restricted access (lockable doors) into and out of the lab work area
- Doors to separate containment versus non-containment areas
- Impermeable washable bench tops and floors
- Biohazardous signage
- Storage for user lab coats to remain within the containment zone
- Primary containment devices
    - Biological safety cabinet

- centrifuges with sealed rotors or safety cups

The CBS lists in matrix 3 and 4 the requirements for CL2 work areas (reproduced below for your convenience).

| CBS Identifier | CL2 Requirement |
|---|---|
| 3.1.1 | Containment zones to be separated from public and administrative areas by a door |
| 3.1.2 | Dedicated paper/computer workstations within the containment zone to be segregated from laboratory workstations, animal rooms, animal cubicles, and post mortem rooms (PM rooms). |
| 3.3.1 | Doors to the containment zone to be lockable |
| 3.3.2 | Biohazard warning signage (including the international biohazard warning symbol, containment level, name and telephone number[s] of contact person, and entry requirements) to be posted at the containment zone point(s) of entry. |
| 3.3.3 | Where unique hazards exist, project-specific signage to be posted at the animal room, animal cubicle, and post mortem room (PM room) point(s) of entry |
| 3.3.9 | Space to be provided for the storage of PPE in use. |
| 3.4.1 | Surfaces and interior coatings, including, but not limited to, floors, ceilings, walls, doors, frames, casework, bench tops, and furniture, to be cleanable, non-absorbent, and resistant to scratches, stains, moisture, chemicals, heat, impact, repeated decontamination, and high pressure washing, in accordance with function. |
| 3.4.5 | Floors to be slip-resistant in accordance with function. |
| 3.6.4 | Sinks to be provided and located to facilitate hand washing upon exit from the containment zone |
| 3.6.6 | Emergency eyewash and shower equipment to be provided in accordance with containment zone activities. |

| | |
|---|---|
| 3.7.1 | Certified BSCs and other primary containment devices to be provided, based on work activities |
| 3.7.3 | Class II B2 BSCs, where present, to be installed and set-up in a manner to eliminate reversal of airflow from the face of the BSC (i.e., puff-back) during a failure of the heating, ventilation, and air conditioning (HVAC) system or the BSC exhaust fan; where elimination of puff-back cannot be achieved, the risk associated with puff-back to be mitigated through physical and operational means. |
| 3.7.4 | Process equipment, closed systems, and other primary containment devices to be designed to prevent the release of infectious material or toxins |
| 3.7.6 | BSCs, where present, to be located as far as possible from high traffic areas, doors, openable windows, and air supply/exhaust diffusers |
| 3.7.11 | Decontamination technologies for the decontamination of materials to be provided within the containment zone, or standard operating procedures (SOPs) to be in place to safely and securely move or transport waste out of the containment zone to a designated decontamination area |
| 3.7.14 | Decontamination technologies to be provided with monitoring and recording devices that capture operational parameters. |
| 3.7.15 | An autoclave, where present, to be capable of operating at the appropriate temperature for decontamination, as determined by validation |
| 3.7.17 | Vacuum systems to be equipped with a mechanism that prevents internal contamination |
| 3.7.18 | Two-way communication system(s) to be provided inside the containment barrier that allows communication between inside the containment barrier to outside the containment zone, in accordance with function. |

### 4.4 Standard Operating Procedures (SOPs)

SOPs are detailed, step-by-step procedures that are introduced during training, and are read prior to performing the procedure for the first time, for re-familiarization with procedures that

are performed infrequently, and whenever the SOP is amended. They provide documentation that can be reviewed by internal or external auditors and can facilitate evaluation of compliance with program requirements. Safe work practices and SOPs specific to the containment zone (e.g., personal protective equipment [PPE], entry and exit procedures, and waste management) are developed to address specific biosafety issues for the containment zone and added to the Biosafety Manual so that they are documented and accessible for all containment zone personnel.

While each biosafety protocol is likely to have unique requirements, there are some standard procedures common to all biosafety work. The standardization of common SOPs makes it easier for all end-user to be consistent in the application of safe working practices and the development of training modules. The SOPs listed in table 4.3.A were developed by the IBC, the UFV Biology Department Biosafety Committee, and the UFV Kinesiology Physical Education Department Biosafety Committee and have been made available for use by UFV faculty, staff, and students. As these are standardized SOPs, changes may not be made without the approval of the UFV IBO or IBC.

Table 4.3.A UFV Standardized SOPs

| SOP Identifier | Title |
|---|---|
| UFV-BS01 | Safe Operational Practices for CL1 Facilities |
| UFV-BS03 | Good Microbiological Laboratory Practices for CL2 Facilities |
| UFV-BS05 | Biosafety Training for CL1, CL2 facilities |
| UFV-BS07 | Pathogen Risk Group Assessment |
| UFV BS011 | Operation and Monitoring of Autoclaves |
| UFV-BS013 | Clean Up of Risk Group 2 Biohazardous Spills |
| UFV-BS015 | Decontamination of RG2 Biohazardous Laboratory Waste |
| UFV-BS017 | Operational Practices and Certification of Biological Safety Cabinets |
| UFV-BS019 | Transport of Biohazardous Materials between Containment Zones |
| UFV-BS021 | Operational Practices for Handheld Portable Lactate Analyzers |

| | |
|---|---|
| UFV BS23 | Operational Practices for Saliva Collection and Handling |
| UFV BS25 | Operational Practices for Human Urine Collection and Handling |
| UFV BS27 | Operational Practices for Measuring Maximal Aerobic Capacity Using a Metabolic Cart |

### 4.5 Personal Protective Equipment (PPE)

PPE acts as a barrier between the worker and exposure to biohazardous material and is designed to reduce the risks of transmitting infectious agents to the worker and the public. PPEs provide an additional layer of protection in the event of a failure in administrative or engineering controls. The necessity of PPE is determined by the IBO as part of the Biosafety permit application process and the LRA.

At a minimum, all personnel working within CL1 or CL2 facilities must wear full shoes with no or low heels, long pants or a garment covering the legs and must don a lab coat when entering the facility. This level of protection is intended to prevent splashes from directly contacting the skin. Within CL2 facilities, lab coats must be stored within the facility and may not be removed from the premises without prior decontamination. Personal belongings, such as coats, bags, and backpacks should be stored in an area outside of the containment area.

Additional PPE can include, but is not limited to:

- Gloves: Gloves protect the hands from direct contact with biohazardous materials and reduces the chances of a laboratory acquired infection (LAI) associated with ingestion of infectious agents or toxins.
- Eye and Face Protection: There are many different types of eye and face protection that can be used to shield the eyes, nose, or mouth from flying objects or splashes from infectious liquids or toxins. The type of eye and face protection selected will depend on the degree of coverage needed for the specific task at hand. Safety glasses protect the eyes from injuries associated with larger objects, including chips, fragments, sand, and dirt, as well as minor splashes. Safety goggles provide a higher level of protection due to the snug fit over and around the eyes, which creates a barrier to liquid hazards. Face shields provide coverage of the nose, mouth, and skin, in addition to the eyes. Depending on the type of protective eye and face equipment selected, prescription eye glasses may be worn underneath; safety glasses can also have prescription lenses.

- Respiratory Protection: At UFV respirators are not normally used in CL1 or CL2 facilities. Instead, a biological safety cabinet (see BSM 4.6) is used to mitigate exposures to aerosols. If the IBO deems that respirators are necessary, a fit tested respirator such as N95 disposable respirator or a half face respirator with P100 cartridges may be recommended. Annual fit tests are required if using a respirator.

## 4.6 Containment Equipment

Some containment equipment is common in lab settings not specifically handling biohazardous material. The CBH reviews and addresses potential biosafety concerns when using this equipment with infectious agents or toxins. The material from the CBH has been reproduced here for your convenience.

### 4.6.1 Biological Safety Cabinets

Biological safety cabinets (BSC) provide effective primary containment for work with biohazardous materials and should be used in conjunction with good microbiology laboratory practices (see SOP UFV BS03). CL2 laboratories at UFV contain class II type A BSCs.

- All personnel using BSCs, whether working with biohazardous material or not, must receive training on SOP UFV BS17
- BSCs in CL2 laboratories must be inspected and certified annually or whenever they are moved
- When used correctly, airflow is directed inward through HEPA filters protecting workers and the environment from exposure to biohazardous material.
- BSCs are designed to have only one person working in them at a time
- BSC must be properly located away from areas of high traffic, air vents and opening doors to prevent disrupting normal airflow.
- During the LRA the IBO will determine if the use of a BSC to contain Risk Group 2 biohazardous aerosols is required. The decision about whether or not a BSC is required is based on the actual material being used, the concentration and volume of pathogen in use, whether or not the procedures generate significant aerosols, and the qualifications and experience of personnel

### 4.6.2 Centrifuges

There is a risk of infectious aerosol generation when a centrifuge is used (e.g., tube breakage, improper use of safety cups or rotors, or lack of proper maintenance). The following points highlight some requirements and recommendations for centrifuge use when working with infectious material or toxins:

- The outside surface of cups and rotors should be decontaminated, as required.
- Equipment should be used in accordance with the manufacturer's instructions, which includes the balancing of rotors to prevent rotor damage or explosion.
- Plastic tubes that are suitable for centrifugation should be used (e.g., thick wall external thread plastic tubes with screw caps).
- Sealed centrifuge cups or rotors are to be used to prevent the release of aerosols during centrifugation, and the integrity of the cup or rotor seal regularly inspected.
- Cups and rotors with samples of infectious material or toxins are to be unloaded inside a biological safety cabinet (BSC) to protect against the release of infectious aerosols or aerosolized toxins
- Sufficient time for aerosols to settle should be allowed prior to opening cups and rotors.
- The use of centrifuges inside a Class II BSC will disrupt the airflows and compromise the protection provided by the BSC, and should be avoided.

### 4.6.3 Microtomes

Microtome work with infectious material or toxins that may not have been inactivated by fixation should be performed in a low traffic dedicated area (e.g., taped off) to prevent tracking of wax shavings within or out of the containment zone. Care should be taken as the floors in histopathology areas tend to be quite slippery from the wax. Disposable shoe covers, dedicated to this area, should be worn; slip-resistant shoe covers are recommended for such areas. Respiratory protection should also be worn if deemed necessary by an LRA. Troughs may be installed on the edge of the work bench to contain excess shavings. Care should be taken when installing or removing microtome blades; non-disposable blades can be cleaned with an instrument, rather than by hand, to prevent contact with the blade. When manipulating tissue potentially infected with pathogens or prions, additional personal protective equipment (PPE) such as cut-resistant gloves can be worn to reduce the risk of exposure or injury.

### 4.6.4 Blenders, Sonicators, Homogenizers, Shaking Incubators, and Mixers

The operation of blenders, sonicators, homogenizers, mixers, shaking incubators, and other similar equipment can generate aerosols. The following points highlight some requirements and recommendations when using these types of equipment:

- Laboratory equipment and associated accessories specially designed to contain infectious aerosols can be used for manipulations of pathogens and toxins. For example, cup horn sonicators allow sonication of samples within a contained vessel without direct contact with the material being processed.
- When equipment designed to contain infectious aerosols is not available, equipment should be operated in a BSC (only if the equipment does not disrupt airflow patterns) or another primary containment device.
- Time for aerosols to settle should be allowed before opening or removing the covers.

### 4.6.5 Bunsen Burners

Bunsen burners are commonly used for heating (e.g., fixing cells onto slides) and sterilization (e.g., inoculation loops). Aerosolization of infectious material can occur when inoculation loops are sterilized in the open flame of a Bunsen burner; microincinerators or disposable loops are recommended as alternatives. Sustained open flames are prohibited from use inside a BSC as they will disrupt the airflow patterns, decrease the user protection provided by the air curtain, and have the potential to damage the filters. When suitable non-flame alternatives are not available, touch-plate microburners that provide a flame on demand may be used.

### 4.6.6 Microincinerators

Microincinerators can be used as an alternative to Bunsen burners, especially for use in a BSC. They are often equipped with shields to minimize the dispersal of infectious aerosols. When used in a BSC, the microincinerator should be placed at the rear of the working area inside the cabinet to help minimize disruption of the air curtain at the front of the cabinet.

### 4.6.7 Disposable Loops

Single-use disposable loops are sterile and can be used in a BSC as an alternative to reusable loops that require sterilization with a burner or microincinerator; however, they will add to the amount of waste requiring decontamination. Disposable loops should be placed in a leak-proof, puncture-resistant waste container immediately after use.

### 4.6.8 Pipetting Aids

Pipetting aids minimize the risk of aerosol generation when used properly; they also eliminate the risk of ingestion of infectious material through oral pipetting, which is prohibited at all containment levels. Discharging liquid from a pipette and the aspirate/expel action used to mix cultures can create aerosols. The following points highlight some requirements and recommendations for the safe use of pipetting aids:

- use a BSC when pipetting infectious material or toxins;
- work over plastic-backed absorbent material; the droplets will be absorbed rather than "splash";
- use pipettes calibrated "to deliver", which reduces the risk of creating aerosols by retaining the last drop in the tip;
- use plastic pipettes instead of glass pipettes whenever possible;
- use filtered serological pipettes with pipette aids and filtered pipette tips with micropipettors, as these will prevent contamination of the pipetting device;
- use appropriate decontamination procedures for pipette aids and micropipettors when non-filtered tips are used or when the pore size of the pipette filter is insufficient for filtering the pathogen(s) or toxin(s) in use;
- don't mix liquids by bubbling air from a pipette through the fluid or by alternate suction and forceful expulsion through the pipette;
- discharge liquids as close as possible to the wall of the tubes or to the surface of media;
- avoid forcefully aspirating or expelling liquids from the pipette;
- pipet tips can be ejected directly into a container (e.g., bottle, beaker) for subsequent decontamination or bag for autoclaving; and,
- pipettes should be decontaminated with a suitable disinfectant immediately after use;
    - Serological pipettes can be laid horizontally in a pan and completely immersed in a disinfectant (care should be taken when moving the pan to avoid a spill hazard); or
    - Serological pipettes can be filled with disinfectant and left to drain by gravity into an oversized waxed cup in an autoclave bag (the bag can be closed over the pipettes and this can be autoclaved as a whole in an upright position before reuse).

### 4.6.9 Vacuum Pumps and Systems

Vacuum systems are used to create a void in filtration units and to aspirate liquids. The most common laboratory vacuum systems are centralized vacuum (void) systems, vacuum pumps, or a faucet aspirator vacuum pump attached to the water supply. The primary concern with vacuum pumps is that the process of aspiration can cause the aerosolization of infectious material or toxins, and subsequent contamination of the vacuum line and pump or system. A device (e.g., in-line high efficiency particulate air [HEPA] filter or 0.2 µm filter with disinfectant traps) is used to protect the vacuum system from internal contamination. A maintenance program for the regular inspection and replacement of in-line filters will help prevent a breach in filter integrity and containment. For high containment zones, the use of portable vacuum systems instead of centralized vacuum systems will minimize the risk of a containment breach.

### 4.6.10 Chemical Fume Hoods

Chemical fume hoods are designed for the manipulation of chemical substances, particularly volatile substances. Materials exhausted from chemical fume hoods are filtered with recirculation of the remaining air stream, or exhausted directly to the outside atmosphere. If required, filters are selected according to the type of contaminant to be removed, the efficiency required to meet occupational and environmental exposure limits, and the required residence time. Locating filters upstream of the exhaust fan, and in such a way as to allow replacement without contaminating the surrounding area, keeps contaminated ducts under negative pressure and prevents the release of chemical substances. Testing and replacement should be more frequent for filters used to trap chemicals that are capable of degrading the filter. It is the responsibility of the facility to determine the compatibility of specific chemicals with various filters, and to determine the appropriate replacement frequency. The inclusion of exhaust air treatment devices (e.g., activated carbon filters) are to be consistent with applicable local regulations.

Chemical fume hoods are not designed for the manipulation of infectious material or toxins, and consideration should be given to minimizing the placement of chemical fume hoods in high containment zones; instead, Class II B2 BSCs, which are designed to handle infectious material or toxins as well as volatile chemicals and radionuclides, should be considered. Fume hoods that are located in high containment zones are to comply with the requirements for HEPA filtration of exhaust (CBS Matrix 3.5). Chemical fume hoods should not be located directly opposite or in close proximity to BSCs in order to prevent disruption of the protective air curtain. The installation of a HEPA filter upstream of the charcoal filter is recommended as a measure to protect the charcoal filter from contamination with infectious material and toxins.

### 4.6.11 Cell Sorters

Cell sorters are used to physically separate a defined subpopulation of cells from a heterogeneous cell population. The risk associated with cell sorters can be attributed to both the nature of the sample (i.e., the presence and type of the infectious material or toxins in the sample), and to the equipment itself (e.g., the use of droplet-based cell sorting, which uses jet-in-air technology that can produce aerosolized droplets). Droplet-based cell sorting involves the injection of a liquid stream carrying the cells through a narrow nozzle that vibrates at a high frequency. High-speed cell sorters with jet-in-air technology use even higher pressures and nozzle vibration frequencies, and consequently produce a large amount of aerosolized material. An LRA can be conducted to determine the physical containment and operational practices necessary to safely work with infectious material or toxins in a cell sorter. A cell sorter may need to be housed inside a ventilated enclosure that is custom-built by the same manufacturer for use with pathogens and toxins if it is not able to be housed inside a BSC.

### 4.6.12 Additional Equipment Considerations for Prions

The following are additional equipment considerations for containment zones dedicated to prion work:

- dedicated laboratory work areas and equipment should be used, where possible;
- disposable equipment and laboratory supplies should be used when handling material known to contain prions;
- blunt cannulas can be used in place of needles; the use of needles, syringes, and other sharp objects are to be strictly limited.
- plasticware can be used in place of glassware; and
- instruments should be kept moist until decontamination.

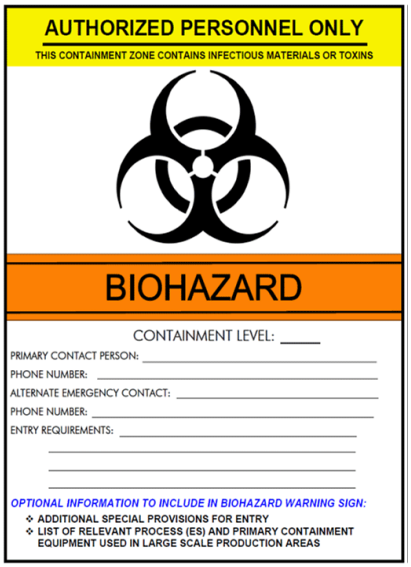
### 4.6.13 Additional Equipment Considerations for Toxins

The following are additional equipment considerations for toxin work:

- plasticware should be used in place of glassware;
- thin-walled glassware should be avoided; and
- glass chromatography columns should be enclosed in a secondary container.

## 4.7 Signage

All level 1 and level 2 facilities must display a biohazard warning sign at the points of entry into the containment zone. An example of a standard biohazard sign used at UFV is shown below.




Properly displayed Biohazard warning signage must include the international biohazard warning symbol, containment level, name and telephone numbers of a contact person, and entry requirements. In addition, anyplace where biohazardous materials are stored (e.g., refrigerators, freezers, cupboards) must also prominently display a biohazard warning sign.

## 4.8 Emergency Response Plan

An emergency response plan (ERP) outlines the necessary steps to be taken in the event of a biohazardous event or incident. The ERP plan is essential to protect lives and safeguard the environment. UFV's Risk and Safety office has developed an overarching ERP for facilities at UFV that addresses response measures relevant to any foreseeable situations such as: accidents, medical emergencies, fires, spills, power failure, animal escape, or natural disasters. In addition, UFV's SOPs BS11 Operation and Monitoring of Autoclaves, BS13 Control of Biohazardous Spills, BS15 Decontamination of Infectious Materials, and BS17 Biological Safety Cabinet: Certification and Use are available for review in case of a biological spill or failure of the biological safety cabinet.

Matrix 4.9 of the CBS specifies the minimal requirements and has been reproduced here for your convenience.

| CBS Identifier | CL2 Requirements |
|---|---|
| 4.9.1 | The ERP is to describe emergency procedures applicable to the containment zone for:<br>• accidents/incidents;<br>• medical emergencies;<br>• fires;<br>• chemical/biological spills (small/large; inside/outside BSC and centrifuge);<br>• power failure;<br>• animal escape (if applicable);<br>• failure of primary containment devices;<br>• puff-back from class II B2 BSCs, where present;<br>• loss of containment;<br>• emergency egress;<br>• notification of key personnel and relevant federal regulatory agency (or agencies);<br>• natural disasters;<br>• incident follow-up and recommendations to mitigate future risks |
| 4.9.2 | ERP to include procedures for any infectious material or toxins stored outside the containment zone |
| 4.9.7 | Incidents involving pathogens, toxins, other regulated infectious material, infected animals, or involving failure of containment systems or control systems to be reported immediately to the appropriate internal authority |

| | |
|---|---|
| 4.9.8 | Incident investigation to be conducted and documented for any incident involving pathogens, toxins, other regulated infectious material, infected animals, or failure of containment systems or control systems, in order to determine the root cause(s). |
| 4.9.9 | The Public Health Agency of Canada (PHAC) to be informed without delay via the submission of an exposure notification report following:<br>• an exposure to a human pathogen or toxin; or<br>• recognition of a disease that has or may have been caused by an exposure to a human pathogen or toxin. |
| 4.9.10 | An exposure follow-up report documenting the completed investigation, to be submitted to the PHAC within:<br>15 days of the submission of an exposure notification report involving a security sensitive biological agent (SSBA); or<br>30 days of the submission of an exposure notification report involving a human pathogen or toxin other than an SSBA. |
| | |

Emergency response procedures must be in place for any incidents that might occur while handling biohazardous materials. Each facility's Emergency Response Plan should contain SOPs to address those items listed in CBS section 4.1.10 and section 4.9. UFV SOP BS13 describes procedures to follow in the event of a biohazardous material spill and an incident report form can be found in BSM Appendix 6.

The CBS recommends annual emergency response training for existing personnel and immediate training for any new personnel. The Emergency Response Plan, for a specific containment zone, must be posted and clearly visible. All personnel must be familiar with the contents of the protocol and know where it is posted.

If you are not able to, or if is unsafe for you to clean up the spill, evacuate the lab, post a "Do Not Enter" sign on the door and immediately contact UFV security at 1-855-239-7654 (local 7654).

### 4.8.1 Spill Response Procedures

Spills are the most likely incidents to occur that require an emergency response. The nature of the spill will determine the appropriate response. For example, spills have the potential to expose personnel to pathogens or their toxins, contaminate surfaces or equipment or to produce aerosols. Each CL2 facility is required to have a biological spill kit (BSK) to facilitate an effective spill response and all personnel are to be adequately trained to follow the spill response procedures.

### 4.8.2. General Spill Clean-Up Procedure

After the risk of injury has been controlled, the following steps are recommended to contain a spill of infectious material and decontaminate the area affected by a spill:

1. Remove any contaminated or potentially contaminated clothing and personal protective equipment (PPE).
2. Contaminated personnel doff their outer layer of PPE and any contaminated or potentially contaminated clothing and follow normal exit procedure, including hand washing. In the case of a large spill, personnel remove the outer layer of protection in proximity to the spill. Depending on a local risk assessment (LRA) and SOPs, personnel may proceed to a change room to remove the inner layer of PPE, which is placed into an autoclave bag for decontamination. Personnel proceed to wash any other potentially contaminated parts of their body.
3. Notify all staff in the immediate vicinity that a spill has occurred and to leave the area.
4. Exposed persons should be referred for medical attention. The laboratory supervisor or responsible authority should be informed without delay and Security contacted for large spills.
5. Allow aerosols to settle (e.g., for 30 minutes) before re-entering the area. If the laboratory does not have a central air exhaust, entry should be delayed (e.g. for 24 hours) to allow sufficient air exchanges to exhaust any aerosols and to allow heavier particles to settle. Signs should be posted indicating that entry is forbidden.
6. Don fresh PPE appropriate to the risk, which may include gloves, protective clothing, face and eye protection, and a respirator.

7. Assemble required clean-up materials (e.g., biological spill kit) and bring them to the site of the spill.
8. Cover the spill with cloth or paper towels to contain it.
9. Pour an appropriate disinfectant (i.e., sufficient concentration, effective against the pathogen(s) spilled, freshly prepared) starting at the outer margin of the spill area, and concentrically working toward the center, over the cloth or paper towels and the immediately surrounding area.
10. After the appropriate contact time (i.e., for the pathogen and disinfectant), clear away the towels and debris. If there is broken glass or other sharps involved, use a dustpan or pieces of stiff cardboard to collect and deposit the material into a puncture-resistant container for disposal. Glass fragments should be handled with forceps. Dustpans can be autoclaved or placed in an effective disinfectant.
11. Clean and disinfect the area of the spillage. If necessary, repeat the previous steps.
12. Dispose of contaminated materials in a leak-proof, puncture-resistant waste disposal container.
13. Once the spill clean-up is complete, as per the general spill clean-up procedure, personnel doff contaminated PPE and don clean PPE prior to returning to work in the laboratory.
14. After disinfection, inform the appropriate internal authority (e.g., containment zone supervisor, IBO) that the site has been decontaminated.
15. Depending on the nature and size of the spill, a complete room decontamination may be warranted.

### 4.8.3 Spill Inside a Biological Safety Cabinet

The size of the spill is determined by how far it spreads, and less by its volume. When a small spill occurs inside a BSC, the worker is not considered contaminated unless a splash or spillage has escaped the BSC; however, the gloves and sleeves may be contaminated. A large spill in a BSC may result in material escaping the BSC and the worker becoming contaminated. In this case, the outer layer of PPE is considered potentially contaminated and should be removed at the BSC. The following general procedure is recommended for spills inside a BSC:

1. Remove gloves and discard within the BSC. If two pairs are worn, discard the outermost layer. If sleeves are potentially contaminated, the lab coat or gown should also be removed. Fresh gloves should be donned and if necessary, also a fresh lab coat or gown.
2. Leave the BSC blower on and the sash at the appropriate level.

3. Follow the instructions outlined in for general spill clean-up, keeping head outside the BSC at all times.
4. Surface disinfect all objects before removing them from the BSC, or place them into bags for autoclaving. Remove contaminated gloves and dispose of them inside the cabinet.
5. Place PPE into bags for autoclaving.
6. If material has spilled through the grill of the BSC, pour disinfectant through the grill to flood the catch tray underneath.
7. Wipe all inside surfaces with disinfectant.
8. Raise the work surface, clean the catch tray, and then replace the work surface.
9. Allow BSC to run for at least 10 minutes before resuming work or shutting down.

### 4.8.4 Spill inside a Centrifuge

If a breakage occurs or is suspected while a centrifuge is running, the motor should be switched off and the centrifuge left closed (e.g., for 30 minutes) to allow aerosols to settle. Should a breakage be discovered only after the centrifuge has been opened, the lid should be replaced immediately and left closed (e.g., for 30 minutes).

1. Inform the appropriate internal authority (e.g., containment zone supervisor, IBO).
2. Follow the instructions outlined in for general spill clean-up.
3. If possible, use a non-corrosive disinfectant known to be effective against the pathogen concerned. Whenever possible, consult the centrifuge manufacturer's specifications on the unit to confirm the chemical compatibilities.
4. All broken tubes, glass fragments, buckets, trunnions, and the rotor should be placed in a non-corrosive disinfectant (forceps are to be used to handle and retrieve glass and other sharps debris). Unbroken sealed safety cups may be placed in disinfectant and carried to a BSC to be unloaded.
5. The centrifuge bowl should be swabbed with the same disinfectant, at the appropriate dilution, and then swabbed again, washed with water, and dried.

### 4.8.5 Spill Clean Up Kit

To facilitate a quick response to spills of biohazardous materials, each CL2 facility must contain a spill clean-up kit containing the following:

- Disposable gloves

- Disposable gown
- Respirator N95
- Effective disinfecting agent (Clinicide or 5% bleach)
- Paper towels
- Dustpan and broom
- Tongs
- Biohazardous autoclave bags
- Waterproof copy of spill clean up SOP UFV BS13

### 4.8.6 Medical Emergencies

Procedures for workplace emergencies are listed under UFV Risk & Safety and are found within the UFV Emergency Procedures Guide (EPG). The EPG states the following for any Chemical, Biohazard, or Radiation Spill:

Any uncontrolled release of hazardous materials is considered a spill and these procedures must be followed:

- Evacuate immediate area. If able, shut down equipment.
- Isolate area and notify others in the area to prevent re-entry.
- Stay calm and evacuate in a quick and orderly manner.
- Close doors on your way out, but ONLY DO SO IF IT IS SAFE.
- Upon exiting the building, proceed directly to an area that is at a safe distance outside the main entrance of the building and wait for emergency personnel. Provide emergency personnel with information on hazardous materials involved (e.g. Safety Data Sheets (SDS)).
- Call 911
    - State your name.
    - Give the address where the spill is and the nearest intersection.
    - Provide information about the spill:
        - Injuries
        - Chemical Name

  - Quantity
  - Hazards (Information on SDS)
- Call Security at 1.855.282.7770 (Emergency)
- Inform Supervisor or Department Head.
- DO NOT RE-ENTER THE BUILDING until the Fire Department gives permission to do so

### 4.8.7 Accidental Contact with Biohazardous Material

- Immediately inform Supervisor or Lab instructor who will contact UFV Security
- Rinse for 15 minutes with water at the emergency wash station
- Remove contaminated clothing or lab coats for autoclaving
- Have your supervisor complete a UFV incident report form

### 4.8.8 Accidental Needle sticks or cuts involving Biohazardous Material

- Immediately inform Supervisor or Lab instructor who will contact UFV Security
- Wash with soap and water
- Apply a bandage if necessary
- Have your supervisor complete a UFV incident report form

### 4.8.9 Animal Emergencies

The health and welfare of animals used in research or for teaching purposes falls under the guidance of the UFV Animal Care Committee (ACC). The ACC maintains an external contract with a local Veterinarian. For more information contact Animal Care at acc@ufv.ca or 604-557-4011

## 4.9 Medical Surveillance Program

The purpose of a medical surveillance program (MSP) is to help prevent and detect illnesses due to the exposure of personnel to biohazardous materials. An MSP identifies the biohazardous material handled or stored in the containment zone and identifies any risks. The MSP complements UFV's medical emergency procedures and is part of UFV's emergency response plan.

Personnel who work in areas where biohazardous materials are used, have an increased risk of contracting a Laboratory Acquired Infection (LAI). The MSP needs to be appropriate to the

agents in use, and as such, it is reviewed by the IBO as part of the local risk assessment which is performed as part of the Biohazard Permit Application process. The LRA will determine if a specific MSP is required for each biosafety application. If required, the program may include: a medical examination; serum screening; immunizations; testing and/or storage; and possibly other tests as determined by the risk assessment process. The requirements for an MSP are specified in the CBS matrix 4.2 and are reproduced here for your convenience.

| CBS Identifier | CL2 Requirement |
|---|---|
| | |
| 4.2.2 | Containment zone personnel to immediately inform appropriate internal personnel or authority of any:<br>• Incident that may have resulted in an exposure of an individual to a human pathogen or toxin in a facility; or disease that may have been caused by an exposure to a human pathogen or toxin in a facility. |
| 4.2.4 | Emergency medical contact card to be issued to containment zone personnel handling non-human primates or a pathogen identified by a local risk assessment (LRA). |

The risks to lab personnel should be reviewed in order that they each gain an understanding of the biological hazards as they relate to personal immune system susceptibility and medical conditions. Appropriate risk mitigation methods must then be employed.

### 4.10 Incident Reporting at UFV

All incidents involving infectious material, infected animals, or toxins, such as a containment systems failure, an exposure to a human pathogen or toxin, or release of an animal pathogen, must be reported immediately to the Principal Investigator (PI) or laboratory supervisor. The PI or lab supervisor will report to the UFV IBO and complete an incident report (UFV BSM appendix 6). The IBO, or designate, will make an initial assessment, and may conclude that reporting to senior management and the PHAC is required. As stated in the CBS, all persons working under the authority of a licence are legally obligated to notify the appropriate facility personnel if they have reason to believe that an incident has occurred involving inadvertent

release, inadvertent production, disease (i.e., any exposure incident), or a missing human pathogen or toxin.

Incident reports help to protect the health and safety of students and university employees and are a key to assessing the most important areas for additional training at the university. Therefore, reporting any lab incidents in a timely manner is a critical part of the safety process.

### 4.10.1 Incident Report Procedure

Note: Extremely small spills, e.g., from a culture tube onto a laboratory bench of not more than 10 mLs, do not require to be reported to the IBO. However, the supervisor or member of faculty present must be notified of the spill. If in doubt, contact the IBO immediately.

**General Procedure**

- Immediately contact the PI or Lab supervisor
- If required, contact 911 for emergency help and/or UFV first aid (1-855-282-7770 or local 7770 from any UFV phone) and/ or UFV security (1-855-239-7654)
- PI, lab instructors, or lab technicians should fill out an Incident report form (UFV BSM appendix 6) and contact the UFV IBO as soon as possible (within 24 hours) after the incident
- Laboratory instructors, laboratory technicians, or principal investigators can submit an incident report.
- Types of incidents that are reportable include, but are not limited to:
    - Spill or accident involving infectious substance
    - Spill or accident with material that may have become infectious through storage (i.e., potential media for microorganisms allowing for their growth)
    - Personal exposure such as a spill or splash to the eyes, nose, or mouth of infectious substance
    - Personal injury such as a needle stick injury, exposure of a cut to infectious substance, or potential inhalation of a biohazardous substance
    - Breach of containment or failure of a primary containment device (e.g., BSC)
    - When a human pathogen or toxin has caused, or may have caused, a LAI

- When there is reason to believe that a human pathogen or toxin has been stolen or is otherwise missing

A UFV Incident Report form can be found in BSM Appendix 6.

### 4.11 Moving and Transporting Biohazardous Materials

Movement of biohazardous materials can take different forms. For example, pathogens can be moved from one area within a containment zone to another (e.g., bench top to centrifuge) or from one containment zone to another zone in the same building (e.g., from a student lab in one zone to an autoclave for disposal in another zone). However, movement of biohazardous material from one building to another falls under the Transportation of Dangerous Goods Regulations (TDGR) which must be followed (BSM 4.11.3) if transported on a public roadway.

#### 4.11.1 Moving Biohazardous Materials within the Same Containment Zone

When moving infectious material or toxins within a containment zone the infectious material or toxins should be adequately protected from being dropped, tipped, or spilled. The precautions taken by personnel to prevent mishaps should correlate with the inherent risk associated with the infectious material or toxins (i.e., the greater the risk associated with the material, the greater the care that should be taken when moving it).

Closed containers provide primary containment for the movement of infectious material and toxins. Moving infectious material or toxins within a containment zone using closed containers, in conjunction with a cart, when necessary (e.g., for large number of specimens, large volumes, or heavier items), will help reduce the likelihood and extent of a drop, spill, or leak. Labelled containers will promote timely and appropriate spill response and post-exposure follow-up in the event of a spill or leak. Leak-proof, impact-resistant containers are recommended, and specially designed containers equipped with lid clamps are commercially available. Externally threaded tubes with screw caps should be used instead of snap-cap tubes or internally threaded tubes with screw caps to prevent leaking and minimize contamination of the lid surface. With higher risk agents and multiple samples, carts with rails or raised edges should be used and absorbent material placed on each cart shelf; cart pans may also be used. Samples should be loaded in a manner that will prevent them from being tipped or spilled if a collision occurs. Individuals should move slowly and with caution whenever carrying infectious material or toxins. Following established directional traffic and workflow patterns within the containment zone, based on a local risk assessment (LRA), will help facilitate the movement of

personnel and materials from "clean" areas (i.e., areas of lower contamination) to "dirty" areas (i.e., areas of higher contamination) in a manner that minimizes the spread of contamination. A biological spill kit available inside the containment zone allows for a prompt, appropriate clean-up in the event of a spill.

### 4.11.2 Moving Biohazardous Materials between Containment Zones Within the same Building

Using leak-proof and impact-resistant containers to move infectious material and toxins between containment zones in the same building will help prevent a spill or leak if a container is dropped. In the event that an incident occurs, such as the container is dropped, breaks, or its contents are spilled, the use of appropriate labels on the container to identify the contents and the hazards will assist with the appropriate response. Surface decontamination of containers performed prior to removal from the containment zone helps prevent the spread of infectious materials and toxins. This includes the movement of waste to a centralized decontamination area within the building, but outside the containment zone. Large or heavy items should be transported on carts and loaded in a manner that will prevent them from tipping. A cart designed with guard rails or raised edges can be considered to protect the items from falling off the cart during relocation. An emergency response plan (ERP) for infectious material or toxins stored outside the containment zone, and spill kits available outside the containment zone, will allow for a prompt, appropriate response in the event of a spill. Wet or dry ice used to keep specimens or samples cold during transit should always be used in accordance with the current requirements of the Workplace Hazardous Materials Information System (WHMIS). To prevent gas build-up, dry ice should never be placed inside an airtight secondary container.

### 4.11.3 Moving Biohazardous Materials between Containment Zones in Different Buildings or on Different Campuses

UFV is a multi-campus university and as such transporting biohazardous material between campuses can occur. In addition, research projects may collect primary samples from off campus locations which require transportation to containment zones within the university.

Under these circumstances, transportation of biohazardous materials requires documentation and should be packaged in labelled containers that are sealed, leak-proof, and impact-resistant (in accordance with the TDGR). Additionally, pathogen and toxin accountability measures (e.g.,

inventory) need to be considered when biohazardous materials are being transported and relocated between different locations.

## 5.0 Risk Control

### 5.1 Training

UFV's SOP BS05 lists the different personnel training groups and the associated training requirements for each group. All biosafety training programs at UFV share a common goal irrespective of the biohazardous material being handled. That goal is to educate and train UFV personnel about the potential biohazards present in their environment, and to establish mitigating practices that can protect them from these hazards. Due to the wide range of activities encountered by the various end-user groups, different training levels, containing different content, are necessary.

Regardless of the biohazardous material handled, biosafety training is not a one size fits all. Many activities may require one training module for one group (i.e., experienced faculty teaching a new lab) and a different module for inexperienced personnel. For example, students new to a lab activity are much more likely to expose themselves or others to an infectious agent compared to a highly experienced lab technician. During the LRA, the IBO or their designate will consider the training needs as part of the LRA. The IBO will help the PI or laboratory instructor develop an appropriate training program suitable for all personnel working under a specific biohazard permit.

A training program encompasses two related but very different instructional activities. The first is education which provides personnel with general information and theoretical knowledge. Educational training can take the form of classroom instruction, PowerPoint presentations, review of SOPs, pathogen safety data sheets, and posters. The second activity is a more hands on approach that demonstrates proper pathogen handling techniques, the proper use of PPE and trains personnel in the use of specific primary containment equipment (e.g., BSC or centrifuges). Individual SOPs, specific to the biohazardous material, the techniques used to manipulate this material and the facilities where the activities will be performed, can be developed, and used as both educational and hands on training resources.

#### 5.1.1 PI, Faculty, Laboratory Instructors and Laboratory Technician Training

For PI, faculty, laboratory instructors and laboratory technicians training related to the potential hazards associated with the work carried out is of the utmost importance, not only for themselves, but also for those who are under their supervision. Therefore, all previously untrained PI, faculty, lab instructors and lab technicians, regardless of the nature of the work

handled (i.e., CL1 or CL2), are required to undergo training protocols covering the material listed below. Training may include, but is not limited to, the following elements:

- Personnel should be familiar with the contents of the UFV BSM
- Understand the biosecurity measures developed for the containment zone they are using
- Be familiar with UFV's emergency response plan (ERP) and how to respond accordingly in a medical emergency
- Demonstrate proficiency with all required SOPs identified in the LRA
- Demonstrate proper use of all relevant primary containment equipment
- Be informed on the nature of the pathogens and toxins used in the working environment
- Know the signs and symptoms of diseases caused by the pathogens or toxins used
- Know the safe work practices and physical control measures associated with the biohazardous material in use
- Demonstrate the correct choice, use and proper donning and removal of PPE
- Understand the proper and effective decontamination and waste removal procedures for all biohazardous material in use

Training evaluations will be carried out by the IBO through a written online test and by hands-on evaluations by the IBO or their designate. Successful completion of training will be recorded and stored by the PI, Lab supervisor or their designate.

### 5.1.2 CL1 Training for Students Working Under Supervision

This level of training is for student groups that work with RG1 organisms or work within a CL1 containment zone and who are directly supervised by the PI or lab instructor. It may also apply to students working with PI permit holders that are handling human body fluids that have been designated by a LRA as CL1 biohazardous material (e.g., non in vivo work using sample sources from healthy individuals not likely to harbor an infectious agent).

Training of students is the responsibility of the PI or lab instructor. In conjunction with the IBO, the PI or lab instructor will develop training material. The PI or lab instructor will review with the students any pertinent LRA identified SOPs (e.g., SOP UFV BS01) and demonstrate safety

procedures deemed appropriate for the work being carried out and for the biohazardous material being used. Additional classroom material may also be included.

After all relevant material has been reviewed, the PI or lab instructor will administer an online test. The PI or lab instructor will record and store this material for the duration for the semester for course-based work and for the duration of the Biosafety permit for research-based work. Students must receive a grade of 70% before they are permitted to work with CL1 biohazardous material. At the request of the IBO, the PI or lab instructor will make available all related evaluation material.

The IBO may require retraining of any student demonstrating insufficient biosafety knowledge or who fails to follow all biosafety guidelines.

### 5.1.3 CL2 Training for Students Working Under Supervision

This level of training is for student groups that work with RG2 organisms or work within a CL2 containment zone and who are directly supervised by the PI or lab instructor. Note: CL2 training is required for all personnel that work within a CL2 containment zone whether they work with CL2 biohazardous materials or not. For example, room A336 on the Abbotsford campus is designated as a CL2 research laboratory. A336 is a multi-use room where undergraduate student projects are carried out. A student researcher, whose project does not handle CL2 biohazardous material, but is working within the A336 CL2 containment zone, is required to undergo CL2 level training. Exceptions are not permitted.

CL2 training will also apply to students working with permit holders that are handling human body fluids that have been designated by a LRA as potentially CL2 biohazardous material.

Training of students is the responsibility of the PI or lab instructor. In conjunction with the IBO, the PI or lab instructor will develop training material. The PI or lab instructor will review with the students any pertinent LRA identified SOPs which will include, at a minimum, UFV BS03, UFV BS13, any other SOP identified in the LRA, and demonstrate safety procedures deemed appropriate for the work being carried out and for the biohazardous material being used. Additional classroom material may also be included.

After all relevant material has been reviewed, the PI or lab instructor will administer an online test. The PI or lab instructor will record and store this material for the duration of the semester for course-based work, and for the duration of the Biosafety permit for research based work. Students must receive a grade of 70% before they are permitted to work with CL2 biohazardous

material. At the request of the IBO, the PI or lab instructor will make available all related evaluation material.

The IBO may require retraining of any student demonstrating insufficient biosafety knowledge or who fails to follow all biosafety guidelines.

### 5.1.4 CL2 Training for Students Working Without Supervision

This level of training is for a student who is working independently with RG2 organisms or working within a CL2 containment zone. Prior to the commencement of any work handling biohazardous material, the PI, or a qualified designate, will individually train the student on all SOPs identified in the LRA, which at a minimum will include, UFV BS03, 11, 13, and 15. In addition, students must receive training on:

- biosecurity appropriate for the containment zone and the biohazardous material in use
- proper use of all relevant primary containment equipment
- applicable spill clean-up procedures
- proper waste decontamination and disposal
- transport of CL2 biohazardous materials between containment zones

Upon completion of training, the PI will record the SOPs used for student training. The trainer and student will sign and date the form. The signed original form is to be kept by the PI or supervisor and made available to the IBO upon request.

Students are also required to complete a written test based on information in the UFV Biosafety Manual and the SOPs used for training. Records of completion are to be maintained by the PI, or Lab supervisor, or departmental assistant, or their designate, for the duration of the Biosafety permit.

The IBO may require retraining of any student demonstrating insufficient biosafety knowledge or who fails to follow all biosafety guidelines. The IBO, may at any time, inspect CL2 containment zones for compliance with UFV biosafety regulations. Any student researcher found in non-compliance will be required to immediately shut down their research until approval from the IBO is reinstated.

## 5.2 Biosecurity Plan

The CBS requires all licensed facilities working with biohazardous materials to develop a Biosecurity plan. Biosecurity refers to the security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of infectious material or toxins. The UFV biosecurity plan is to be implemented by all research and teaching laboratories that handle biohazardous materials.

As part of the LRA the IBO will review a biosafety permit application and assess the level of biosecurity risk posed by the biohazardous material being handled. A local biosecurity risk assessment (BSA) considers the inherent nature of the pathogen or toxin as well as the concentration, quantity, and state of the material. Biohazardous material is prioritized according to its biosecurity risk based on several key factors, including the consequences of malicious use, the ease of use of the material, and the impact of loss of material on the facility. The PHAC maintains the ePathogen website that contains information on the characteristics of many pathogens including if the pathogen is considered a security sensitive biological agent (ssb). In general, biosecurity risk can be assigned to three different levels.

- assets that are deemed to be at low risk of unauthorized access needing minimal management and control measures
- assets that are at medium or high risk of unauthorized access requiring moderate management and risk mitigation
- assets that are at very high risk require extensive management and controls.

In addition, the IBO will consider any potential dual use risks and outline appropriate mitigation strategies. Based on the conclusion of a biosecurity risk evaluation, the IBO has the authority to prohibit the use of any infectious material or toxin. Materials considered by the PHAC to be SSB agents are not permitted for use at UFV.

### 5.2.1 Inventory of Biohazardous Material

The first step of the biosecurity risk assessment is to identify all the relevant assets. The PI or senior lab instructor or senior lab technician must maintain a current inventory of all biohazardous material in their possession or under their administration. The inventory should routinely be updated as required and a printed copy or working file should be readily available to the IBO. The inventory information should include:

- Pathogen or toxin name
- State of the material including storage vessel (e.g., lyophilized vial, glycerol tube, serum in screw capped vial etc.)
- Quantity on hand
- RG level
- Disposal date (if appropriate)
- Storage location

### 5.2.2 Physical Security

Just like biosafety measures, biosecurity is not a one size fits all. Specific laboratories and containment zones have unique inherent characteristics and will contain a varied set of equipment and storage facilities. During the LRA the IBO consider these differences while performing the BSA. In general, the following elements are required for each of the different containment levels.

#### 5.2.2.1 CL1 Containment Zones

- Doors are to be kept closed unless the PI or lab instructor is present
- Doors are to be lockable and must be locked when the lab is not in use
- Access to the containment zone is restricted to authorized personnel

#### 5.2.2.2 CL2 Containment Zones

- Doors are to be kept closed at all times
- Doors are to be lockable and must be locked when the lab is not in use
- Access to the containment zone is restricted to authorized personnel
- Primary storage equipment, such as refrigerators or freezers, must be lockable or contained within a lockable area located outside of a shared room

### 5.2.3 Personnel

All CL1 and CL2 containment zones are restricted to authorized personnel only. Non-authorized personnel, such as 3rd party contractors or visitors, must be escorted by the PI, lab instructor or their authorized designate. All non-escorted personnel must have received the appropriate biosafety training for the containment zone they are in.

### 5.2.4 Incident Reporting

All incidents of unauthorized entry or access should be reported to security and the IBO. Missing pathogens or toxins, loss of keys or passwords should be reported to security and the IBO. Depending on the incident, the IBO may consider reporting the incident to local law enforcement and may be obligated to report the incident to the Public Health Agency of Canada (PHAC) under the conditions of licence.

## 5.3 Facility Inspection

To ensure that all facilities with CL2 areas follow the UFV BSM and all applicable biosafety guidelines from the CBS and CBH, periodic inspections will be undertaken by the IBO at regular intervals (yearly for A331 and A336 Abbotsford campus) and re-inspections may occur at anytime. In addition, PHAC regulators may also conduct periodic inspections.

### 5.3.1 Scheduling of Inspections and Issues of Non-compliance

The IBO, or designate, will inspect CL2 labs annually. In general, the IBO will schedule an inspection at the time of the biosafety permit application or renewal. If warranted, the IBO will issue a report identifying items requiring attention and suggest a time frame for conformance. A follow up inspection will be scheduled to address any concerns identified as requiring attention.

Labs that fail to address deficiencies identified by the IBO will be in non-compliance and the inspection results will be reviewed by the IBC. Options for the IBC are to allow the lab additional time for compliance (with the possibility of suspended work with biohazardous materials) or permit suspension until all deficiencies had been fully rectified.

## 6.0 Waste Decontamination and Disposal

The handling of any biohazardous material has the potential to contaminate the workplace. Therefore, to reduce the risk of pathogen release, it's essential that policies, plans, and procedures are in place to ensure all contaminated material is decontaminated and disposed of correctly. Decontamination is the process that renders the work area, and all the equipment and materials in it, safe and relatively free of microorganisms. Disposal refers to an acceptable process for the removal of decontaminated material from the containment zone. The requirements for waste management are specified in Matrix 4.8 of the CBS and are reproduced here. Additional guidelines can be found at the Standards Council of Canada website.

| CBS Identifier | CBS Requirement |
|---|---|
| 4.8.1 | Gross contamination to be removed prior to decontamination of surfaces and equipment, and disposed of accordingly |
| 4.8.2 | Disinfectants effective against the pathogen(s) in use and neutralizing chemicals effective against the toxin(s) in use to be available and used in the containment zone |
| 4.8.3 | Sharps to be discarded in containers that are leak-proof, puncture-resistant, and fitted with lids, or specially constructed for the disposal of sharps waste |
| 4.8.4 | Primary containment devices to be decontaminated prior to maintenance |
| 4.8.5 | All clothing and personal protective equipment (PPE) to be decontaminated when a known or suspected exposure has occurred. |
| 4.8.7 | Contaminated liquids to be decontaminated prior to release to sanitary sewers |
| 4.8.8 | Contaminated equipment, materials, and waste to be:<br>• decontaminated and labelled as decontaminated prior to cleaning, disposal, or removal from the containment zone or prior to removal from the animal rooms, animal cubicles, or post mortem rooms (PM rooms), as described in SOPs; or |

| | |
|---|---|
| | • placed in closed, labelled, and leakproof containers that have been surface decontaminated prior to removal from the containment zone, animal rooms, animal cubicles, or PM rooms, as described in SOPs for the safe and secure movement or transportation to a designated decontamination area or storage outside of the containment zone. |
| 4.8.10 | Decontamination technologies and processes to be validated prior to initial use and when significant changes to the processes are implemented or new pathogens are introduced |
| 4.8.11 | Decontamination technologies and processes to be routinely verified, as described in SOPs. Frequency of verification to be determined by a local risk assessment (LRA). |
| 4.8.13 | Contaminated bedding to be: removed at a ventilated cage changing station or within a certified biological safety cabinet (BSC) prior to decontamination; or decontaminated within containment cages. |

### 6.1 Decontamination of Biohazardous Agents

Decontamination can be achieved by several means, the most common of which are sterilization by moist heat (autoclave) and disinfection through chemical means. During the LRA the IBO will review any containment zone specific waste management procedures for effectiveness.

Sterilization is a process that eliminates all living microorganisms, including bacterial spores. Sterilization is absolute (i.e., there is no middle range of sterility). Given that toxins and prions are not living microorganisms, the concept of sterilization does not apply.

Disinfection is a process that eliminates most forms of living microorganisms but is less lethal than sterilization. The effectiveness of the disinfection process is affected by several factors, including the nature and quantity of microorganisms, the amount of organic matter present, the type and state of items being disinfected, and the temperature.

In general, decontamination processes and practices follow the following guidelines:

- Disinfectants effective against the infectious material in use, and neutralizing chemicals effective against the toxins and prions in use, are to be available in the containment

zone and used for contaminated or potentially contaminated material, including equipment, specimen and sample containers, surfaces, rooms, and spills

- Decontamination parameters (e.g., time, temperature, chemical concentration, humidity) consistent with the technology or method used are to be validated to demonstrate they are effective against the infectious material and toxins of concern under the conditions present
- Prions and toxins can be resistant to the chemical disinfectants commonly used to effectively decontaminate microorganisms due to their proteinaceous nature. When working with prions and toxins, a neutralizing chemical capable of denaturing and inactivating the toxins or prions is needed for effective decontamination in the containment zone
- Clear and strict procedures are to be in place to support routine decontamination and routine verification of the decontamination process
- Decontamination processes and methods are to be conducted in accordance with applicable federal, provincial or territorial, and municipal regulations
- Decontamination procedures are to be included in personnel training on the hazards and exposure/release mitigation strategies associated with the work being done. This includes information on the products used, and the factors influencing their effectiveness

## 6.2 Decontamination Processes

### 6.2.1 Autoclaves

The proper use of the autoclaves at UFV can be found in the SOP UFV BS11. For each biohazardous agent used in a containment zone and prior to the routine use of an autoclave for the decontamination of materials in that zone, the procedure employed must be verified as effective.

Biological indicators can be used to confirm that treatment parameters have been achieved throughout a representative load. Placing indicators at various locations throughout the representative load will enable conditions in different parts of the load to be monitored. The selection of an appropriate biological indicator is critical so that the resistance of the test organism adequately represents the resistance of the pathogens handled in the containment zone. In general, Geobacillus stearothermophilus spores are adequate for heat-based technologies and processes, whereas Bacillus subtilis spores can be used to validate chemical-based technologies and processes.

Validation of the decontamination processes is required prior to initial use and whenever significant changes are implemented or new pathogens are introduced so that decontamination procedures and standard operating procedures (SOPs) can be established, amended, or updated as necessary. Validation using representative loads is required annually. Performing validation tests on non-contaminated representative loads that simulate a batch of materials of similar type (e.g., gloves, plastics, liquids, reusable personal protective equipment [PPE]) and quantity (i.e., number of items or size) that will be regularly processed allows an operator to place indicators safely to demonstrate that appropriate decontamination parameters are achieved throughout the load (e.g., in the bottom, middle, and top of the batch of materials). By demonstrating this with a representative load, it can be extrapolated that similar conditions are achieved in a routine load (i.e., contaminated waste) of similar type and quantity.

### 6.2.2 Verifying the Autoclave Run

1. After decontaminated material has been removed from the autoclave, and prior to disposal, it is important to verify that the run has been effective (i.e., that all validated parameters have been reached). Biological indicators can be used for routine monitoring of the decontamination process.
2. Remove the indicator from the autoclaved material and visually inspect. When using a biological indicator, the material cannot be released for disposal or reuse until the results of the biological indicator are known.
3. Biological indicators require incubation for a pre-determined period of time before reading.

### 6.2.3 Chemical Disinfectants

Chemical disinfectants are generally used for the decontamination of surfaces and equipment that cannot be autoclaved (e.g., bench top surfaces, BSC), and for spills of infectious materials. It is important that containment zone personnel are knowledgeable about the products required for the disinfection of the infectious material and toxins with which they will be working, including the recommended directions for use (e.g., application method, concentration, contact time, PPE, first aid, disposal) and chemical characteristics (e.g., toxicity, chemical compatibility, storage stability, active ingredient, identity, concentration).

A 0.8% solution of Clinicide, (a quaternary ammonium compound) is recommended for universities, hospitals and veterinary clinics and has been verified to be effective for all biohazardous agents handled in UFV biology labs. For other areas within UFV, a typical testing procedure for laboratory in-use disinfectant testing is outlined below.

1. Apply a known quantity of the microorganism in use in the laboratory to a carrier material or vessel. This quantity should be representative of the concentrations typically encountered in the laboratory.
2. Apply the test disinfectant to the carrier material or vessel for the contact time used in the laboratory.
3. Neutralize the disinfectant to halt its action. This can be accomplished by dilution or addition of growth media or other suitable reagent known to neutralize the active ingredients of the disinfectant.
4. Assess the viability of the microorganism in a suitable growth medium.

If the microorganism survives, altering the contact time or concentration of the disinfectant, or both, may be required to achieve the desired level of disinfection.

### 6.3 Waste Disposal

Waste leaving the containment zone may be destined for disposal, movement or transportation to a designated decontamination area outside of the containment zone or transported off-site for decontamination via a third-party biohazardous waste disposal. Even if the waste has been thoroughly and effectively decontaminated prior to removal from the containment zone, it may not be acceptable to simply direct it to the normal waste disposal stream for eventual transfer to a local landfill.

Standard operating procedures (SOPs) for waste disposal are developed to support disposal of solid and liquid hazardous material in a manner that minimizes the risk of harm to personnel, the community, and the environment. The SOPs describe all aspects of waste disposal, including handling procedures, from the classification and segregation of infectious waste to decontamination method(s), to storage and disposal. The UFV BSM has included in the Appendix a waste disposal SOP to allow UFV personnel to consult protocols as needed.

When developing containment zone specific waste disposal SOPs, some aspects to consider are the quantity and type of waste that will be generated, as well as the availability of decontamination systems. Decontaminating all contaminated or potentially contaminated waste prior to disposal minimizes the risk of introducing the infectious pathogens or toxins used in the containment zone into the environment. Failure to follow SOPs can result in the unintentional release of infectious material or toxins from the containment zone, or personnel exposure. It's the responsibility of the PI or laboratory supervisor to ensure that proper procedures are followed, and that containment is not breached. It is also important to note that PI or lab supervisors remain accountable for all waste transported off-site for

decontamination, until the waste has been effectively decontaminated. Shipping records, validation reports, and records of verification of decontamination equipment used by third-party waste disposal companies can be maintained to demonstrate compliance with decontamination requirements specified in the CBS.

All manipulations and processes that will generate contaminated waste should be identified, and the waste categorized according to type. Developing specific handling procedures for each type of waste generated in the containment zone supports disposal of all waste materials in a safe manner. The choice of decontamination method is determined by the nature of the infectious material or toxin and the nature of the item being decontaminated. Typically, biohazardous waste at UFV falls into the general categories outlined below.

### 6.3.1 Biomedical Waste

Biomedical waste can be defined as waste generated in human and animal health care facilities, medical or veterinary research and training facilities, clinical testing, or research laboratories. Biomedical waste is segregated from the general waste stream as it requires decontamination prior to disposal.

Decontamination of all biomedical waste prior to disposal in the regular waste stream is essential for the protection of public health, animal health, and the environment. It is important to segregate and dispose of biomedical waste near the point that the waste is generated. For example, it is recommended that unbreakable discard containers (e.g., pans, jars) be placed at every workstation to collect microbiological laboratory waste such as contaminated pipette tips. In containment zones where multiple types of biomedical waste are generated, colour-coded waste holding bags or containers can be used to differentiate between types of waste.

It is important that the waste container used is suitable for the type of infectious waste generated. Human anatomical waste, blood and body fluids, and animal waste should be placed in impervious, leak- and tear-resistant waste bags. Waste bags should be sealed, placed in leak-proof containers, and stored in a freezer, refrigerator, or cold room to await decontamination. Reusable containers may be used, if they are decontaminated and cleaned after every use. Sharps waste is disposed of directly into a puncture-resistant container in accordance with National Standard of Canada (CAN)/CSA Standard CAN/CSA Z316.6, Sharps Injury Protection- Requirements and Test Methods- Sharps Containers). Broken glassware should never be handled with gloved or bare hands. Forceps, tongs, or a dustpan should be

used to pick up broken glassware and a wet paper towel held in tongs should be used to pick up tiny glass particles.

If waste is not decontaminated and disposed of immediately, it may be stored temporarily if it is in a designated area that is separate from other storage areas and clearly marked with a biohazard symbol. Some types of waste (e.g., human anatomical waste, animal waste) need to be stored in a refrigerated area to prevent putrefaction. Once materials have been decontaminated on-site, the biohazard symbol on the receptacle is removed or defaced to indicate that the infectious material has been inactivated. Decontaminated material may be disposed of as regular waste in areas of heavy traffic or public areas, provided that the facility has specific labelling procedures in place. In other cases, it may be necessary to transport waste off-site for decontamination and disposal. Whether the waste will be decontaminated on-site or off-site, placing waste in appropriate disposal containers promptly and labelling the containers accordingly will keep all infectious waste segregated from regular waste until decontamination and disposal.

Limiting the movement of waste disposal containers to the point of use in the work area, storage (e.g., dedicated area, cold room) or disposal areas, and connecting corridors, will help minimize the risk of release of pathogens and toxins, and personnel exposure.

#### 6.3.1.1 Microbiology Laboratory Waste

Microbiology laboratory waste consists of cultures, stocks, microorganism specimens, prions, toxins, live or attenuated vaccines, human and animal cell cultures, and any material that has come in contact with one of these. Inactivation of pathogens and toxins prior to disposal is a critical step in preventing release of harmful material into the environment. Microbiology laboratory waste is no longer considered biomedical waste once it has been effectively decontaminated.

#### 6.3.1.2 Human Blood and Body Fluid Waste

Human blood and body fluid waste consist of all human blood or blood products, all items saturated with blood, any body fluid contaminated with blood, and body fluids removed for diagnosis. Human blood and body fluid waste is no longer considered biomedical waste once it has been effectively decontaminated.

#### 6.3.1.3 Sharps Waste

Sharps waste consists of needles, syringes, blades, or glass contaminated with infectious material and capable of causing puncture wounds or cuts. This can include pipettes and pipette tips that have come into contact with infectious material or toxins, unless they have been decontaminated prior to disposal. Using puncture-resistant containers located close to the point of use minimizes the risk of injury during handling. Sharps waste may be reduced by product substitution for some applications. Sharps waste is no longer considered biomedical waste once it has been effectively decontaminated.

#### 6.3.1.4 Human Anatomical Waste

Human anatomical waste consists of all human tissues, organs, and body parts, excluding hair, nails, and teeth. Even after disinfection or decontamination, human anatomical waste is still considered biomedical waste and may require special means of disposal (consult with the IBO for more information).

#### 6.3.1.5 Animal Waste

Animal waste consists of all animal anatomical waste (carcasses, tissues, organs, body parts), bedding contaminated with infectious organisms, blood and blood products, items highly contaminated with blood, and body fluids removed for diagnosis or removed during surgery, treatment, or autopsy. Hair, nails, teeth, hooves, and feathers are not considered animal waste. Even after disinfection or decontamination, animal waste is still considered biomedical waste and may require special means of disposal (consult with the IBO for more information).