St. Francis Xavier University
Biosafety Manual
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Acknowledgements

Information in this manual has been drawn from a variety of sources including the Canadian Biosafety Standards and Guidelines, 1st edition, 2013 [http://canadianbiosafetystandards.collaboration.gc.ca/index-eng.php], Canadian Biosafety Standard, 2nd edition, 2015, [https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/second edition.html], the Dalhousie University Biosafety Manual, 2015 [https://www.dal.ca/content/dam/dalhousie/pdf/dept/safety/Biosafety/Dalhousie%20University%20Biosafety%20Manual%20-%202015%20ed..pdf]; the University of Manitoba Biosafety Manual, 2014 [http://umanitoba.ca/admin/vp_admin/risk_management/ehso/media/2012_Biosafety_Guide.pdf], the Public Health Agency of Canada website [http://www.phac-aspc.gc.ca/lab-bio/index-eng.php], and the Canadian Food Inspection Agency (aquatic animal pathogens, non-indigenous and emerging animal disease pathogens) [http://www.inspection.gc.ca/animals/biohazard-containment-and-safety/eng/1300121579431/1315776600051].

Additional information may be found at:

the Canadian Biosafety Handbook, 2nd edition, 2016, [https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/handbook-second-edition.html], Pathogen safety data sheets [https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html], suppliers such as American Type Culture Collection [www.ATCC.org] and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2016 [http://osp.od.nig.gov/office-biotechnology-activities/biosafety/nih-guidelines].

Contents

Chapter 1 Introduction

The StFX Biosafety Manual and Protocol are intended to help foster a safe environment which supports teaching and research. The Biosafety Manual provides information, guidelines, and policies that should be used in conjunction with other resources to minimize the risk of laboratory incidents and to aid in the protection of laboratory personnel and the surrounding environment from possible exposure to biohazardous material.

1.1 Definitions

Biological material – refers to microorganisms, proteins, and nucleic acids along with other biological matter that may contain microorganisms, proteins and nucleic acids, whether or not they are infectious or toxic. This material may pose a risk to health and safety, or the environment.

Biohazard – biological material (microorganisms [bacteria, fungi, protozoa], parasites, animal cells, tissues and body fluids, particles [viruses], toxins, infectious molecules [prions, viroids]) that constitutes a threat or hazard to the health and safety of humans, animals, plants or the environment.

Biosafety - deals with all aspects of containment to prevent exposure to or accidental release of biohazards.

Biosecurity – procedures adopted to prevent the theft, misuse or intentional release of biohazards.

1.2 Responsibilities

The policies, regulations, and procedures of the Biosafety Program shall apply to all activities involving the use, storage, transportation, and disposal of biohazardous materials in or on the buildings and grounds of St. Francis Xavier University. The organization of the Biosafety Program include the following:

- Biosafety Committee
- Biosafety Officer
- Principal Investigators
- Users of biohazardous materials

The Biosafety Committee reports to the Academic Vice-President and Provost. The committee is mandated to:

1. offer advice on the safe use of biohazardous materials;

2. ensure adherence to the Government of Canada's *Canadian Biosafety Standard*, *Canadian Biosafety Handbook*, and to the National Institutes of Health *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

The Biosafety Committee members are appointed by the Academic Vice-President in consultation with the appropriate Dean(s) of Faculty. The Committee membership shall be appointed as follows:

1. one Faculty member from each building in which biohazardous materials are used;
2. one Science Faculty member who is a non-user and who Chairs the Committee;
3. The University Biosafety Officer;
4. The University Health and Safety Officer.

Members shall be appointed such that the committee has expertise in biohazardous materials, techniques and procedures utilizing these materials and infection control.

The term of office for all members shall be three years with the exception of the Biosafety Officer and the Health and Safety Officer who shall be permanent ex-officio members of the Committee. The University Biosafety Officer may not serve as Chair.

The Committee shall meet at least twice per year or more frequently as required to fulfill the responsibilities of the Committee. Minutes shall be recorded and distributed to members, the Academic Vice-President, the Associate Vice-President Research and Graduate Studies (AV-PRGS) and the appropriate Dean(s) of Faculty.

Where a member has an actual, potential or perceived conflict of interest regarding the approval of a project, the member shall not be present during the discussion and decision.

Responsibilities of the Biosafety Committee are to:

1. Establish and from time to time review the University Biosafety Program governing activities involving the use of biohazardous materials;
2. Review and approve all activities involving the use of biohazardous materials, determine the level of containment required and assess the biosecurity measures before the initiation of the activity;
3. Assess the Principal Investigators qualifications, training, and experience in relation to the biohazardous materials to be used;
4. Ensure that facilities in which biohazardous materials are used are inspected to ensure satisfactory containment measures are available and in use;
5. Ensure that there are procedures for the acquisition, secure storage, transport, handling, and disposal of biohazardous materials;
6. Ensure that there are methods of record keeping and biohazard inventory in place;
7. Ensure that emergency response plans for biohazardous material incidents have been established;
8. Interpret policies, standards, and guidelines where necessary and provide information to Principal Investigators as appropriate;
9. In cases of non-compliance with this protocol or any federal, provincial or municipal legislation,
    (i) inform the Principal Investigator, Department Chair, Associate Vice-President Research and Graduate Studies and appropriate Dean of the non-compliance, and in consultation with the Biosafety Officer, specify actions to be taken to deal with the non-compliance and set deadlines for such actions.

(ii) refer continuing issues of non-compliance to the Academic Vice-President.

The Chair of the Biosafety Committee shall:

1. Submit an annual report on biosafety activities to the Associate Vice-President Research and Graduate Studies. A copy to be retained by the Biosafety Officer. Where the Chair of the Committee provides the Academic Vice-President with written recommendations on behalf of the Committee, the Academic Vice-President shall provide a written response to the Committee
2. Sign approved biosafety certificates.

The Biosafety Officer, Principal Investigators, and laboratory personnel must work together to ensure safety when working with biohazardous materials. All faculty, staff, and students are expected to take individual responsibility for safe work practices and procedures so as to safeguard their own individual health and well-being as well as that of their colleagues. The day-to-day operation of the Biosafety Program is overseen by the Biosafety Officer. Principal Investigators are primarily responsible for the safe operations within their laboratory and must ensure safe work practices are implemented, while laboratory personnel must follow the procedures as outlined in this manual and by their supervisor. Additional responsibilities are outlined as follows:

Responsibilities of the Biosafety Officer are to:

1. Assist Principal Investigators to assess facilities and assist in the preparation of the biosafety certificate application;
2. Co-sign approved biosafety certificates;
3. Provide advice on biohazardous materials and work procedures;
4. Provide general biosafety training;
5. Perform inspections and sign documentation for import permit applications;
6. Ensure that steam sterilization cycles are verified using biological indicators on a regular basis and that records of users and cycles are maintained;
7. Investigate all incidents relating to biosafety;
8. In cases of non-compliance with this protocol or any federal, provincial or municipal legislation,
    (i) inform the Principal Investigator and Chair of the Biosafety Committee of the non-compliance, specify actions to be taken to deal with the non-compliance and set deadlines for such actions;
    (ii) refer continuing issues of non-compliance to the Academic Vice-President.

Responsibilities of the Principal Investigator (PI) are to:

1. Apply to and receive approval from the Biosafety Committee **before** obtaining and/or commencing work with biohazardous material;
2. Comply with and enforce the guidelines and standards set by regulatory and granting agencies, University policies and all certificate and permit terms and conditions;

3. Ensure that amendments to the certificate including addition of new personnel, changes in organism or termination of projects are submitted in a timely manner;
4. Maintain a current inventory of biohazardous materials including the source;
5. Provide competent supervision and ensure that all persons working under his/her control have received appropriate training in working with biohazardous materials;
6. Inspect the work area routinely for hazardous conditions;
7. Take appropriate action to remedy unsafe acts and conditions;
8. Ensure the safety of any service personnel (e.g., Facilities Management), contractors or visitors and advise them of any potential hazards in the work area;
9. Ensure all visitors are supervised;
10. Ensure that all containment facilities are functioning and personal protective equipment is available;
11. Develop and continually review site-specific emergency response plans for the work areas and ensure that appropriate spill response supplies are available;
12. Ensure that the work area is secured against unauthorized access at all times and that all biosecurity measures are followed.

Responsibilities of the Laboratory Personnel are to:

1. Follow the policies and safe work practices outlined in the StFX Biosafety Manual or by their supervisor;
2. Participate in all training courses as directed by their supervisor ;
3. Use the appropriate personal protective equipment when working with biohazardous material;
4. Ensure full understanding of the risks associated with the biohazards used in the laboratory and seek information when unsure about any potential biohazard;
5. Report all incidents, laboratory acquired infections, and unsafe conditions to the Principal Investigator immediately.

Chapter 2 Biological Material, Risk Groups and Containment Levels

2.1 Classification of Biological Material

Biohazardous materials are biological materials (microorganisms [bacteria, fungi, protozoa], parasites, animal cells, tissues and body fluids, particles [viruses], toxins, infectious molecules [prions, viroids]) that constitute a threat or hazard to the health and safety of humans, animals, plants or the environment. The threat can be direct through infection or indirect through damage to the environment. Biohazardous agents can be classified into the following groups:

- Microorganisms
- Parasites
- Toxins
- Prions
- Recombinant DNA
- Animals, animal cells, tissues and body fluids
- Viral vectors

Microorganisms **-** This group includes bacteria, viruses, fungi, and protozoa.

Parasites **-** This group refers to multi-cellular organisms, including helminthes, that live on or within another organism and feed on its body tissues.

Toxins **–** Although toxins are poisonous substances produced by bacteria, animals, or plants, the *Canadian Biosafety Standards and Guidelines* consider only toxins of bacterial origin. Toxins vary greatly in their severity, ranging from mildly poisonous to lethal and may be effective at very low concentrations.

Prions – Infectious proteins responsible for progressive neurodegenerative diseases in humans and animals. Prions are resistant to destruction by chemical and physical procedures that normally inactivate viruses, including autoclave sterilization.

Recombinant DNA – Novel nucleic acid molecules created by joining natural or synthetic DNA segments (constructed outside living cells; in vitro). Recombinant DNA may be created by moving a gene from one organism into a different organism, generally of a different species. A gene in its native genome may not pose a risk, however, when the gene is transferred to a foreign genome or when the gene is modified in some way that affects its expression or function the risk level may change.
The *Canadian Biosafety Standards and Guidelines* indicate that in evaluating the level of risk for genomic manipulations, the following should be considered:
- Gene(s) being transferred
- Modification to genes already present in the organism
- Gene expression in the recombinant organism
- Biological containment offered by the host organism
- Interactions between the gene(s) transferred and the host vector systems
- The viability of the host vector systems

Additional information may be found in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, 2016 [http://osp.od.nig.gov/office-biotechnology-activities/biosafety/nih-guidelines].

Animals, animal cells, tissues and body fluids - Animals found in the field may pose a number of risks. Exposure to animal dander can result in allergies or other adverse reactions. Animals can also harbor agents that cause disease zoonoses. By definition, all work involving animals is considered to be a biohazard risk since animals can harbour infectious organisms that can be transmitted to humans.

Animal cells, tissues, blood, and body fluids also have the potential to harbor and transmit infectious agents. It is prudent to consider all cell lines to be potentially infectious. Cell lines known or suspected to contain infectious agents, or primary cultures derived from animals or humans known or suspected to be infected, should be assigned to the risk group for the suspected agent.

Viral Vectors – Vehicles used to deliver genetic material into host cells for subsequent gene expression. Viral vectors are based on viruses present in the human population including adenoviruses, herpesviruses and retroviruses that have been genetically modified to reduce their virulence (they are usually replication-deficient) but enhance their gene delivery.
Biosafety concerns associated with viral vectors include:

1. Tropism (host range) – most viral vectors can infect human cells.
2. Replication-deficient viral vectors may regain deleted genes required for replication through recombination.
3. Genes may be expressed in tissues and/or organisms where they are not normally expressed.

2.2 Risk Factors

Many of the biological agents used in research laboratories are pathogenic to humans, animals, or plants. Their use poses risk, which varies with each agent and how it is used. The *Canadian Biosafety Standards and Guidelines* classifies microorganisms into four risk groups based on the criteria;

- the severity of the disease produced,
- the likelihood of transmission, and
- the availability of preventative measures (i.e., vaccines) or treatment.

These classifications are based upon the World Health Organization (WHO) criteria which in turn are based on the relative hazards of these infective agents. The risk group assigned must consider the context of laboratory work. The Public Health Agency of Canada has conducted a risk assessment for many microorganisms and this information is summarized in **Pathogen Safety Data Sheets** (available at [https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html]. In addition to this information, other factors which must be considered when assigning a risk group include:

1. ***Pathogenicity/Virulence*** – Is the pathogen able to infect and cause disease in humans or animals (i.e., pathogenicity)? What is the degree of disease severity in individuals (i.e., virulence)?
2. ***Mode of Transmission*** – How does the pathogen travel to the host (i.e., direct contact, indirect contact, casual contact, aerosolized droplet or airborne transmission, vectors, zoonosis, intermediate host)?
3. ***Route of Infection*** – How does the pathogen gain entry into the host (i.e., ingestion, inhalation, mucous membranes, subcutaneous, wound entry)?
4. ***Survival in the Environment*** – How stable is the pathogen outside the host?
5. ***Infectious Dose*** – What amount of pathogen is required to cause an infection in the host (measured in number of organisms)?
6. ***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?
7. ***Natural Distribution*** – Is the pathogen present in Canada?
8. ***Impact of introduction and or Release into the Environment*** – What would be the economic, clinical and biosecurity impact if the pathogen were introduced into the population or released into the environment.

A Pathogen Risk Assessment Protocol may be found in Appendix 4 and can be used to assist in assigning a risk group for biohazardous materials.

2.3 Risk Group Categories

Risk Group 1 Agents
Risk Group 1 (RG1) agents include microorganisms, nucleic acids, or proteins which are not capable or unlikely to cause disease in healthy humans or animals. RG1 agents also pose a low risk to public health, livestock, or poultry. Many biohazardous materials at StFX fall into this risk group and include many strains of *Escherichia coli* used as cloning or expression vectors in molecular biology.

Risk Group 2 Agents
Risk Group 2 (RG2) agents are pathogens that pose a moderate risk to the health of individuals or animals, and a low risk to public health, livestock, poultry or plants. Pathogens that fall into this category are those that can cause human, animal and plant disease, but under normal circumstances are unlikely to do so. Laboratory exposures rarely cause infection leading to serious disease. Included in RG2 are:
- Bacteria such as *Salmonella enterica; Escherichia coli 0157:H7*
- Viruses such as Hepatitis A, B, C; influenza; measles; mumps; chickenpox
- Cell lines exposed to or transformed by oncogenic viruses, samples of human tissues and fluids, *Mycoplasma*-containing cell lines, and cell lines new to the laboratory. All other animal cell tissue culture work can be considered to be RG1.
- All human blood, body fluids or tissues should be considered as RG2 or higher as they could contain pathogens such as influenza, HIV, hepatitis.
- Viral vectors should be considered as RG2.
- Prions, when handling neurological tissue from infected or potentially infected humans or animals always handle as RG2 or higher. Similarly, handle formalin fixed tissues and paraffin-embedded blocks as infectious materials at RG2.

Risk Group 3 Agents

Risk Group 3 agents pose a high risk to the health of individuals and animals, but low risk to public health. Pathogens that fall under this category are those that are likely to cause serious disease in humans and animals. Treatment options and preventive measures are usually available and thus the risk of transmission is low. Depending on the pathogen, the risk of spread to livestock or poultry can range from low to high. Included in RG3 are:

- Bacteria, i.e., *Bacillus anthracis, Mycobacterium tuberculosis*
- Viruses, i.e., HIV, Yellow fever virus
- Unconventional agents such as Creutzfeldt-Jakob prion

Risk Group 4 Agents

Risk group 4 agents pose a high risk to the health of individuals, animals, and public health. Pathogens that fall into this category are likely to cause serious disease which can often lead to death. Effective treatment and preventive measures are not usually available for these pathogens and as a result they are readily transmitted from one individual to another. Depending on the pathogen, the risk of spread of disease to livestock or poultry can range from low to high. Included in RG4 are:

- hemorrhagic viruses, Lassa fever virus and Ebola virus

2.4 Containment Levels

Containment level refers to the minimum physical containment and operational practices required for handling infectious material or toxins safely. Generally, the containment level (CL) and risk group of the pathogen are the same (i.e., RG2 pathogens are handled at CL2). However containment level may change if the pathogen has been modified or if the original conditions of use have changed. The source of the material, the volume and concentration of the infectious agent, the extent of culturing and incubation, and the types of manipulations to be conducted, should all be considered when determining the containment level required.

Containment Level Categories

Containment Level 1

CL1 is a basic laboratory that provides the foundation for biocontainment. Biosafety is achieved through good microbiological laboratory practices and physical design.

Containment Level 2

CL2 builds upon criteria established for CL1 laboratories. Biosafety and biosecurity are achieved through operational practices and physical containment requirements.

Containment Level 3

CL3 requires stringent facility design, engineering controls (i.e., inward directional airflow) as well as specialized biosafety equipment to minimize the release of infectious agents. Biosafety and Biosecurity are achieved through comprehensive operational practices.

Containment Level 4

CL4 is the highest level of containment available and requires a complex facility design with a maximum of engineering controls and the maximum level of operational practices.

There are no CL3 or CL4 facilities at StFX.

Table 2-1. Factors considered when assigning Risk Group to a particular biohazardous material.

	RG 1	RG 2	RG 3	RG 4
Pathogenicity /Virulence	- Unlikely to cause disease	- Any pathogen that can cause disease but under normal circumstances is unlikely to be a serious hazard to workers, the community, livestock or the environment	- Any pathogen that usually causes serious human disease or can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another	- Any pathogen that usually produces very serious human disease, often untreatable , and may be readily transmitted from one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact
Infectious Dose	- N/A	- 1000 – 5000 organisms or greater	- 10 – 1000 organisms	- 1 -10 organisms
Mode of Transmission/ Route of Infection	- N/A	- Ingestion, inoculation and mucous membrane route	- Ingestion, inoculation and mucous membrane route. May be transmitted through airborne route, direct contact, vectors	- Readily transmitted, potential for aerosol transmission
Communicability	- N/A	- Limited geographical risk of spread if released from the lab, direct animal-to-animal or human-to-human transmission is relatively limited, limited transmission between different animal species	- Moderate geographical risk of spread if released from the lab, direct animal-to-animal or human-to-human transmission relatively easy, transmission between animal species may readily occur	- Widespread geographical risk of spread if released from the lab, direct animal-to-animal or human-to-human transmission occurs very easily, transmission between different animal species may occur very readily directly or indirectly or by casual contact
Environmental Stability	- N/A	- Short term survival, can survive under ideal conditions	- Resistant (days to months)	- Highly resistant (months to years)

Chapter 3 Laboratory Biosafety

To prevent exposure when working with biohazardous materials it is critical that safe laboratory practice be followed. Anyone planning to work with biohazardous materials must be trained **prior** to initiating the work. Principal Investigators are responsible for ensuring that all personnel in their laboratories are adequately trained.

3.1 Biosafety Training

Biosafety describes the containment principles, technologies and practices that are implemented to prevent unintentional exposure to infectious material or toxins or their accidental release. **Prior** to working with biohazardous materials, all new personnel must read the StFX University Biosafety Manual. The Public Health Agency of Canada's website offers a variety of instructional videos that can be found at: [https://training-formation.phac-aspc.gc.ca/course/index.php?categoryid=7], Additional information is available from the *Canadian Biosafety Standard,* 2nd edition, 2015 [https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/second edition.html] and the Canadian Biosafety Handbook, 2nd edition, 2016, [https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/handbook-second-edition.html]. It is the Principal Investigator's responsibility to provide for all personnel, training on the potential hazards associated with the work involved and the necessary precautions to prevent exposure to infectious agents and release of contained material. Personnel must show evidence that they understood the training provided. Training may include:

- Information on the nature of the infectious material used
- Safe work practices and physical control measures, including handling and disposal of infectious material
- Instruction pertaining to safety information (i.e., pathogen safety data sheets)
- Safe operation of specialized equipment

All new personnel are required to complete the StFX BSF-1 Training Form (available at the Research Services Group/Certifications/Biosafety website: [http://sites.stfx.ca/research/policies_and_certification/biosafety] to provide a record of this training. Completed forms are to be forwarded to the Biosafety Officer as part of the Biosafety Certificate application or to be included in existing applications as an appendix.

3.2 Access/Biosecurity Controls

All laboratories, rooms, and storage locations, housing biohazardous materials, requiring CL2, must display the international biohazard warning symbol (Figure 3-1) as mandated by the *Canadian Biosafety Standards and Guidelines*. Signage must also include the Containment Level of the laboratory.

Figure 3-1. Universal biohazard symbol.

Biosecurity refers to the security measures designed to prevent the loss, theft, misuse, diversion or intentional release of infectious material or toxins. To minimize opportunities for the unauthorized entry of individuals into containment zones and the unauthorized removal of infectious materials from the facility, laboratory doors should be locked when the laboratory is unoccupied. Only authorized persons are permitted to enter laboratory working areas. Unauthorized persons may enter only if accompanied by an authorized individual. Children under the age of 14 years are not permitted to enter laboratory working areas.

3.3 Use of Personal Protective Equipment (PPE)

PPE is protective equipment and clothing that is designed to minimize the risk of exposure to various hazards. It includes hand and foot protection, eye and ear protection, respiratory protection and full body protection. PPE must be available, maintained and used appropriately.

Laboratory coats, enclosed footwear, and gloves prevent biohazardous materials from contact with the skin, including any areas where there might be open wounds. A properly fastened ***laboratory coat*** also protects street clothing from becoming contaminated and helps prevents possible cross contamination from microbiota present on the skin. It is important that laboratory coats remain in the laboratory to prevent spread of contamination to non-laboratory areas.

Enclosed footwear with no or low heels protect feet from spills as well as injuries from dropped sharps.
Gloves protect the hands from contamination and reduce the risks associated with ingestion (i.e., hand-to-mouth), transfer or absorption through the skin. ***Open cuts or wounds must be covered before applying gloves.***
In addition to the minimal protective equipment described above, other protective equipment may be needed when working with infectious agents.
Safety glasses or ***face shields*** offer protection from splashes of biohazardous materials, impacting objects and ultraviolet light.

Chapter 9 of the *Canadian Biosafety Standards and Guidelines* details the use of personal protective equipment in Containment Level 2 laboratories.

3.4 Safe Work Procedures

In accordance with the Canadian Biosafety Standards and Guidelines the following general practices are required for all laboratories handling biohazardous materials.

1. Eating, drinking, smoking, storing of either food, personal belongings, or utensils, applying cosmetics, and inserting or removing contact lenses are not permitted in any laboratory; the wearing of contact lenses is permitted only when other forms of

corrective eyewear are not suitable; wearing jewelry is not recommended in the laboratory; wearing of ear buds or headphones is prohibited.
2. Oral pipetting of any substance is prohibited in any laboratory.
3. Long hair is to be tied back or restrained so that it cannot come into contact with hands, specimens, containers, flames or equipment.
4. Access to laboratory and support areas is limited to authorized personnel.
5. Doors to laboratories must be locked when the room is unoccupied (this does not apply to an open area within a laboratory).
6. Open wounds, cuts, scratches and grazes should be covered with waterproof dressings.
7. Laboratories are to be kept clean and tidy. Storage of materials that are not pertinent to the work and cannot be easily decontaminated (e.g., journals, books, correspondence) should be minimized; paperwork and report writing should be kept separate from such biohazardous materials work areas.
8. Protective laboratory clothing, properly fastened, must be worn by all personnel, including visitors, trainees and others entering or working in the laboratory; suitable footwear with closed toes and heels must be worn in all laboratory areas.
9. Where there is a known or potential risk of exposure to splashes or flying objects, whether during routine operations or under unusual circumstances (i.e., accidents), eye and face protection must be used.
10. Gloves (i.e., latex, vinyl, co-polymer) must be worn for all procedures that might involve direct skin contact with biohazardous material; gloves are to be removed when leaving the laboratory and decontaminated with other laboratory wastes before disposal.
11. Protective laboratory clothing must not be worn in non-laboratory areas; to minimize contamination, laboratory clothing must not be stored in contact with street clothing.
12. If a known or suspected exposure occurs, contaminated clothing must be decontaminated before laundering.
13. The use of needles, syringes and other sharp objects should be strictly limited; caution should be used when handling needles and syringes to avoid auto-inoculation (needle stick injury) and the generation of aerosols during use and disposal; where appropriate, procedures should be performed in a Biosafety Cabinet (BSC); needles should not be bent, sheared, recapped or removed from the syringe; they should be promptly placed in a puncture-resistant sharps container (in accordance with Canadian Standards Association [CSA] standard Z316.6-95(R2000)) before disposal.
14. Hands must be washed after gloves have been removed, before leaving the laboratory and at any time after handling materials known or suspected to be contaminated.
15. Work surfaces must be cleaned and decontaminated with a suitable disinfectant after use and after any spill of potentially biohazardous material; work surfaces that have become permeable (i.e., cracked, chipped, loose) to biohazardous material must be replaced or repaired.
16. Contaminated materials and equipment leaving the laboratory for servicing or disposal must be appropriately disinfected.
17. Efficacy monitoring of autoclaves used for decontamination with biological indicators must be done regularly (depending on the frequency of use of the autoclave), and the records of these results and cycle logs (i.e., time, temperature and pressure) must also be kept on file.

18. All contaminated materials, solid or liquid, must be decontaminated before disposal or reuse; the material must be contained in such a way as to prevent the release of the contaminated contents during removal; centralized autoclaving facilities are to follow the applicable Containment Level 2 requirements.
19. Disinfectants effective against the agents in use must be available at all times within the areas where the biohazardous materials are handled or stored.
20. Leak-proof containers are to be used for the transport of infectious materials within facilities (i.e., between laboratories in the same facility).
21. Spills, accidents or exposures to infectious materials and losses of containment must be reported immediately to the laboratory supervisor; a **StFX Biosafety Injury/Hazardous Incident Report** form (Appendix 3) must be completed; this written record of the incident must be maintained, and the results of incident investigations should be used for continuing education.

Reprinted from: Public Health Agency, Laboratory Biosafety Guidelines, 2004

3.5 Containment Level 2

In addition to these general practices required for all laboratories handling infectious substances, the following describe the minimum operational practices required for Containment Level 2.

1. Good microbiological laboratory practices intended to avoid the release of infectious agents are to be employed.
2. BSCs must be used for procedures that may produce infectious aerosols and that involve high concentrations or large volumes of biohazardous material.
3. Appropriate signage indicating the nature of the hazard being used (i.e., biohazard sign, containment level) must be posted outside each laboratory; if infectious agents used in the laboratory require special provisions for entry, the relevant information must be included on the sign; the contact information of the laboratory supervisor or other responsible person(s) must also be listed.
4. Entry must be limited to approved laboratory staff, maintenance staff and others on official business to avoid unnecessary exposure to ancillary personnel and to maintain the security of biological agents.
5. All people working in the containment area must be trained in and follow the operational protocols for the project in process. Trainees must be accompanied by a trained staff member. Visitors, maintenance staff, janitorial staff and others, as deemed appropriate, must also be provided with training or supervision commensurate with their anticipated activities in the containment area.
6. All laboratory personnel must become familiar with the biohazards that are likely to be encountered in their particular laboratories **prior** to the start of any work with biohazardous agents.
7. A biosafety manual including standard operating protocols (SOPs) specific to the work being conducted and to the individual laboratory must be available for all personnel.
8. Emergency procedures for spill clean-up, medical, power failure, fire, and other emergencies must be developed, included in the biosafety manual and followed. A record must be made of other people entering the facility during an emergency.

Modified from: Public Health Agency, Laboratory Biosafety Guidelines, 2004

Chapter 4 Sterilization and Disinfection

All contaminated materials must be decontaminated prior to disposal, washing and re-use. Proper disinfection is essential to reduce the risk of transmission within containment zones, the environment and the community. Biohazardous materials vary in their susceptibility to physical and chemical treatments.

Sterilization – a process that completely eliminates (by removal or destruction) all living cells and spores and inactivates viruses.

Disinfection – a process which reduces the number of microorganisms on surfaces and equipment rendering them safe to handle but which does not necessarily sterilize.

Most bacteria, fungi, parasites and enveloped viruses are relatively susceptible to chemical and physical sterilization. Non-enveloped viruses and bacteria with waxy cell envelopes occupy mid-range of resistance. Spores of spore-forming bacteria and prions are the most resistant to disinfection.

The following methods may be used to achieve sterilization or disinfection:
- Steam sterilization (autoclaves)
- Dry heat
- Gas sterilization
- Irradiation - Ultraviolet lamps
- Chemical disinfectants

Though there are UV lamps associated with various equipment, StFX is equipped to perform steam sterilization and to use chemical disinfectants only.

4.1 Steam sterilization - Autoclaves

Infectious material can be effectively sterilized using an autoclave. Autoclaves function like pressures cookers, using steam under pressure. High pressure allows the temperature at which water boils to increase above 100°C. Typically, pressure is raised to 15 psi, allowing the temperature to increase to 121°C without water boiling. This temperature is sufficient to kill all living cells and spores as well as to inactivate viruses provided that materials achieve this temperature for a specific period of time. The effectiveness of decontamination by steam sterilization is a dependent upon the length of time materials are exposed to this temperature. As such, larger volumes of liquid and dense materials require longer sterilization times. Materials must also be distributed within the autoclave to allow free circulation and penetration of steam – this allows all contents to reach the desired temperature. Proper operation, loading and monitoring of autoclaves is critical to ensure the decontamination is achieved. JBBH is equipped with 2 autoclaves (room 319).

There are two basic autoclave cycles:

Gravity* or *"fast exhaust" cycles are used to sterilize dry goods, glassware, etc. This cycle charges the chamber with steam and holds it at a set temperature (121°C) for a set period of time (usually 30 minutes). This is followed by a 15 minute dry time (to reduce condensation). At the end of the cycle the exhaust valve opens and the chamber rapidly returns to atmospheric pressure.
Liquid* or *"slow exhaust" cycles are used to sterilize water based materials such as culture media, buffers, etc. The chamber is filled with steam to achieve pressure and temperature for set periods of time (normally 18, 20 or 30 minutes); the time is measured after pressure and temperature have been reached. At the end of the sterilization cycle, steam is exhausted slowly allowing the super-heated liquids to cool without boiling over.
Note: water based materials cannot be autoclaved on a gravity cycle.

Autoclaving is an ideal technique for sterilizing biohazard waste, glassware, microbiological media, and liquids but is not good for equipment or materials sensitive to heat and moisture. Autoclaving should not be used to sterilize radioactive materials or volatile or toxic chemicals.

Autoclave Operation

1. All autoclave users must be trained by L. Graham prior to operation of the JBBH autoclaves. Autoclaves are not to be used after hours or on weekends. Only trained, approved users may operate the autoclaves.
2. Autoclaves are turned off at the end of each day and must be started for use. Start-up procedures require that the steam generator be flushed upon start-up. Start-up requires about 10 minutes and then another 30 minutes must pass to allow sufficient steam pressure to be generated.
3. Autoclave **log books must be filled out for each autoclave cycle**. There are separate log books for each machine. Individuals turning on autoclaves must indicate that the generator was flushed, the strainer was cleaned and whether the chamber was cleaned.
4. All materials to be autoclaved must be placed in the autoclave trays providing sufficient space for steam circulation around individual items.
5. When loading the autoclave, ensure that approved autoclave bags only are used. Bags must have a steam vent. Caps on containers of liquids must be loosened to allow pressure release and containers must provide at least 50% head space. Confirm that all materials are compatible with autoclaving **prior** to treatment.
6. After the cycle is completed ensure that chamber pressure has been reduced to < 0.4 atm before opening chamber door (the screen indicates that the chamber may be opened).
7. When opening the autoclave door, stand to one side of the chamber so your body is shielded from the contents of the unit and released steam.
8. Use heat resistant autoclave gloves to remove trays from the chamber. Trays may be left on the counter to cool provided appropriate signage indicates heat hazard. Materials are not to be left on the counter or in trays for more than 1 – 2 hours.
9. Autoclave trays are to be rinsed and stored to properly dry after each use.
10. Autoclave trays and gloves are **NOT** to be removed from JBBH 319.

All autoclaves must be monitored for efficacy and records of this monitoring maintained.

4.2 Irradiation - Ultraviolet lamps

Ultraviolet (UV) light falls within the electromagnetic spectrum between 190 - 400 nanometres (nm). UV radiation is divided into several regions: UV-A (315-400 nm); UV-B (280-315 nm); and UV-C (200-280 nm). Germicidal lamps used in laboratory settings emit UV-C radiation.

Intense or prolonged exposure to UV light can result in painful eye injury (photokeratitis, retinal burns), skin burns, premature aging of the skin, and skin cancer. Shielding and PPE must be employed. Regular glass does not afford complete protection from the harmful effects of UV light.

UV Light Protective Measures

1. Wear PPE, which would include gloves, laboratory coat, goggles, and UV-protective face shields.
2. Post a UV light symbol where UV light sources are operating at a wavelength capable of germicidal irradiation are present.
3. Limit exposure times.

Table 4-1. Common laboratory ultraviolet light generating devices*.

Device	Use/Function	PPE	Maintenance
Transilluminator	Visualizing nucleic acids following gel electrophoresis and ethidium bromide staining	Gloves, lab coat, UV light face shield	As per manufacturer's instructions
Hand-held UV units	Visualizing nucleic acids following gel electrophoresis and ethidium bromide staining	Gloves, lab coat, UV light face shield	As per manufacturer's instructions
Germicidal lamps in Biosafety Cabinets**	In conjunction with chemical disinfection, disinfection of the interior surfaces of the biosafety cabinet prior to and after use	Gloves, lab coat, UV light face shield	Clean UV light bulb on a monthly basis and replace when necessary as per manufacturer's instructions

* Modified from Dalhousie University Biosafety Manual, 2015.
**The use of germicidal lamps to disinfect BSCs is discouraged

Symptoms of UV Light Overexposure

- Skin: Sunburn-like symptoms.
- Eyes: Burning painful sensation, sensitivity to light, sensation of a foreign object (sand) in the eye, and tearing.

These symptoms usually develop several hours after overexposure to UV light has occurred. Medical attention should be sought immediately, especially if the eyes are involved.

UV irradiation should never be used as the sole means of decontamination in containment zones. As UV light lacks penetrating power, it is only effective in reducing airborne and surface contamination. If UV lamps are being used, they must be properly cleaned and periodically verified for function (i.e., emitting appropriate intensity and wavelength of light).

4.3 Chemical Disinfectants

Chemical disinfectants are generally used for the decontamination of surfaces and equipment which can be damaged by the high temperatures and moisture associated with autoclaving. Personnel need to be aware of the efficacy of various chemical agents against biohazardous materials and realize that the ability of these products to kill infectious agents also renders them potentially harmful to humans and the environment. Chemical disinfectants may be irritating to the skin and respiratory tract while others are toxic. Care must be taken to avoid skin exposure, inhalation or ingestion. Appropriate PPE when using these agents would include laboratory coats, gloves, and eye or face shields if there is any likelihood of splashes.

Chemical disinfectant effectiveness depends on the active ingredient(s), the biological material to which it is being applied, and the conditions under which the agent is used. Typical active ingredients fall into the following categories:

- Acids/alkalis
- Alcohols
- Oxidizing agents (e.g., bleach, iodine)
- Aldehydes
- Metals
- Phenolics
- Quaternary salts

Resistance to chemical disinfectants can be substantially altered by the following factors:

- Contact time
- Concentration of chemical agent
- Presence of organic matter or soil
- Temperature
- Humidity
- Condition and nature of the surfaces
- Types and numbers of microorganisms

Not all biological material is equally susceptible to all types of chemical agents. It is essential that the effectiveness of a disinfectant be verified. This is most easily accomplished by exposing an inoculum to the disinfectant for a specific period of time and then assessing the viability of the inoculum. Pathogen Safety Data Sheet (PSDS) provide information pertaining to the effectiveness of chemical disinfectants against individual microbial agents.

Table 4-2. Chemical disinfectants.

Chemical Disinfectant	Common Form	Mechanism of Action	Application	Limitations	Antimicrobial Spectrum
Chlorine	-Chlorine gas -Sodium hypochlorite (bleach) -Chloramines	-Protein oxidation -Membrane leakage	-water treatment -skin antiseptic -equipment disinfectant	- Inactivated by organic matter - Objectionable odour	- bacteria, bacterial spores, enveloped virus, naked virus, fungi, fungal spores
Alcohol	-ethyl alcohol or isopropyl alcohol, 70% in water	-Denatures proteins -Dissolves lipids -Dehydrating agent	- Instrument disinfectant - Skin antiseptic	- Precleaning necessary - Skin irritation	- Vegetative bacterial cells; enveloped viruses; fungi, protozoa
Phenolics	-Cresols -Trichlosan -Hexachloro-phene -Hexylresorcinol -Chlorhexidine	- Coagulates protein - Disrupts cell membranes	- General preservatives - Skin antisepsis with detergent	- Toxic to tissue - Disagreeable odour	- Gram-positive bacteria - Some fungi
Quaternary ammonium compounds	-Cetylpyridinium -Benzalkonium	-disrupt cell membranes	- Disinfection of instruments	-reduced activity in presence of organic matter	-vegetative bacterial cells; enveloped virus; fungi
Cationic detergents	- Commercial detergents	- Solublizes lipids in cell membranes	- Industrial sanitization - Skin antiseptic - Disinfectant	- Neutralized by soap	- Broad variety of microorganisms
Formaldehyde	- Formaldehyde gas - Formalin	- Reacts with functional groups in proteins and nucleic acids	- Embalming - Vaccine production -Gaseous sterilization	- Poor penetration - Allergenic - Toxic to tissues - Neutralized by organic matter	- Broad variety of bacteria, fungi, protozoa and viruses
Glutaraldehyde	-Glutaraldehyde	- Reacts with functional groups in proteins and nucleic acids	-Sterilization of surgical supplies	- Unstable - Toxic to skin	- All microorganisms, including spores
Hydrogen peroxide	- Hydrogen peroxide	- Creates aerobic environment - Oxidizes protein groups	- Wound treatment - Room decontamination in vapour form	- Limited use - requires specialized equipment to use vapour form	- Anaerobic bacteria 6% effective against vegetative bacterial cells; naked virus; enveloped virus; fungi

Modified from Dalhousie University Biosafety Manual, 2015.

If using a diluted bleach (sodium hypochlorite) solution as the chemical disinfectant, note the concentration of sodium hypochlorite on the supply bottle. Bleach is not supplied at the same concentration from all manufacturers, and you may unknowingly prepare a more dilute bleach solution than what is effective against the pathogen. Bleach is typically supplied at 5 - 6% and should be diluted to 1% or 0.5% for routine use. If no concentration is provided on the manufacturers label, assume a concentration of 4%. All sodium hypochlorite solutions are, however, corrosive so sensitive surfaces should be thoroughly washed with water after disinfection.

4.4 Disinfection of common laboratory equipment

Prior to repair, laboratory equipment must be disinfected. The proper disinfection procedure will vary with the equipment. Protocols are usually found within the operating manual under "user maintenance".

Most equipment may be disinfected by spraying or wiping down all surfaces with diluted bleach, typically a 0.5% solution is used (1 part 5% bleach [sodium hyochlorite] to 9 parts water). This solution is mildly caustic so surfaces should be well washed with water after decontamination. For corrosion sensitive surfaces do not use diluted bleach, but rather use 70% ethanol or a broad spectrum disinfectant.

Automatic Pipets

Place the tip cones and tip ejectors in a 70% ethanol bath for at least one hour. The handle can be wiped with ethanol. Some automatic pipets are autoclavable.

Re-usable Glass Pipets

Place re-usable glass pipettes (tips up) into a pipet wash bucket so that the pipets are completely covered with disinfectant. Pipets may be stored here until autoclaved to sterilize, and then may be washed, dried and re-used.

4.5 Decontamination of waste

All infectious waste must be segregated and disinfected prior to disposal or cleaning for re-use. It is the responsibility of the laboratory personnel to ensure that proper procedures for waste handling are followed in order to prevent personnel exposure to or the unintentional release of infectious material.

Microbiology Waste

Microbiology laboratory waste consists of cultures, stocks, microorganisms live or attenuated cultures, human and animal cell cultures, and any material that has come in contact with infectious material. Laboratory waste can typically be separated into re-usable and single use materials.

Re-usable materials include glassware, autoclavable plastics and metals, laboratory coats.

Single use materials include plastics (pipette tips, petri plates, tissue culture materials), gloves, paper towels, syringe barrels and needles.

Spent (used) or old prepared culture media including agar-based medium in petri plates, tubes or flasks, and fluid medium in bottles, tubes or flasks, must be sterilized prior to disposal.

One method for the segregation of contaminated wasted is:

1. Single use materials with the exception of sharps (needles, contaminated broken glassware) should be collected in autoclave bags. This includes plastics, gloves, used or old agar plates, and paper towels used in disinfection. Plastic pipette tips can be collected in containers at individual work stations and then placed in autoclave bags for disinfection and disposal with regular waste.
2. All contaminated sharps must be segregated. A puncture proof sharps container is to be used to collect used needles and razor blades.
3. Contaminated broken glass, microscope slides, pasteur pipets and single use pipets are to be collected in a puncture proof, autoclavable container (i.e., a galvanized steel bucket), which can be placed into the autoclave for sterilization. Following sterilization, this material may be discarded together with non-contaminated glass.
4. Non-contaminated broken glass, may be disposed of in a plastic lined cardboard box.
5. Contaminated re-usable glass pipettes are to be placed tips up into a pipet wash bucket so that pipets are completely covered with disinfectant. These pipettes must be autoclaved, prior to washing, drying and re-using.
6. Contaminated re-usable glass, metal or plastic materials are to be stored in a tray or other containment item, until disinfected, at which time items can be washed and re-used.

All biohazardous waste collection materials must be properly labelled as such.

Chapter 5 Biological Safety Cabinets (BSC)

A biological safety cabinet is a ventilated hood which uses a combination of High Efficiency Particulate Air (HEPA) filtration and laminar air flow to provide protection to personnel and the environment when working with infectious materials or toxins. These cabinets are used when infectious materials are being exposed in open containers, when there is a high risk of airborne infection, and when there is a high probability of generating contaminated aerosols. A BSC may be distinguished from a chemical fume hood by the presence of HEPA filtration and the laminar nature of the air flow. HEPA filters trap 99.97% of particles of 0.3 µm in diameter and 99.99% of particles of greater size. This enables the HEPA filter to effectively trap all known infectious microbes. Personnel are protected through a continuous stream of inward (inflow) air which prevents aerosols from escaping through the front opening. HEPA filtered air may be directed over the work surface providing protection to work surface materials from contamination. Exhaust air is HEPA-filtered to ensure that only uncontaminated air is discharged from the cabinet.

There are three classes of BSCs each with varying in-flow air velocity, air flow pattern, and exhaust system.

Class I BSC – provide protection to personnel and the environment from RG 1- 3, however they do not protect the product (i.e., culture). These cabinets have unrecirculated airflow away from the operator that is discharged to the atmosphere after filtration through a HEPA filter. They provide good operator protection but do not protect the material within the cabinet (the product) from contamination.They are commonly used to house equipment i.e., fermenters, homogenizers, sonicators.

Air is drawn in through the front opening and passes over the work surface before passing through a HEPA filter and exhausting out of the BSC either into the room or, if hard ducted, into the environment. Thus, contaminated aerosols generated in the BSC are removed before the air is exhausted.

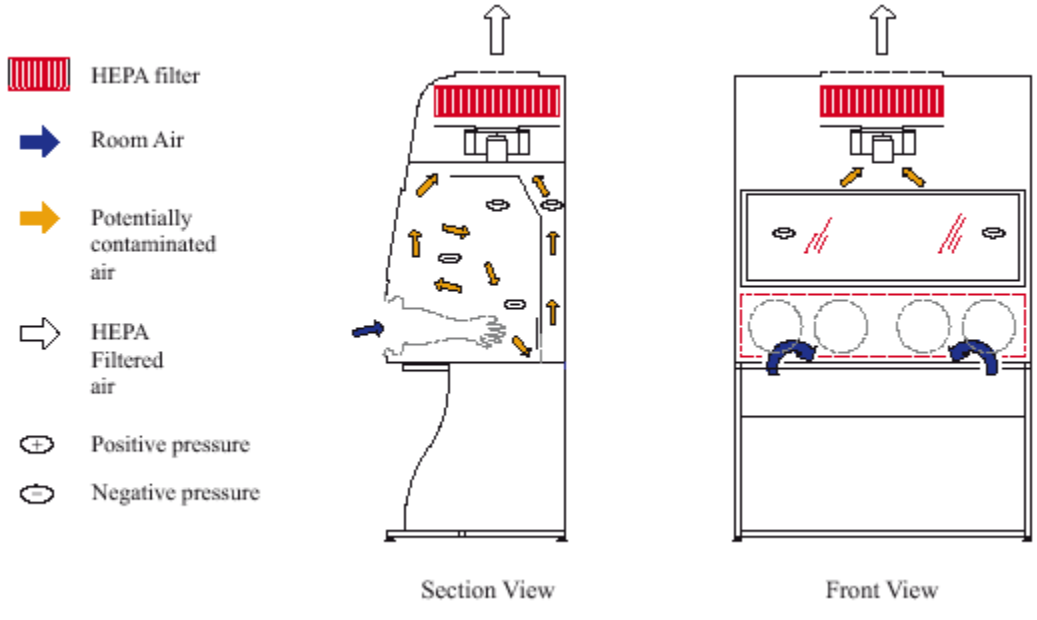


Figure 5-1. Class I BSC. (Image from PHAC, Laboratory Biosafety Guidelines).

Class II BSC – provide protection to personnel and the environment from RG1-3 as well as protecting the product as they allow only HEPA filtered air to flow over the work surface. Class II BSC's come in four types, A1, A2, B1, B2 and vary as a function of (i) air intake velocity; (ii) the amount of air recirculated within the BSC, and, (iii) the type of exhaust system; Type B systems are hard ducted.

Type A1 – Room air (inflow velocity 0.3 m/s) and a portion of the BSC's recirculated air is drawn down through the front grille and HEPA filtered before blowing down onto the work surface. About 30% of the air is exhausted and 70% is re-circulated. Type A1 BSC's may exhaust directly into the room and cannot be used with volatile chemicals or radioisotopes as the re-circulated air can lead to a buildup of these materials within the BSC or within the room.

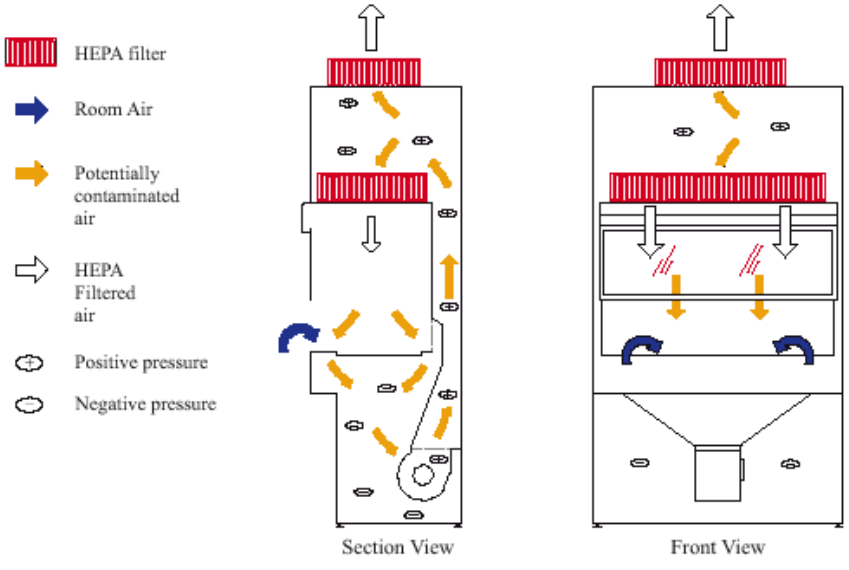


Figure 5 -2. Class II Type A1 BSC. (Image from PHAC, Laboratory Biosafety Guidelines).

Type A2 – A2 BSC have greater inflow velocity (0.51 m/s) than A1 BSC's.

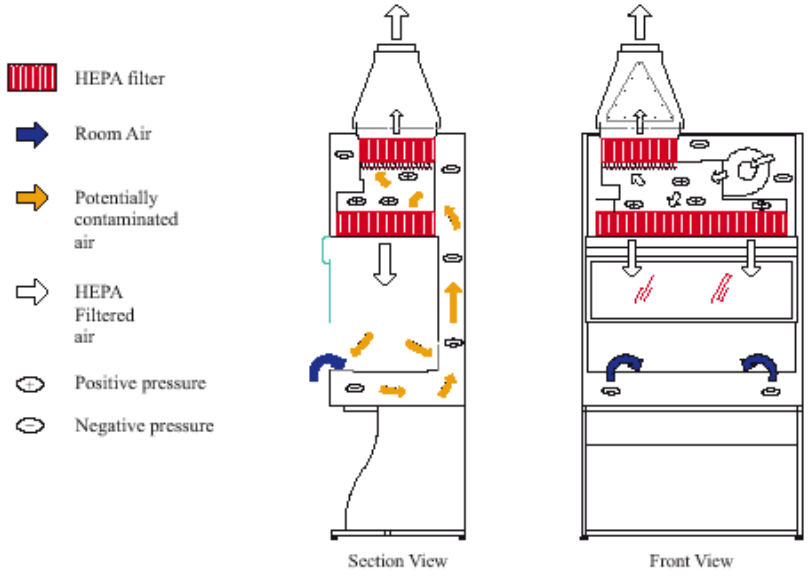


Figure 5-3. Class II, Type A-2 BSC. (Image from PHAC, Laboratory Biosafety Guidelines).

Type B1 – Room air (inflow velocity 0.51 m/s) and recirculated air are drawn into the front grille and pass through 2 HEPA filters before flowing down onto the work surface. About 50% of this air flows through the rear grille, through another HEPA filter and is exhausted, the remaining air (< 50%) mixes with room air and then passes through the two HEPA filters.

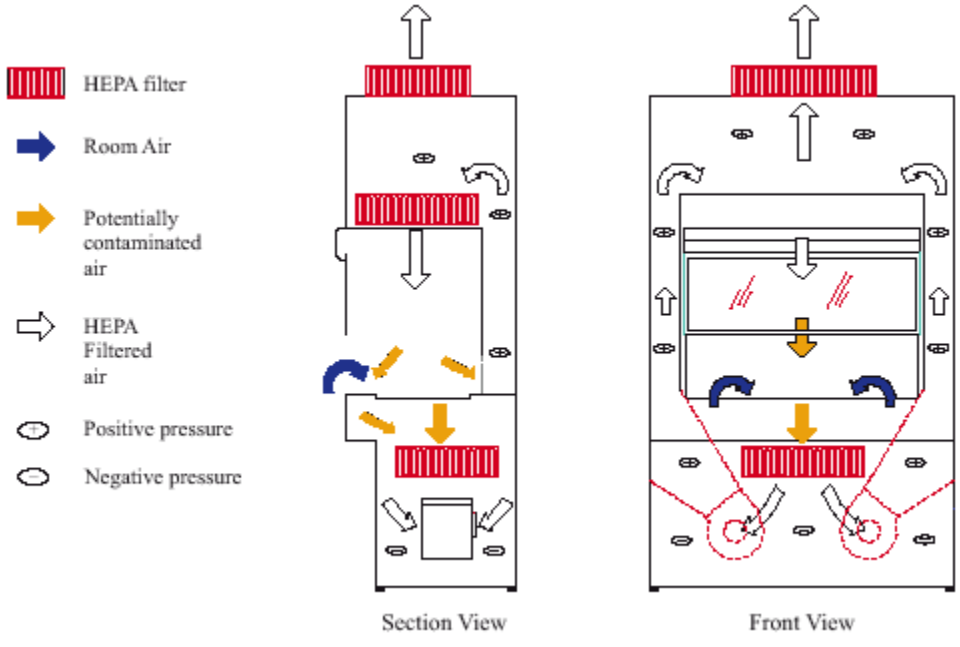


Figure 5-4. Class II Type B1 BSC. (Image from PHAC, Laboratory Biosafety Guidelines).

Type B2 – Do not recirculate air within the cabinet. Room air is drawn into the top of the cabinet, though a HEPA filter and then downwards over the work surface. The building ventilation system draws in air though the front and rear grilles, through a HEPA filter and is exhausted directly into the environment. Type B2 cabinets maintain a minimum average face velocity of 0.5 m/s (100 ft/min) and are hard-ducted through a dedicated duct exhausted to the atmosphere, 100% of cabinet air, after passage through a HEPA filter is exhausted. As air never recirculates, these cabinets are suitable for work with volatile toxic chemicals and radioisotopes.

Class III – Class III cabinets are totally enclosed and gas-tight with HEPA filtered supply and exhaust air. Work is performed with attached long-sleeved gloves. The cabinet is kept under negative pressure of at least 120 Pa (0.5 in. w.g.), and airflow is maintained by a dedicated exterior exhaust system. Class III cabinets protect the worker and the product. They are designed for work with Risk Group 4 pathogens and provide an alternative to the positive-pressure suits made for maximum containment laboratories.

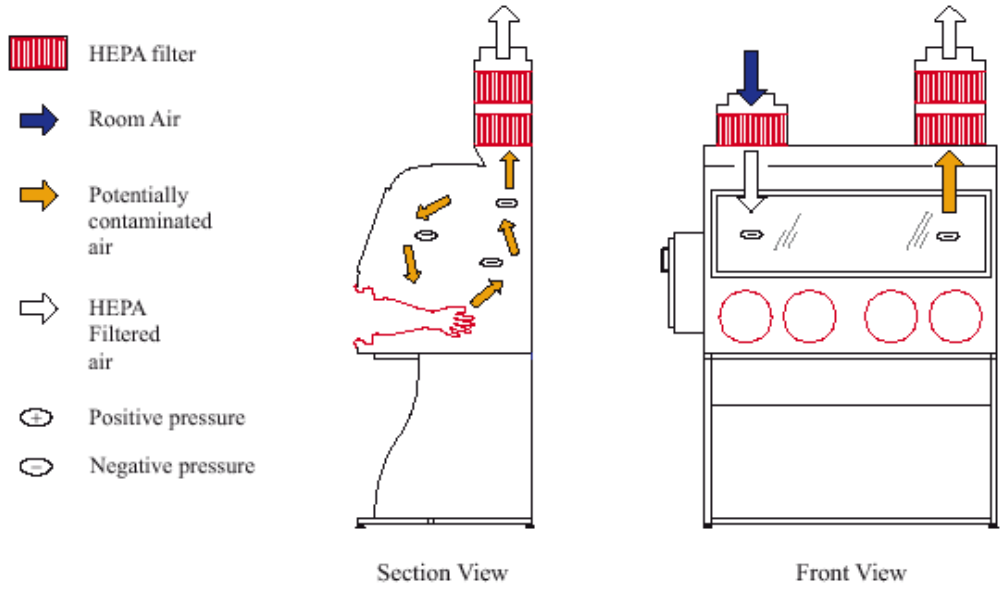


Figure 5-5. Class III BSC. (Image from PHAC, Laboratory Biosafety Guidelines).

All BSC's must be located away from high traffic areas to prevent disruptions in airflow pattern. All BSC's require regular (annual or biannual) testing and certification by accredited individuals to ensure integrity of the HEPA filters, inflow air velocity and proper air flow patterns within the BSC.

Proper use of a BSC

1. The use of UV light to decontaminate the BSC is not encouraged. If the UV light is in use, turn it off before commencing work in the BSC.
2. Turn on the BSC light and fan. Check gauge to ensure proper air flow velocity. Allow the blower to run 15 minutes before using.
3. Don PPE, gloves, lab coat.
4. Disinfect the interior surfaces with 70% ethanol.
5. Load required materials into the BSC, taking care to not block either the front or rear grilles.
6. Allow time for air flow to stabilize.
7. Perform operations in the back half of the work area, ensuring that arms do not rest on the grille or work surface.
8. Clean up spills as they occur
9. Segregate non-contaminated, clean items from contaminated items. Place contaminated items towards the rear of the BSC work surface.
10. Upon completion of work, allow time for air in the BSC to pass through the filter.
11. Remove materials and disinfect the interior surfaces of the BSC with 70% ethanol.
12. Leave the fan blower on in the cabinet for five minute after you have finished your procedure to allow the system to purge.
13. Turn off fan and lights.

Chapter 6 Inventory and Record Keeping

To adequately account for, protect and safeguard infectious materials and toxins from loss, theft, misuse or release, an **up to date** inventory must be maintained. This allows items to be quickly located and discrepancies (i.e., missing items) identified.

Individual PI's must maintain an inventory of all of the infectious material and toxins that are handled and stored both within and outside the containment zone. The inventory is to include:

- a description of the material i.e., organism type, name (genus, species, strain)

- risk group

- quantity (number of aliquots, volume, concentration) and form, i.e., lyophil, frozen culture

- location (building, room, cryotank, -80°C freezer, refrigerator). Often materials are stored in 2 mL cryovials in cryoboxes. A road map indicating position of individual items within this storage system must be used and up dated as required.

- source of material including associated documentation (this could include CFIA/PHAC import permits or ATCC documentation). For genetically manipulated materials, details of generation should be available.

Inventories must be readily available and easily searchable. Inventory control systems may use record books or database systems. All infectious materials and toxins should be stored within a facility accessible by authorized personnel only. Infectious material should be stored in the containment zone where they are handled or in a zone at the same containment level.

Chapter 7 Emergency Response Protocols

7.1. Biohazardous spill response.

- All biohazardous spills must be handled by trained personnel.
- All laboratory staff working in a biocontainment zone must be trained in the spill clean-up procedure and know the location of the spill kit.
- Biohazardous spills should never be cleaned up by Facilities Management staff nor should FM equipment (i.e., mops and buckets) be used in spill clean-up.

Recommended Biohazard Spill Kit Contents

- A labelled 5-gallon pail with lid – spill kit materials may be stored in the pail and the pail acts as a waste container in the event of a spill.
- Spill Clean-up Procedures – instruction list (**Appendix 6**)
- Paper towels or old cloth towels
- Disposable gloves (4 pairs per person) and one pair of reusable chemical-resistant gloves
- Safety glasses and laboratory coat
- Autoclave bags (at least 2)
- Large forceps or tongs to pick up sharps
- Sharps container (or access to a 'contaminated broken glass bucket')
- Dust pan and brush (an inexpensive plastic set is fine as they will be discarded)
- Jug of household bleach (sodium hypochlorite), write date of purchase on side and replace annually. If no concentration is provided on the manufacturers label, assume a concentration of 4%
  - on solid surfaces, use 1% bleach
  - for liquids, dilute liquid with concentrated bleach to a final concentration of 1%

7.1.1 *Biohazardous Spills Outside of a Biological Safety Cabinet*

Minor spills: - release of Risk Group 1 organisms without splashing or agitation
- release of a small volume (<50 mL) of a Risk Group 2 or Risk Group 1 organism

Major spills: - release of RG2 or RG1 organisms with splashing or aerosols
- release of a large volume (>50 mL) of RG2 or RG1 organisms
- any spill that requires additional assistance (i.e., involves injury or eye splash)

1. **Assess the area for incident severity.**
   (a) How pathogenic is the organism involved?
   (b) What volume and concentration of biohazardous material is involved?
   (c) Do I need assistance?
2. **Immediately secure all other biological materials in the vicinity of the spill.**
   (a) Ensure your own personal safety.
   (b) Clear the area of all non-essential personnel and request assistance if required.
   (c) **For major spills, wait 30 minutes to allow dissipation of aerosols created by the spill.** Close door and set up signage to prevent people entering the spill area.

3. **Deal with personal or co-worker injuries or potential injuries.**
   (a) Assess the area for personnel contamination. Decontamination of personnel must be completed before clean-up of other affected surfaces. Refer to **Appendix 8 – Decision chart to assist in the assessment of an incident to determine if exposure to a biohazardous material has occurred**. Remove contaminated items and put them in an autoclave bag. Contaminated clothing must be autoclaved prior to laundering.
   (b) Initiate first aid if required: wash the exposed area well with soap and water.
   (c) Encourage bleeding if the exposure includes a sharps injury and repeat washing.
   (d) For eye exposures flush eyes for 15 minutes in eye wash. Seek medical attention.
   (e) If the incident involves a potential exposure to human blood, body fluids or cell lines via broken, cut, punctured or otherwise non-intact skin, wash and **seek medical attention within two hours.**
4. **Don appropriate protective equipment for clean-up.**
   (a) Double gloves, lab coat, eye protection.
   (b) Acquire 2 autoclave bags. **Autoclave bag 1** will be used for contaminated waste (i.e., disposable gloves, absorbent material, etc.). **Autoclave bag 2** will be used to contain contaminated clothing (i.e., lab coats) which will be sterilized (autoclaved) prior to laundering.
5. **Attend to the spill.**
   (a) Contain the spill by gently placing paper towels or towels over the spill or surround the spill with absorbent spill dams.
   (b) Gently pour disinfectant (concentrated bleach) onto the absorbent material beginning at the outside and moving towards the centre. Alternatively soak cloth towels in diluted disinfectant (bleach diluted to 1%) and gently lay them on the spill area. The entire spill must be covered.
   (c) Let stand for 30 minutes.
   (d) Remove outer layer of gloves and place in autoclave bag 1. Remove all contaminated clothing and place in autoclave bag 2. Remove inner pair of gloves and place in autoclave bag 1 and wash hands with soap and water.
6. **Clean-up disinfected spill.**
   (a) Don appropriate protective equipment, double gloves, lab coat, eye protection.
   (b) Pick up contaminated broken glassware with brush and dust pan, forceps or tongs – **do not use your hands**. Place in "contaminated broken glass bucket" or sharps container for autoclaving.
   (c) Using dust pan and brush or tongs, place all materials soaked with disinfectant (i.e., paper towels, towels, absorbent material) into autoclave bag 1. Chemically disinfected material does not need to be autoclaved but is still considered chemical waste.
   (d) Reapply disinfectant to the spill area after initial clean-up. Wait 30 minutes and clean-up again (repeat step 6).
   (e) Disinfect/decontaminate the surface of any items or equipment that may have been contaminated.
   (f) The contaminated brush and dustpan may be placed in autoclave bag 1. Contaminated tongs or forceps may be disinfected by autoclaving (if appropriate) or placed in a bath of 70% ethanol for 1 hour, followed by a water wash. Remove outer layer of gloves and place in autoclave bag 1.

Place lab coats in autoclave bag 2. Remove inner pair of gloves and place in autoclave bag 1 and wash hands with soap and water.

(g) Autoclave bag 1, containing used paper towels/towels, gloves, etc. may be thrown out with regular waste. Autoclave bag 2, containing clothing must be autoclaved prior to laundering.

7. **Report incident and complete the Biosafety Injury/Hazardous Incident Report form** (Appendix 3)**.**
8. **Make arrangements to restock items used in the spill kit.**

7.1.2 *Biohazardous Spills Inside a Biological Safety Cabinet*

1. Leave the cabinet fan running and immediately secure all other biological materials in the vicinity of the spill. Remove all items not in contact with the spilled material.
2. For small spills (<50 mL) on the working surface, cover the spill with paper towels and gently flood the surface with disinfectant (disinfectant [usually 70% ethanol] should already be present). Let stand for 20 minutes.
3. For larger spills or if the spill has run through the front or back grills into the catch basin beneath the work surface, those surfaces will also require decontamination. Prepare a fresh solution of diluted bleach (1% bleach). Place paper towels on these surfaces and soak with diluted bleach. Let stand 30 minutes.
4. Remove used paper towels and transfer to an autoclave bag for discard. Remove broken glass using forceps and place in an autoclavable sharps container or "contaminated broken glass bucket". Wipe surfaces dry with paper towels and wash the surfaces well with distilled water and a final wash with 70% ethanol to prevent corrosion.
5. Wipe all interior cabinet surfaces and any remaining equipment and supplies located inside the cabinet with disinfectant. Remove gloves and place in autoclave bag.
6. Allow the cabinet to run for at least 10 minutes after clean-up.
7. **Report incident and complete the Biosafety Injury/Hazardous Incident Report form** (Appendix 3)**.**

7.1.3 *Biohazardous spills 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 (supervisor, Biosafety officer).
2. Follow the instructions for general spill clean-up. If possible use a non-corrosive disinfectant known to be effective against the biohazard concerned. (consult the centrifuge manufacturer's specifications on the unit to confirm the chemical compatibilities).

3. Use forceps to handle and retrieve broken tubes, glass fragments, and other sharps debris. These can be decontaminated according to procedures for disposing of contaminated broken glass. Forceps, unbroken sealed safety cups, buckets, and the rotor should be placed in a non-corrosive disinfectant.
4. The centrifuge bowl is to be washed with the disinfectant twice, washed with water and dried.
5. **Complete the Biosafety Injury/Hazardous Incident Report form** (Appendix 3)**.**

7.2 Medical

All personnel working with biohazardous agents (organisms, toxins, body fluids, etc.) must read the Pathogen Safety Data Sheets or Material Safety Data Sheets associated with the agent. For relevant biohazardous agents, personnel must be aware of the potential exposure routes by which the agents may enter their body and self-monitor for symptoms of disease. Should exposure be suspected, regardless of the ability to identify the exposure event, the individual must consult the Principal Investigator. If medical attention is required, the individual must inform the attending physician that they work in a research or teaching laboratory and identify the biohazardous agents with which they are currently handling.

All personnel working with biohazardous agents must know the location of the first aid kits and the list of first aid emergency responders.

All injuries and potential biohazard exposures must be reported using the **Biosafety Injury/Hazardous Incident Report** (**Appendix 3**) form.

7.2.1 Needlestick – accidental puncture of the skin occurring when needles are used, disassembled or being disposed of.

(a) Remove personal protective equipment if covering affected area
(b) Wash affected area well with soap and water and flush with water for 5 minutes while squeezing wound site to promote bleeding
(c) If exposure involves human blood, clinical specimens, or human pathogenic organisms seek medical attention

Prevention of needlestick injuries

1. Needles and syringes should only be used when there is no alternative
2. Never bend, shear or remove needles from syringe barrels. If a needle must be recapped do so using forceps
3. Maintain an approved puncture proof sharps container in the immediate work area and dispose of needles immediately after use
4. Ensure individuals know how to safely use and dispose of sharps and how to prevent needlestick injuries.

7.2.2 Cuts

(a) Remove personal protective equipment if covering affected area
(b) Wash affected area well with soap and water and flush with water for 5 minutes
(c) Apply appropriate bandage if required
(d) Seek medical attention as necessary

7.2.3 Burns

(a) Remove personal protective equipment if covering affected area
(b) Flush affected area with cold water until pain subsides
(c) Cover loosely with sterile gauze and seek medical attention as necessary

7.2.4 Eye splash

(a) Rinse eyes at eyewash station for a minimum of 5 minutes
(b) Seek medical attention as necessary

7.3 Fire and building evacuation

All fire alarms are to be treated seriously. It is every person's responsibility to:

1. know the location of the nearest fire alarm pulls
2. know the location of the nearest fire blankets and fire extinguisher
3. be familiar with the laboratory floor plan and the location of the nearest exits
4. know the muster station

Do not attempt to fight the fire unless:

- all personnel in immediate danger have left the area
- the fire is small (no larger than a wastepaper basket) and contained (as in a wastepaper basket)
- your safety is not in jeopardy and you have a clear escape route
- the fire is not producing thick smoke or toxic fumes
- the proper extinguisher is immediately at hand
- you have received fire extinguisher training and know how to use the extinguisher

If the fire is not extinguished immediately (<10 seconds), leave it for professional fire-fighters.
Sound the alarm and exit the building.
Wait for security (extension 4444) to arrive and provide information about the fire.

A **Biosafety Injury/Hazardous Incident Report** form (**Appendix 3**) must be filed following any fire, regardless of the size of the fire.

When a fire alarm sounds:

1. Immediately secure all biohazardous agents (replace lids on open petri dishes, culture tubes or flasks, etc.)
2. Turn off all equipment and close gas ports to extinguish open flames
3. Remove PPE (i.e., gloves, lab coats)
4. Exit the laboratory, shutting off the lights and closing, **but not locking** the door
5. Report to muster station and do not re-enter the building until authorized by Security or Fire personnel.

7.4 Power Failure

In the event of a power failure, seal and secure all biohazardous agents in use (i.e., replace lids on open petri dishes, culture tubes and flasks, etc.). Do not continue to work with biohazardous materials when power is not available for BSC's and laboratory ventilation. Avoid opening freezers, refrigerators, cold rooms and incubators. Some buildings are equipped with emergency generators which provide emergency lighting and power to selected equipment (i.e., freezers). Evacuation is recommended if the power fails after sunset.

7.5 Floods or Water Leaks

Water may accumulate on the floor from leaks in the roof, around windows, plumbing failures, cooling system leaks (environmental chambers, electron microscopes), refrigerator failures or spills. These are primarily a slipping hazard. To prevent contamination of these sites, do not transport or manipulate biohazardous materials where flooding has or is occurring. Check to ensure there are no bare wires or flooded electrical connections that could pose an electrocution hazard. Identify the source of the water. Alert other people in the area of the leak and notify Facilities Management (extension 2149) or after hours, Security (extension 4444) of the leak.

7.6 Gas leak

In the event of a gas leak, leak of a hazardous chemical or unidentified odour, immediately secure all biohazardous materials (i.e., replace lids on petri dishes and re-cap culture tubes or flasks) and extinguish all open flames. Attempt to identify the source of the odour. If the source is determined and found to be non-hazardous attempt clean-up. If the source is determined to be hazardous, evacuate the area, and close the doors. Sound the fire alarm and evacuate the building. Notify Security (extension 4444) and do not re-enter the building until authorized by Security.

7.7 Natural Disasters – earthquake

In the event of an earthquake, immediately secure all biohazardous materials (i.e., replace lids on petri dishes and re-cap culture tubes or flasks) and extinguish all open flames. Take cover under the nearest lab bench and remain until shaking subsides. Carefully, using stairwells, exit the building.

7.8 Other potential hazards – Aerosols

Handling of biohazardous material or toxins in a manner which generates aerosols poses the threat of inhalation or splashing. Pipetting, the use of sonicators, culture stirrers, shakers or agitators are likely mechanisms for generating aerosols. To reduce the generation of aerosols when:

7.8.1 Pipetting

(a) Never mouth pipet. Use a mechanical pipet aid.
(b) Where possible, pipette biohazardous materials in a biosafety cabinet
(c) Never discharge biohazardous materials forcibly from pipettes
(d) Avoid splashing biohazardous materials by allowing them to run down the wall of the receiving container
(e) After use, re-usable pipettes should be placed in a proper container containing appropriate disinfectant to completely submerge the pipet. These pipettes must be autoclaved and washed prior to re-use.

7.8.2 Sonicating

(a) Operate sonicators in a sealed container or biosafety cabinet. A towel moistened with disinfectant may be placed over the sonicator probe while in operation to contain aerosols
(b) Ensure proper ear protection is used
(c) Allow aerosols to settle for 30 minutes prior to opening and removing sonicated materials
(d) Wear gloves when retrieving materials from sonicator

7.8.3 Agitating or Shaking Cultures

(a) For shaking biohazardous materials, always use appropriate equipment certified for this use
(b) Use heavy duty screw-capped containers or culture flasks and tubes where possible to prevent escape of aerosols
(c) Allow all aerosols to settle for 10 minutes prior to opening and removing contents

Chapter 8 Risk Assessment and Risk Mitigation

"Risk" is a function of the probability of an undesirable event occurring and the consequences of that event. With biohazardous materials, it is essential to mitigate risks for the safety of the community. While it is not possible to eliminate all risk, it is possible to reduce risk. Everyone handling pathogens or toxins must understand the risks associated with the materials they are handling, ways to prevent exposure and ways to prevent the release of pathogens or toxins into the environment. Risk assessment happens at multiple levels:

Overarching risk assessment – completed at the University Level. The StFX "Administrative Plan for the Oversight of Pathogens and Toxins in a Research Setting" states that only Risk Group 2 or RG 1 materials are to be used/stored/acquired based upon existing facilities, the type of work to be completed, (i.e., research and teaching utilizing biohazardous materials), and the equipment and procedures utilized.

Local risk assessment – completed for each project involving biohazardous materials. This is a site- and project-specific assessment which identifies hazards based on the pathogen, toxin or infectious material in use, the activities to be performed with these materials, and the personnel handling the materials.

Biosecurity risk assessment – occurs at both the University level and at the individual project level. This assessment identifies consequences to the community in the event of the escape, loss of containment or unauthorized access to biohazardous materials.

Pathogen risk assessment – identifies the risk group of a pathogen or toxin, which in tum, is used to determine the appropriate containment level. Information pertaining to some pathogens is available as Pathogen Safety Data Sheets (PSDs). For unlisted pathogens, pathogen risk assessment can be performed using the "Template for Pathogen Risk Assessment" (Appendix 4, Biosafety Manual).

Local risk assessment

A local risk assessment is completed:

- during the initial submission of a Biohazard Certification Application Form
- upon renewal of Certification
- upon changes to documented protocols for handling biohazardous materials (including introduction of new biological agents or changes in the quantity of biohazardous materials to be used)
- upon development of new protocols
- following incidents involving potential or actual exposure to a biological agent
- following construction or modifications to laboratories and equipment
- upon the introduction of unplanned staffing arrangements (including contractors, visitors and other non-core personnel).

The goals of a local risk assessment are to:

- identify hazards associated with a pathogen or toxin
- identify activities that might lead to exposure to a pathogen or toxin
- identify activities that might lead to release of or loss of biocontainment of a pathogen or toxin

- identify activities that might lead to contamination of equipment, materials or property with a pathogen or toxin
- to describe mitigation strategies for identified hazards
- to assess the risk associated with each step of a standard operating protocol in which exposure to biohazardous material would result in a laboratory acquired infection and the severity of that infection
- to determine whether additional engineering controls (facilities, equipment), administrative controls (training, supervision, updated protocols) or personal protective equipment are required

In conjunction with the Biosafety Officer, this assessment is completed by the primary investigator who must be familiar with the pathogens or toxins involved, the procedures being performed and the equipment to be used. The input of other individuals including health and safety specialists, security personnel may also be required. To perform a local risk assessment:

1. Identify the pathogens, toxins or biohazardous material to be used.
2. Identify all procedures in which biohazardous materials are to be used, i.e., harvesting bacteria from liquid cultures, bacterial infection of animal cells.
3. For each procedure, break the procedure into specific steps.

   i.e., for the procedure "harvesting bacteria from liquid cultures" the steps are:
   i. Aseptically transfer culture into centrifuge tubes, balance, seal tubes
   ii. Centrifuge
   iii. Aseptically remove supernatant to discard
   iv. Resuspend cell pellet in buffer.

4. Identify hazards and potential for exposure at each step (i.e., quantity of biohazardous material, creation of splashes, droplets or aerosols, use of sharps, possibility of a spill, route of transmission of pathogen)
5. Identify mitigation measures that are in place, including engineering controls (facilities, equipment), administrative controls (training, supervision, updated protocols) and personal protective equipment (PPE).

To identify hazards associated with the procedure "harvesting bacteria from liquid cultures";

1. Can an organism of lower risk be substituted for this work?
2. Since the transfer of culture involves pipetting, an aerosol could be generated. If this organism is transmitted as an aerosol, this constitutes an elevated risk.
3. Mitigate the risk by completing this transfer in a biologic safety cabinet (engineering control). If the organism is not transmitted as an aerosol, good microbiological practice might suffice. Ensure that the individual has sufficient training (administrative control) to complete this procedure and is trained in the use of a centrifuge. To minimize spills or equipment contamination, ensure the centrifugation utilizes sealed tubes, sealed rotor and is equipped with HEPA filter (engineering control). Latex gloves and lab coat (PPE) could be used to minimize exposure in case of a spill.

Thus, a better standard operating procedure for "harvesting bacteria from liquid cultures" in which a local risk assessment has been conducted could be:
For RG 1 bacteria:

1. Disinfect lab bench.
2. Using an automatic pipettor, aseptically transfer the liquid culture into sterile centrifuge tubes and seal loosely.
3. Balance the tubes using sterile media. Seal the tubes completely.
4. Transfer the tubes to a sealable rotor, ensuring tubes are balanced in the rotor. Seal the rotor. Centrifuge.
5. After centrifuging, wait 10 minutes to allow aerosols to settle.
6. Open rotor and remove tubes.
7. Using an automatic pipettor, aseptically remove the supernatant from each tube and place the supernatant into an autoclavable container for discard.
8. Using an automatic pipettor, aseptically add sterile buffer to the pellet, seal the tube and resuspend cells.
9. Disinfect lab bench.

The protocol described above could be included in a Biohazard Certification Application and would be documented as a "standard operating protocol" and retained in the facility or laboratory where this task would be completed. This is a local risk assessment in which the hazards and potential for exposure have been identified in a procedure and the procedure modified using engineering controls (facilities, equipment), administrative controls (training, supervision, updated protocols) and personal protective equipment (PPE) to mitigate these risks.

Biosecurity risk assessment
A biosecurity risk assessment is performed during the initial submission of a Biohazard Certification Application Form, or following a potential or actual theft, loss or intentional misuse of biohazardous material.
Biosecurity measures are designed to prevent the loss, theft, misuse, diversion or intentional release of infectious material or toxins. An up to date inventory of pathogens, toxins or biohazardous materials must be generated and available. Most biosecurity risks can be mitigated using physical security measures to reduce the risk of unauthorized access (i.e., locked doors, password protected digital materials) and effective incident reporting.

Pathogen risk assessment
The pathogen risk assessment uses the following characteristics to identify the risks associated with a pathogen or toxin and the risks that material poses to humans, animals, plants and the environment.

- **Pathogenicity and virulence**: can the pathogen infect and cause disease in humans, animals or plants? What is the severity of the disease?
- **Route of infection**: how does the pathogen gain entrance in the hosts (i.e., ingestion, inhalation, inoculation, contact with skin or mucous membranes?)
- **Mode of transmission**: how does the pathogen travel to hosts (i.e., direct contact, fomites, aerosolized droplets, insect vectors?)

- **Survival in the environment**: how stable is the pathogen outside the host? Under which environmental conditions can the pathogen remain infectious and for how long?
- **Infectious dose**: what amount of pathogen is required to cause infection in a host?
- **Availability of effective preventive and therapeutic treatments**: are effective preventive measures (i.e., vaccines) or treatments (i.e., antibiotics, antivirals) available?
- **Host range**: does the pathogen cause infection in a wide range of species, or is host range restricted? What are the primary, intermediate and dead-end hosts?
- **Natural distribution**: is the pathogen present in Canada or is it exotic to Canada (i.e., non-indigenous)? Is the pathogen prevalent in a particular location, region or host population?
- **Impact of introduction and/or release in the environment**: if the pathogen were introduced into the human, animal, or plant population or released into the environment (within Canada), what would be the economic, clinical and biosecurity impact?

This information assists with assigning risk group to biohazardous material. In turn, the risk group will determine the specific physical containment requirements (laboratory facilities and equipment specifications) and operational practice requirements (standard operating procedures, training, quantity and concentration of biohazardous material). This information is included in the Biohazard Certification Application (Biohazard Certification Application Form – Research; Biohazard Certification Application Form – Teaching; BSF-2 Microorganisms; BSF-3 Cell Cultures; BSF-4 Biological Toxin; BSF-5 Human and Non-Primate Source Material).

Chapter 9 Incident Reporting and Investigation

An **accident** is an unplanned event that results in injury, harm or property damage. An **incident** is an event that had the potential to cause injury, harm or property damage (i.e., near miss, dangerous occurrence). An incident could be:

- A **potential or actual exposure to a biological agent**, whether it results in a laboratory acquired infection or not.
- An **injury or near-miss incident related to work with biological agents**
- A **potential or actual theft, loss or intentional misuse of a biological agent**

To determine whether an incident involves exposure to biohazardous materials refer to "**Decision Chart to assist in the assessment of an incident to determine if exposure to a biohazardous material has occurred**" (**Appendix 8**).

All incidents and accidents must be properly reported, documented and investigated. Incidents involving infectious material, toxins, infected animals or plants, or biocontainment failure must be reported immediately to the laboratory supervisor or principle investigator. Documentation of the accident or incident must be reported to the Biosafety Officer within 48 h.

It is the supervisor's or Principal Investigator's responsibility to complete the StFX University **Biosafety Injury/Hazardous Incident Report** form (**Appendix 3**, and available on line at [Research Services Group/Certification/Biosafety]) and forward the completed form to the Biosafety Officer. Required information for the report includes but is not limited to:

- Who were the people involved in the incident (i.e., personnel, bystanders)?
- What infectious material or toxin was involved in the incident?
- What quantity or concentration of infectious material was involved?
- Where and when did the incident take place?
- How did the incident happen (i.e., what factors contributed to the incident)?

The Biosafety Officer will investigate and provide feedback including identifying corrective actions to prevent a recurrence of the incident; identifying opportunities for improvement; and communicating the investigation results and corrective actions taken to the appropriate parties (i.e., laboratory personnel, Biosafety Committee, Dean and Associate Vice-President Research and Graduate Studies (AV-PRGS))

The goal of the reporting, documentation and investigation is to identify failures in biosafety or biosecurity procedures such that corrective action may be implemented. Root causes of incidents may include inadequate safe work procedures, inadequate training of personnel, or degrading equipment and infrastructure. It is important to identify the sequence of events and the subsequent root cause(s) that led or contributed to the incident.

St. Francis Xavier University has a "**Biosafety Laboratory Inspection Report**" (**Appendix 2**) which is a compliance checklist to be used for inspections by the Biosafety Officer. These inspections and the checklist are used to identify potential equipment/procedures or practices that could result in a potential incident.

All individuals handling biohazardous materials are required to follow procedures and practices appropriate to the containment level. Violations in compliance are categorized as either major or minor offences.

A **major offence** would result from violations which cause immediate risk or danger to the safety or health of personnel or which could result in the loss, theft or negligent release of biohazardous materials to the environment. A major offence would include:

- Use, handling or storage of biohazardous materials in the absence of approved StFX certification
- Consumption or storage of food or drink in the laboratory
- Inadequate training of personnel
- Refusal to wear required personal protective equipment
- Inadequate security measures to safeguard biohazardous materials
- Negligent release of a biohazardous material into the environment

A **minor offence** would be a violation which poses no immediate risk or threat to health, safety or the environment but which could lead to an incident. A minor offence would include:

- Inadequate signage
- Inappropriate use of warning labels
- Inadequate inventory records

Major Offence Actions

1. On the **first** occurrence, written notification will be sent to the Biosafety Certificate holder, with a copy to the Department Chair, the appropriate Dean, and the Associate Vice-President Research and Graduate Studies (AV-PRGS), outlining the nature of the offence. **Immediate** attention to and correction of the violation is required.

2. On a **second** occurrence within a twelve month period, the Biosafety Certificate holder will be notified in writing, with a copy to the Department Chair, the appropriate Dean, and the AV-PRGS, that the certificate will be revoked until a meeting with the Biosafety Committee can be held. The certificate holder may attend the meeting to explain why the certificate should be renewed. Unless the certificate is reinstated, no further work involving biohazardous materials is permitted.

3. On a third occurrence within twelve months of the second occurrence, the Biosafety Certificate will be cancelled and all inventory disposed of by the Biosafety Officer. Notification of this action will be copied to the Department Chair, the appropriate Dean, and the AV-PRGS.

Minor Offence Actions

1. On the **first** occurrence, the Biosafety Certificate holder will be notified verbally by the Biosafety Officer of the violation observed. Minor offences must be corrected within seven (7) calendar days of verbal notification.

2. On a **second** occurrence within a twelve month period, the Biosafety Officer will send written notification of the violation to the Biosafety Certificate holder, with copies to the Department Chair and the Biosafety Committee.

3. On a **third** occurrence, within twelve months of the second occurrence, the Biosafety Certificate holder will be notified in writing, with a copy to the Department Chair, the appropriate Dean, and the AV-PRGS, that the certificate will be revoked until a meeting with the Biosafety Committee can be held. The certificate holder may attend the meeting to explain why the certificate should be renewed. Unless the certificate is reinstated, no further work involving biohazardous materials is permitted.

4. On a **fourth** occurrence within twelve months of the third occurrence, the certificate will be revoked.

Chapter 10 Transportation of Biohazardous Materials

The *Canadian Biosafety Standards and Guidelines* distinguish between movement of infectious materials and transportation of infectious materials. ***Movement*** refers to the transfer of biohazardous materials within a containment zone or building, whereas ***transportation*** refers to the movement of materials between buildings at one location, within Canada or abroad. Transportation or shipment of biological materials is governed by law and must meet **Transportation of Dangerous Goods** (TDG) regulations as well as **International Air Transport** (IATA) regulations. Transportation must minimize risks to employees of the carrier, the public, shipping and receiving staff, transportation workers and emergency responders.

10.1 Movement of infectious materials.

When moving infectious materials or toxins within a containment zone or building it is essential to prevent contamination and spills. Infectious materials should be protected from being dropped, tipped or spilled. Closed containers (i.e., sealed tubes, and flasks) provide primary containment. Placing materials in leak proof trays with raised sides, on a cart when necessary, reduces the likelihood of a drop and contains any spills.

10.2 Transportation of infectious materials.

10.2.1 Transportation of infectious material between buildings.

All infectious materials transported between buildings must be packaged and moved in a manner which prevents spills and release. All materials must be in sealed, labelled containers, placed within leak proof, impact resistant, buckets or trays.

10.2.2 Domestic and international transportation of infectious materials.

Transportation of materials known to contain or suspected of containing infectious materials or toxins using commercial carriers must be packaged in accordance with national and international regulations. Regulations specify the packaging, documentation and certification requirements required to ensure the safe shipment of these materials. Technical instructions for transport is up-dated annually and is available at the International Civil Aviation Organization (ICAO) or International Air Transport Association (IATA) websites.

Under the Transportation of Dangerous Goods (TDG) regulations, biohazardous materials fall under ***Class 6.2 Infectious*** (substances which are known or suspected to cause disease, may be hazardous to animals or humans or both). There are six main categories under IATA and TDG Class 6.2 requirements:

1. **Infectious substances** - contain or reasonably expected to contain pathogens, including bacteria, viruses, parasites, fungi, or recombinant microorganisms known to cause disease.

2. **Genetically modified organisms and micro-organisms that meet the definition of infectious** - genetically modified organisms known or suspected to be dangerous to humans, animals or the environment; genetically modified organisms capable of altering animals, plants or microbiological substances.

3. **Biological products** - products derived from living organisms such as vaccines and diagnostic products.

4. **Diagnostic specimens** - human or animal material including excreta, secreta, blood, tissue, tissue fluids being transported for diagnostic and investigative purposes.

5. **Clinical waste and medical waste** - wastes derived from the medical treatment of humans, animals, or from biological research, have a relatively low probability that infectious substances are present.

6. **Infected animals** - a live animal known or suspected to contain an infectious substance. Infected animals must not be transported unless the infectious substance cannot be consigned by other means.

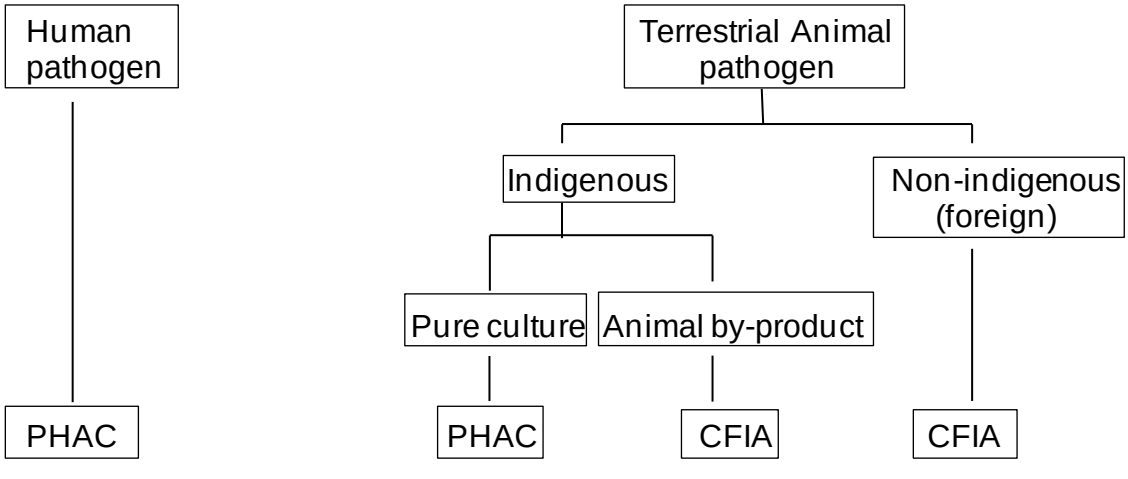
10.3 Import, Export and Transfer of infectious materials.

The Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) regulate the importation and transportation of human and animal infectious material or toxins into and within Canada. Any individual importing or transporting pathogens must have a valid permit for that pathogen, and must have a containment zone that complies with the applicable operational practices and physical requirements for that pathogen risk group. The permit must accompany the pathogen during transport. Information pertaining to permit application may be found at the PHAC (for human and terrestrial animal pathogens) or CFIA (for aquatic animal pathogens, non-indigenous and emerging animal disease pathogens) websites.

10.4 Paperwork required for importation of terrestrial, avian and amphibian pathogens.

(This information was presented in the PHAC webinar "Importation and Licensing Requirements" June 5, 2019).

Importation may require a license (PHAC) and a form (CFIA) depending upon the nature of biohazard – refer to the flow chart.



If you are importing tissue that contains a pathogen, but you are not extracting the pathogen – no paperwork is required.

Based upon the flow chart, determine whether you must apply to PHAC and/or to CFIA

For PHAC:

- apply for license through the Biosafety and Biosecurity Portal
- importation requires a “Pathogen and toxin license” (replaces import permit)
- once license is obtained from PHAC importation may occur

For CFIA:

- CFIA system uses forms and checklists
- an Import permit (CFIA), form 5083 is required
- form 5083 is available at “my CFIA” (must set up a profile to acquire forms)

Note: CFIA also deals with: plant pathogens
: aquatic animal pathogens
: bee pathogens

Appendix 1: Safety Guidelines for Working with Human Body fluids

The following is a **DRAFT** document produced by the Department of Biology but not formally approved by the Faculty of Science, for the safe handling of bodily fluids. The "Safety Guidelines for Working with Body Fluids" document is taken from the *Guidelines and Best Practices, Faculty of Science* manual. This protocol was developed to provide a standard operating protocol for teaching laboratories. As the overarching Biosafety Protocol at StFX applies to "human and non-human primate cell cultures, tissues and body fluids (e.g., blood, urine)" the following document has been included in the Biosafety Manual.

DRAFT

GUIDELINES AND BEST PRACTICES

FACULTY OF SCIENCE

V4: Edited June 2014

Safety Guidelines for Working with Body Fluids

Laboratory and clinical sessions provide hands-on experiences for students in a variety of disciplines and courses. Some sessions pose little or no risk to students or staff, while others pose some risk of a physical injury such as cuts, a risk of infection, or some other hazard. Working with body fluids is informative and at the same time, potentially hazardous. This document provides guidelines to professors, instructors, and research supervisors to mitigate the risks. Working safely with body fluids involves rather simple procedures, all centering on *preventing contact* and *containing, disinfecting and disposing of fluids*.

Prior to the Laboratory or Clinical Session

The professor, instructor or research supervisor should introduce the procedures and risks of a particular laboratory or clinical session in advance.

Students are required to read and understand the risks and preventative measures outlined in this document. Knowledge and preparation are the keys to working safely in the laboratory or clinical arena.

During the Laboratory or Clinical Session

At the beginning of the laboratory or clinical session, the professor, instructor or research supervisor responsible must review the required procedures and risks. The professor, instructor or research supervisor should emphasize that although the laboratory or clinical session is itself mandatory, no individual is required to provide samples of his/her body fluids.

General Regulations

To avoid exposure to body fluids, the following basic procedures apply to all practical work in the laboratory or clinical session:

1. Avoid contact with the face (mouth, eyes, nose) during the laboratory session. For example, no eating, drinking, smoking, chewing gum or applying eye drops or cosmetics is permitted in the laboratory. No object (such as a pen) should be licked or placed in the mouth.
2. Disposable gloves (latex, vinyl or nitrile type gloves) should be available for student and staff use. Gloves are required if contact with another individual's blood is possible. Students and staff with non-intact skin (who have cuts or other lesions) on their hands either should not handle other individual's body fluids, or else they should don gloves before doing so.
3. Immediately after use and before performing other tasks, gloves should be removed aseptically (by peeling them off inside out), discarded as directed, and hands must then be washed thoroughly.
4. Personal belongings such as pens and notes should be protected from contact with body fluids. When possible, personal belongings should be left outside the laboratory or clinical area during sessions involving body fluids.
5. Closed-toe/heeled shoes must be worn; open footwear is not permitted because of the risk of injury from dropped glassware, forceps, chemical solutions, etc.
6. All injuries, splashes, spills and broken or dropped laboratory equipment associated with body fluids should be reported to the professor, instructor or research supervisor immediately for decontamination and cleaning procedures (see below).
7. All students and staff must wash hands thoroughly with soap and water after handling body fluids and before leaving the laboratory or clinical arena.

Effective Handwashing Guidelines

See: The Canadian Centre for Occupational Health and Safety at
http://www.ccohs.ca/oshanswers/diseases/washing_hands.html

Disinfection Using Household Bleach

Household bleach (sodium hypochlorite) concentrations range from 3% to 6% (ultra or concentrated bleach). To clean and disinfect surfaces contaminated with body fluids, use between 0.05% and 0.5% bleach, according to Infection Control Guidelines (December 1998) published in the Canada Communicable Disease Report Vol. 24S8: See also http://www.ccohs.ca/oshanswers/hsprograms/cleaning_staff.html for other details.

This can be achieved by mixing 1 part of bleach to be mixed with 99 parts of tap water (1:100) or one part of bleach to be mixed with 9 parts of tap water (1:10), depending on the amount of body fluids present on the surface to be cleaned and disinfected.

Spills

To clean up spills according to the World Health Organization guidelines available at
http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

Cover the spill with cloth or paper towels to contain it. Pour disinfectant over the paper towels and the immediately surrounding area. Apply disinfectant concentrically beginning at the outer margin of the spill area, working toward the center. After the appropriate amount of time (e.g. 30 min), clear away the materials. If there is broken glass or other sharps involved, use a dustpan or a piece of stiff cardboard to collect the material and deposit it into a puncture-resistant container for disposal.

Collection and Handling Procedures

Urine

- urine should be collected in disposable cups
  - at the end of the experiment, the cups should be carefully rinsed, to avoid splashes and aerosol formation, and the rinse water treated as for *waste urine*, below
- waste urine should mixed with household bleach to achieve a 1:10 dilution before pouring down the drain of one designated sink in the laboratory
  - care should be taken to pour the disinfected urine down the drain directly, not first into the sink
  - water from the tap should be used to flush the disinfected urine away so it does not pool in the (inappropriately named) p-trap
- all supplies and equipment which contact urine should be either decontaminated in bleach before normal washing or else placed in a closed bag (gloves, paper, disposable cups) or other container appropriate to the item before disposal

Blood

Blood sampling for measuring blood glucose levels only requires finger pricks. The use of modern sampling devices makes for a simple, safe sampling procedure when a few basic rules are followed. The following are procedure is based on Health Canada Recommendations available at:

http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2005/blood-capill_lanc-ponc_dev-dis_nth-aah-eng.php

- blood sampling devices have two parts: a lancet holder, and a lancet which is the sharp point or needle that is placed in the holder
- each lancet is for single use on one individual only
- dispose of lancets in an appropriate biohazard-labeled sharps container after a single use
- all supplies and equipment which contact blood or are used to handle blood should be either decontaminated in bleach before normal washing or disposed of as biohazardous waste in a container appropriate to the item (biohazard bag for steam-sterilization of gloves etc. or a biohazard sharps container for lancets)
- reusable lancet holders must be soaked in a 1:10 dilution of household bleach for 30 minutes between users
  - this is because blood may contact the end of the device during sampling and get transmitted to the next user
  - stand the sampler in a beaker of bleach and record the time. After 30 minutes, thoroughly rinse off the blood sampler before using

Appendix 2: Biosafety Laboratory Inspection Report

St. Francis Xavier University

Biosafety Laboratory Inspection Report

Principal User(s): _____ Room Use: _____

Building Name: _____ Building Address: _____

Room Number: _____ Date: _____

Satisfactory (√) Unsatisfactory (X) Not Applicable (-)

SAFETY AWARENESS & INFORMATION

Material Safety Data (MSD) sheets available
in room for : Chemicals (MSDS) _____
Pathogens (PSDS) _____
Special procedures documented _____
Appropriate signage _____
General laboratory safety awareness _____

EMERGENCY PREPAREDNESS

Emergency telephone numbers posted _____
Qualified First Aid Responders posted _____
Map indicating:
- nearest fire extinguisher _____
- fire alarm pull station _____
- evacuation plan & nearest exit _____

FIRE EXTINGUISHERS

Appropriate _____
Accessible _____
Charged, inspected _____
Seal intact _____

SPILL CONTROL

Eye and face protection available _____
Gloves appropriate for hazard _____
Aprons available _____
Absorbent available _____
Absorbent appropriate for hazard _____

HAZARDOUS MATERIALS CHEMICALS

Chemical storage areas appropriate _____
Chemical stock appropriate _____
Chemical inventory in room _____
Chemical inventory up to date _____
Stock chemicals: supplier labels _____
WHMIS labels _____
Temporary _____

COMPRESSED & LIQUIFIED GASES

Supplier/Workplace labels _____
WHMIS labelled _____
Cylinders secured _____
Protective caps used _____
Regulators appropriate _____
Glass dewars taped _____

BROKEN GLASS/SHARPS

Sharps containers available for:
- glass _____
- razor blades, scalpel blades, syringes _____
Labelled _____

FUME HOOD

Airflow indicator _____
Certified _____ Date: _____
Unobstructed - within _____
- surrounding area _____

GENERAL COMMENTS

LABORATORY FACILITIES

- containment zone separated from public/administrative areas by a door ____
- doors into containment zone lockable ____
- doors kept closed ____
- appropriate signage, biohazard, containment level, contact personal ____
- controlled access ____
- windows have effective security, screens ____
- space allocated for personal protective equipment ____
- personal belongings kept separate from containment zone ____
- bench-tops have non-absorbent surface ____
- bench-tops uncluttered ____
- floors slip-resistant ____
- aisles, doorways unobstructed ____

LABORATORY SERVICES

- hand washing sinks near exits ____
- soap, paper towels available ____
- emergency eye wash equipment ____
- wiring, cords in good condition ____
- electrical apparatus properly grounded ____

BIOSAFETY EQUIPMENT

- biological safety cabinet (BSC) ____
- BSC certified ____ Date: _____
- BSC located away from traffic ____
- equipment designed to prevent release of infectious materials ____
- decontamination equipment available ____
- records of decontamination effectiveness ____
- communication between containment zone and outside area, i.e., telephone ____

BIOSAFETY MANAGEMENT

- biosafety manual ____
- StFX biosafety applications ____
- incident reporting procedures ____
- standard operating protocols documented ____
- inventory of infectious materials ____
- record of training personnel ____
- trainees supervised by authorized personnel while handling biohazardous materials ____
- controlled access to biohazardous materials stored outside containment area ____

PERSONAL PROTECTIVE EQUIPMENT

- lab coats worn and stored in containment area ____
- face protection available, good condition ____
- safety glasses available, good condition ____
- disposable gloves available ____
- hand washing performed after handling infectious materials ____

BIOHAZARDOUS WASTE MANAGEMENT

- effective bench disinfectant available ____
- puncture resistant sharps containers ____
- appropriate disposal of liquids ____
- appropriate disposal of solids ____
- record of decontamination effectiveness ____

EMERGENCY RESPONSE PLAN

- describing emergency procedures within the containment zone for:
  - accidents/incidents ____
  - medical emergency ____
  - fire ____
  - spills, large and small ____
  - power failure ____
  - natural disaster ____
  - notification of key personnel ____
  - incident follow-up ____
- described procedures for infectious materials stored outside of containment zone ____
- records retained of incidents involving infectious materials ____

Appendix 3: Biosafety Injury/Hazardous Incident Report

BioSafety Injury/Hazardous Incident Report

St. Francis Xavier University

Biosafety Injury/Hazardous Incident Report **See final page** *For Instructions*

☐No Injury
☐Hazardous incident

☐ Injury requiring:
☐first aid
☐health care (medical aid)
☐lost time

Complete this form if you have encountered a hazardous situation or suffered an injury associated with the handling of biohazardous materials. Return the completed form to the StFX Biosafety Officer (L. Graham, JBBH 419) within three days of the incident.

Individual involved	Last Name	First Name	Initial

☐Student
☐Visitor
☐Employee…Position:

Years Experience in that position: _____

Date of Incident:	**Time of Incident:**	**Name(s) of First Aider(s):**

Describe the first aid given:	**Time that first aid was initiated:**

Description of Incident
State exactly the sequence of events which lead up to the incident, where the incident occurred, and what the individual involved was doing. Use a separate sheet if necessary.

Type of Incident
(See Instructions for description)
Exposure to Hazardous Material:
☐Infectious Materials
Organism/toxin
_____
Concentration/Volume:
_____
☐Chemical
_____
☐Struck or contact by
☐Struck against, contact with
☐Contact with electrical current
☐Fall
☐Over exertion/strain
☐Repetitive motion
☐Other

Names and Addresses of witnesses or persons having knowledge of the incident.

Contributing Factors. What conditions contributed to the incident (number all contributing **causes** in order of importance)

☐ Operating without authority	☐ Failure to use personal protective devices	☐Unsafe equipment
☐Failure to lock out	☐Not guarded or improperly guarded	☐Insufficient care
☐Insufficient training	☐Improper position or posture	☐Inadequate illumination
☐Infraction of safe practice	☐Outside hazardous condition	☐Other (explain below)

Explanation of Contributing Factor(s)

Details of Property Damage

Corrective Measures. Mark with an (x) those actions taken to prevent recurrence; mark with a (p) other corrective actions decided upon planned but not yet carried out. More than one item may apply.

☐Reinstruction of person	☐Equipment repair or replacement	☐Check with manufacturer
☐Reassignment of person	☐Correction of congested area	☐Inform department supervisor
☐Order job safety analysis done	☐Installation of guard or safety device	☐Discipline personnel involved
☐Improved personal protective equipment	☐Actions to improve work procedure	☐Other (explain)

Describe actions taken to prevent recurrence.

Describe injury part of body involved and specify left (L) or right (R) side.

☐Chest ☐Internal ☐Back ☐ Hands ☐Legs ☐Feet ☐Eyes
☐Head ☐Arms ☐Other: _____

Attending Physician	To your knowledge has the individual involved had a previous similar disability? ☐ Yes ☐ No

Treatment of Injury: ☐ University Health Services ☐ Hospital ☐ Other ☐ None

Name of Person Reporting Incident	Signature of Person Reporting Incident	Signature of Department Head

Copy 1: BioSafety Officer	Copy 2: Occupational Health & Safety	Copy 3: Dean of Science	Copy 4: Dept. Chair

PURPOSE OF THE INCIDENT REPORT

1. Ensure compliance with Workers' Compensation Board Regulations which require a report of occupational injury or disease to be filed within 3 days of the occurrence. **Important:** if the filing of the report to the StFX Health and Safety Committee is unavoidably delayed, report the incident by calling Security (ext. 4444).
2. Ensure compliance with provincial regulations with respect to the keeping of records of injuries.
3. Ensure compliance with the Canadian Biosafety Standards and Guidelines.
4. Collect factual data relating to the occurrence of a work injury or biosafety incident.
5. Provide a form on which to record, investigate and take corrective action on an incident.
6. Ensure that corrective action is taken to eliminate recognized causative factors.
7. Collect factual data to develop statistical records.
8. Guide investigators in making an effective investigation.

TYPES OF RESULTS

- **Hazardous Situation**: an incident caused by an unsafe act, an unsafe condition or a combination of both which could have resulted in property damage, physical harm or biocontainment breach.
- **First Aid Injury**: an injury of such minor nature that treatment can be carried out by application of a band-aid or cold compress.
- **Health Care (Medical Aid) Injury**: an incident which requires treatment or a service rendered by medical professionals but does not result in time lost from the workplace.
- **Lost Time Injury**: an injury which results in time lost from work beyond the day of injury.

TYPES OF INCIDENT (DEFINITION OF CODES)

1. **Struck or Contact By**: an incident in which a person has been contacted either abruptly and forcefully by some object in motion, (e.g., bottle falls off shelf, person jabs needle into finger, person pushing cart runs into the injured person), or has been contacted non-forcefully by some substance or agent which has an injury-upon-contact characteristic (e.g., person is splashed by hot or corrosive solution).
2. **Struck Against or Contact With**: an incident in which a person contacts either abruptly and forcefully some object in his surroundings (e.g. person strikes leg against door frame, person bumps head against cupboard door), or comes into contact non-forcefully with some substance or agent capable of producing injury on the basis of mere non-forceful contact (e.g., person touches hot pipe, person places hand in scalding or corrosive liquid).
3. **Contact With Electrical Current**: an incident where an unprotected person or equipment contacts an energized electrical power source or conductor.
4. **Fall:** an incident which can be subdivided into two categories - a "foot level fall" or a "fall to below". A slip or a trip should also be recorded under this category. A "foot level fall" occurs when a person slips, trips, or falls on the same level on which he was standing or walking, e.g., person slips on foreign matter on floor. A "fall to below" occurs when a person falls to below the level on which he was standing or walking, e.g., person falls from ladder, window, chair, or on the stairs.
5. **Over-Exertion or Strain**: an incident in which a person puts excessive strain on some part of the body (e.g., person strains back or some other part of body lifting equipment).

6. **Exposure:** an incident in which a person is exposed to harmful conditions, i.e.., (a) toxic gases, fumes or vapours, (b) infectious organisms or biological toxins, (c) extremes of heat or cold, (d) oxygen deficient atmosphere, (e) radioactive radiation, or (f) intense light brightness.
7. **Repetitive Motion**: incidents which result from work practices which involve repetitive movement of a joint wrist, elbow, etc) resulting in a soft tissue injury.

Appendix 4: Template for Pathogen Risk Assessment

The following document was provided by the Public Health Agency of Canada, Biosafety and Biosecurity group and is intended to be used to assign a Risk Group to infectious organisms not currently covered by Pathogen Safety Data Sheets.

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Risk Assessment Summary:
Performed by: Click here to enter text.
Date Completed: Click here to enter a date.
Human ☐RG1 ☐RG2 ☐RG3 ☐RG4
Animal ☐RG1 ☐RG2 ☐RG3 ☐RG4

This risk assessment tool is intended for stakeholders, already familiar with the concepts of biosafety and risk assessment, to use to classify the agents in their inventories. Any questions about how to use this tool can be directed to the Biosafety Risk Assessment Group at BRA-ERB@PHAC-ASPC.gc.ca.

Pathogen Risk Assessment

Pathogen Name:

Taxonomy:
Agent Type (e.g., Bacteria, Virus):
Family:
Subfamily:
Genus:
Species:
Sub-Species:
Other (e.g., clonal isolate, serotype, serovar, biovar):

1. Pathogen Oversight

Regulatory Authorities

The outcome of this risk assessment will be a risk group classification for humans and animals that will determine the requirements for working with the agent being assessed under the *Human Pathogens and Toxins Act* and *Health of Animals Act*; however, there may be other requirements associated with the agent being assessed. This section will assist you in identifying what additional oversight may exist and determining who to contact prior to commencing work.

During your literature search, determine whether the agent has the ability to infect humans, terrestrial animals, aquatic animals, plants or bees. Even opportunistic infections should be noted, regardless of the risk group outcome of your assessment. Identify whether the agent is subject to official control. This will help you identify who you will need to contact in order to work with the agent in the laboratory.

Is the pathogen a

☐strain, clonal isolate, or recombinant variant of a pathogen with a known risk group (RG)?
☐human pathogen?*
☐terrestrial animal pathogen?*
  ☐non-indigenous animal pathogen?**
  Notes:
  ☐OIE listed disease?**
  Notes:
☐aquatic animal pathogen?**
☐plant pathogen?**
☐bee pathogen?**

Is the pathogen subject to official control?

☐National Notifiable Disease
☐Domestic Substances List
☐Reportable Disease
☐Immediately Notifiable Disease
☐Annually Notifiable Disease
☐Plant Protection Regulations
☐Quarantine Act
☐Provincial Notifiable Disease
Other (list):

*** Human and terrestrial animal pathogens may be regulated by the Public Health Agency of Canada.**
**** Terrestrial animal pathogens that are non-indigenous to Canada (cause foreign animal and emerging animal diseases), aquatic animal pathogens, plant pathogens, and bee pathogens may be regulated by the Canadian Food Inspection Agency.**

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Biosecurity Oversight

Biosecurity refers to security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and other related assets (e.g., personnel, equipment, non-infectious material, and animals).

- Identify whether the agent appears on any of the lists of agents of potential concern for biosecurity. Agents on these lists may be subject to additional security requirements.
- Identify whether there are any biosecurity considerations that should be noted in the risk assessment. Provide a brief summary, supported by references where possible, as to the potential biosecurity concerns related to this agent. Any biosecurity concerns should be fully elaborated in your Biosecurity Risk Assessment and Biosecurity Plan. The requirements related to biosecurity are fully elaborated in the Canadian Biosafety Standard.

☐ Australia Group Common Controls List
☐ Select Agents and Toxins List
☐ Security Sensitive Biological Agent
☐ This pathogen has no known biosecurity concerns. **If so, please proceed to section 2.**

Notes:
Briefly describe biosecurity considerations that could impact the risk assessment. The full details should be elaborated in your Biosecurity Plan.

2. Pathogen Description

Provide background information that could be relevant to the interpretation of the risk assessment or overall risk. Provide references to support your comments. Some of the types of information that may be applicable to the pathogen risk assessment are listed below.

- **Example 1**, when assessing a recombinant virus, the genome structure of the native virus and modifications should be described in sufficient detail to determine how the modifications will impact the different factors being assessed (e.g., pathogenicity).
- **Example 2**, when assessing bacteria or fungi, the ability to product toxins may directly impact pathogenicity.
- **Example 3**, when assessing fungi with complex taxonomy or numerous changes to taxonomy, current and historical nomenclature should be described.

Reconstructed, Engineered or modified pathogens should be assessed throughout the risk assessment by comparing the newly created pathogen to the wild type or a previously assessed variant, linking the various modifications to anticipated effects on the different risk factors (e.g., pathogenicity, communicability).

General Information

- Taxonomy
- Historical background
- Size
- Shape
- Structure
- Genome structure/information
- Ideal growth conditions
- Modifications (e.g., CRISPR gene drives)
- Temperature tolerance

Bacteria

- Motility
- Sporulation
- Toxin production
- Oxygen requirements
- Gram staining, AF staining
- Enzymatic activity

Viruses

- RNA/DNA virus
- Single/Double stranded
- Other classifications

Other (e.g., Fungi, Protozoa)

- Life cycle
- Reproduction
- Morphology
- Growth and physiology
- Toxin production

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3. Pathogenicity (Individual Risk)

Assessment of Human Pathogenicity Indicators

Assess the indicator questions and use these to rate the likelihood of serious disease. Use the rationale section under each question to substantiate your analysis with a description and corresponding references.

Outline uncertainty and assumptions within the rationale for each indicator. The greater the assumptions/uncertainty, the more frequently the risk assessment should be reviewed.

1) If exposed, what is the likelihood that infection would result, with or without overt signs of disease? ☐ None ☐ Low ☐ Moderate ☐ High ☐ Unknown Rationale:
2) If exposure led to disease, what is the likelihood that there would be acute signs of disease? ☐ None ☐ Exclusively in susceptible populations ☐ Low ☐Moderate ☐ High ☐ Unknown Rationale:
3) If exposure led to disease, what is the likelihood that there would be serious sequelae or mortality? ☐ None ☐ Exclusively in susceptible populations ☐ Low ☐Moderate ☐ High ☐ Unknown Rationale:
4) Are certain populations (e.g., pregnant, elderly, immunocompromised) at an increased risk of infection or disease? ☐ Yes ☐ No ☐ Unknown Rationale:
Rate the likelihood of serious disease considering the **Human Pathogenicity Indicators** above. ☐ None, the agent is not a human pathogen; ☐ Low, the agent is an extremely rare opportunistic pathogen. Serious disease may occur in severely ill or immunocompromised; ☐ Moderate, the agent is able to cause serious disease but is unlikely to do so; or ☐ High, the agent is likely to cause serious disease.

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Assessment of Natural Animal Host(s) Pathogenicity Indicators

Assess the indicator questions and use these to rate the likelihood of serious disease in the natural animal host. **Natural animal hosts** are those where infection and/or disease in the animal would occur in a natural environment, and includes wild animal species (e.g., wild rodents, ruminants, etc.). Information obtained under experimental conditions designed to reproduce natural exposure may be of use. Other information obtained from experimentally infected animals should be considered as surrogate data only. Use the rationale section under each question to substantiate your analysis with a description and corresponding references.

Outline uncertainty and assumptions within the rationale for each indicator. The greater the assumptions/uncertainty, the more frequently the risk assessment should be reviewed.

1) If exposed, what is the likelihood that infection would result, with or without overt signs of disease?
☐ None ☐ Low ☐ Moderate ☐ High ☐ Unknown

Rationale:

2) If exposure led to disease, what is the likelihood that there would be acute signs of disease?
☐ None ☐ Exclusively in susceptible populations ☐ Low ☐ Moderate ☐ High ☐ Unknown

Rationale:

3) If exposure led to disease, what is the likelihood that there would be serious sequelae or mortality?
☐ None ☐ Exclusively in susceptible populations ☐ Low ☐ Moderate ☐ High ☐ Unknown

Rationale:

4) Are certain populations at an increased risk of infection or disease?
☐ Yes ☐ No ☐ Unknown

Rationale:

Rate the likelihood of serious disease considering the **Natural Animal Host Pathogenicity Indicators** above.

☐ None, the agent is not an animal pathogen;
☐ Low, the agent is an extremely rare opportunistic pathogen. Serious disease ;may occur in severely ill or immunocompromised;
☐ Moderate, the agent is able to cause serious disease but is unlikely to do so; or
☐ High, the agent is likely to cause serious disease.

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4. Pre- and Post-Exposure Measures (Human Community Risk)

Assessment Human Pre- and Post-Exposure Measures Indicators

Assess the indicator questions and use these to rate the level of protection from infection and/or the development of disease. Use the Rationale section under each question to substantiate your analysis with a description and corresponding references.

1) Are pre-exposure measures available to prevent infection or disease (e.g., vaccines, pre-exposure prophylaxis)?

- ☐ Not available
- ☐ Limited availability
- ☐ Readily available for use on-demand
- ☐ Widely available and in use in the community
- ☐ Unknown

Rationale:

2) Are these pre-exposure measures effective at preventing infection or disease?

- ☐ Not applicable, pre-exposure measures are not available
- ☐ Not effective, minimal protection
- ☐ Moderately effective, partial protection
- ☐ Highly effective*, almost complete protection
- ☐ Unknown

Rationale:

3) Are post-exposure measures available to treat infection or prevent disease (e.g., post-exposure prophylaxis, antibiotics, antifungals, antivirals)?

- ☐ Not available
- ☐ Limited availability
- ☐ Readily available for use on-demand
- ☐ Widely available and in use in the community
- ☐ Unknown

Rationale:

4) Are these post-exposure measures effective at treating infection or preventing disease?

- ☐ Not applicable, post-exposure measures are not available
- ☐ Not effective
- ☐ Moderately effective
- ☐ Very effective
- ☐ Unknown

Rationale:

5) Are there sub-populations in which the use of or access to pre-exposure measures is less than the general population?

☐ Yes ☐ No ☐ Unknown

Rationale:

Rate the level of protection from infection and/or the development of disease considering the **Pre- and Post-Exposure Measures Indicators** above.

- ☐ None, if exposed, the community would not be protected;
- ☐ Moderate to low, if exposed, the community would be somewhat protected;
- ☐ Very high*, if exposed, the community would be generally protected; or
- ☐ Unknown.

*Note. It is rare for the level of protection in the community to be very high. For example, community protection against Measles virus is very high because there is a highly effective vaccine and the majority of Canadians are vaccinated.

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5. Communicability (Human and Animal Community Risk)

Assessment of Human Communicability Indicators

Assess the indicator questions and use these to rate the likelihood of human-to-human transmission by direct or indirect contact. Use the "Rationale" section under each question to substantiate your analysis with a description and corresponding references. Note that route of infection (e.g., ingestion, inhalation) only partially addresses the likelihood of human-to-human transmission. For example, an environmental fungus may be likely to produce infection through inhalation of environmental spore, but not transmit from person-to-person, directly or indirectly. Other modes of transmission (e.g., vertical) can be noted but will not impact the final RG classification.

1) What is the likelihood of infection or disease arising from ingestion?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

2) What is the likelihood of infection or disease arising from injection (e.g., accidental or intentional inoculation, penetrating wounds)?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

3) What is the likelihood of infection or disease arising from arthropod vectors (e.g., through bites of infected arthropod species, such as mosquitoes and ticks)?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

4) What is the likelihood of infection or disease arising from contact of the agent with intact skin?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

5) What is the likelihood of infection or disease arising from contact of the agent with mucous membranes or damaged skin?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

6) What is the likelihood of infection or disease arising from inhalation of the agent (e.g., large or small droplet aerosols, spores)?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

7) What is the likelihood of disease arising from exposure to affected animals, through either direct or indirect contact?
☐ Not zoonotic ☐ Low, unlikely ☐ Moderate, possible ☐ High, common mode of transmission

Rationale:

Based on the analysis of the **Human Communicability Indicators** above, rate the likelihood of human-to-human transmission by the following modes of transmission (more than one may be applicable).

Direct Contact (Casual)
☐ None ☐ Unlikely ☐ Possible ☐ Likely ☐ Unknown

Direct Contact (Intimate)
☐ None ☐ Unlikely ☐ Possible ☐ Likely ☐ Unknown

Indirect Contact (Fomites)
☐ None ☐ Unlikely ☐ Possible ☐ Likely ☐ Unknown

Indirect Contact (Vectors)

☐ None ☐ Unlikely ☐ Possible ☐ Likely ☐ Unknown

Assessment of Animal Communicability Indicators

Assess the indicator questions and use these to rate the likelihood of animal-to-animal transmission by direct or indirect contact. Use the "Rationale" section under each question to substantiate your analysis with a description and corresponding references. Note that route of infection (e.g., ingestion, inhalation) only partially addresses the likelihood of animal-to-animal transmission. For example, an environmental fungus may be likely to produce infection through inhalation of environmental spore, but not transmit from animal-to-animal, directly or indirectly. Other modes of transmission (e.g., vertical) can be noted but will not impact the final RG classification.

1) What is the likelihood of infection or disease arising from ingestion?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

2) What is the likelihood of infection or disease arising from injection (e.g., accidental or intentional inoculation, penetrating wounds)?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

3) What is the likelihood of infection or disease arising from arthropod vectors (e.g., through bites of infected arthropod species, such as mosquitoes and ticks)?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

4) What is the likelihood of infection or disease arising from contact of the agent with intact skin?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

5) What is the likelihood of infection or disease arising from contact of the agent with mucous membranes or damaged skin?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

6) What is the likelihood of infection or disease arising from airborne transmission (e.g., large or small droplet aerosols, spores)?
☐ None ☐ Low, unlikely ☐ Moderate, possible ☐ High, preferred route ☐ Unknown

Rationale:

7) What is the likelihood of disease arising from exposure to affected humans, through either direct or indirect contact?
☐ Not zoonotic ☐ Low, unlikely ☐ Moderate, possible ☐ High, common mode of transmission

Rationale:

Based on the analysis of the Animal Communicability Indicators above, rate the likelihood of animal-to-animal transmission by the following modes of transmission (more than one may be applicable).

Direct Contact (Casual)
☐ None ☐ Unlikely ☐ Possible ☐ Likely ☐ Unknown

Direct Contact (Intimate)
☐ None ☐ Unlikely ☐ Possible ☐ Likely ☐ Unknown

Indirect Contact (Fomites)
☐ None ☐ Unlikely ☐ Possible ☐ Likely ☐ Unknown

Indirect Contact (Vectors)
☐ None ☐ Unlikely ☐ Possible ☐ Likely ☐ Unknown

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6. Assessment of Public Health and Economic Impact of New and/or Emerging Human Pathogens (Human Community Risk)

Complete this section **only for new or emerging human pathogens**. New or emerging pathogens, including engineered or reconstructed pathogens, may pose unique risks to the public. **Economic impact** refers to the costs associated with things like treating disease, hospitalization and long term care, and lost wages due to missed work. **Public health impact** refers to the ability of a pathogen to infect, cause disease, transmit among, and produce serious disease or death in people. Use the Rationale section under each question to substantiate your analysis with a description and corresponding references. **If you identify a new or emerging pathogen, please contact the Public Health Agency of Canada and, for emerging animal pathogens, the Canadian Food Inspection Agency to validate your risk assessment.**

1) Is the agent a new or emerging pathogen? If yes, complete the remainder of this section. If no, proceed to Section 7 (Host Range, Natural Distribution, and Economic Impact).

☐ No **(Proceed to Section 7)** ☐ Yes **(Provide detailed rational for questions 2 and 3 below)**

Rationale:

2) Would there be a significant impact on the economy if the pathogen were released from the laboratory (e.g., costs related to hospitalization, drugs, vaccination, and/or lost work as a result of illness)?

☐ No, the anticipated economic impact would not be very high

☐ Yes, **very high economic impact would be anticipated** if the pathogen were released from the laboratory

Rationale:

3) Would there be a significant impact on public health if the pathogen were released from the laboratory (e.g., significant number of cases, high health care burden)?

☐ No, the anticipated public health impact would not be very high

☐ Yes, **very high public health impact would be anticipated** if the pathogen were released from the laboratory

Rationale:

Based on the analysis of the New and/or Emerging Pathogen Human Pathogen Indicators above, what is the predicted impact of the release of the pathogen from a laboratory on public health or the economy:

☐ Low to moderate, release from the laboratory is unlikely to have a significant impact on public health and/or the economy; or

☐ Significant, release from the laboratory is likely to have a significant impact on public health and/or the economy.

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7. Host Range, Natural Distribution, and Economic Impact (Animal Community Risk)

Assessment of Host Range, Natural Distribution, and Economic Impact Indicators for Natural Animal Hosts

Assess the indicator questions and use these to rate the economic impact of releasing the pathogen from the laboratory on the natural animal host population. Use the Rationale section under each question to substantiate your analysis with a description and corresponding references.

1) How broad is the range of natural animal hosts that are susceptible to disease (host range)? Common classes: Amphibia, Aves, Chondrichthyes, Mammalia, Osteichthyes, Reptilia, Arachnida, Insecta.

- ☐ Extremely limited, single species
- ☐ Limited, single order
- ☐ Broad, single class
- ☐ Very broad, multiple classes
- ☐ Unknown

Rationale:

2) Are the natural host species in Canada?

- ☐ Natural host species are not in Canada
- ☐ Natural host species are present in restricted regions in Canada
- ☐ Natural host species are present throughout Canada
- ☐ Unknown

Rationale:

3) What is the natural distribution of the agent in Canada?

- ☐ Endemic in Canada
- ☐ Found infrequently in Canada; rare imported cases or limited natural distribution
- ☐ Found in Canada, but regionally restricted
- ☐ Not present in Canada
- ☐ Unknown

Rationale:

4) Considering animals in their order of economic importance*, what is the combined economic value of the natural animal host(s)?

☐ None/Not Applicable ☐ Low Value ☐ Medium Value ☐ High Value ☐ Unknown

Rationale:

5) Considering animals in their order of economic importance*, what is the combined economic value of the other animal host(s), for example experimentally infected animals?

☐ None/Not Applicable ☐ Low Value ☐ Medium Value ☐ High Value ☐ Unknown

Rationale:

Based on the analysis of the **Host range, Natural Distribution, and Economic Impact Indicators** above, the economic impact of release on the natural animal host population is:

☐ None ☐ Minimal ☐ Moderate ☐ Significant ☐ Unknown

* The **Canadian Food Inspection Agency (CFIA) has classified animals in terms of their economic value to Canada as follows:**

1. Highest value livestock industries: bovine, equine, porcine, poultry, crustaceans, finfish (wild and farmed).
2. Medium value livestock industries: small ruminants (sheep and goats), bees, molluscs, other farmed ruminants (cervids, bison).
3. Lowest value livestock industries and non-livestock animals: lagomorphs (rabbits), companion animals (dogs, cats, etc), reptiles, amphibians, rodents, non-human primates.

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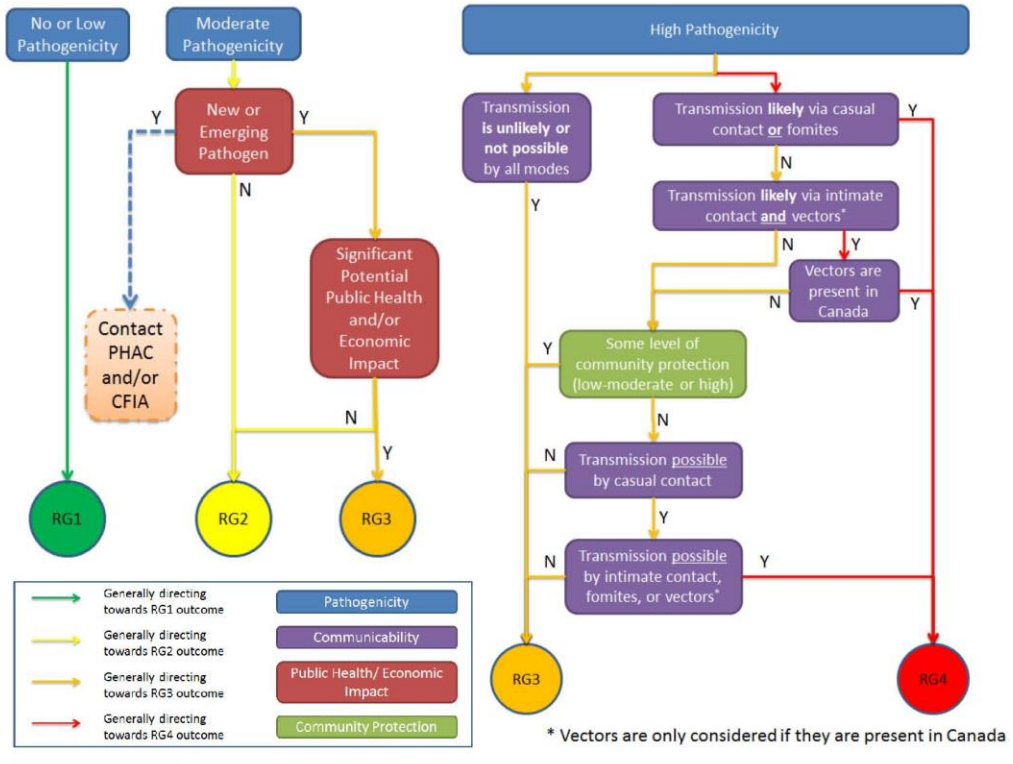
8. Risk Group Decisions

The risk group reflects the risk posed to the human (human risk group) and animal (animal risk group) populations. If the human and animal risk group values differ, **the higher value dictates the level of containment required to work with the agent.** In almost all cases, the risk group value and containment level values are the same (i.e., a risk group 3 agent will be handled in a containment level 3 lab, as described in the Canadian Biosafety Standard). In rare cases, the Public Health Agency of Canada will issue Biosafety Directives that outline specific derogations of containment for certain pathogens and/or activities (http://www.phac-aspc.gc.ca/lab-bio/res/advi-avis/index-eng.php).

Human Risk Group Decision

Use the decision tree to determine the risk group (RG) based on your overall rating of each of the **human** risk factor indicators.



Human Risk Group: ☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4

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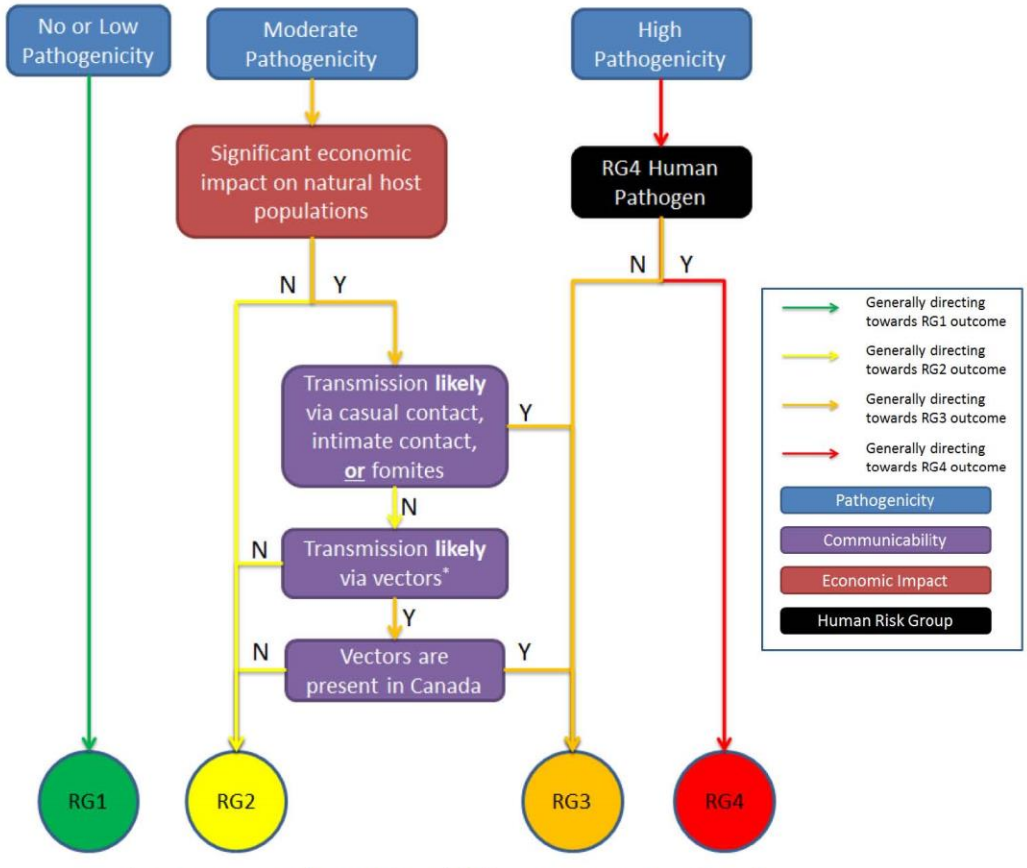
Animal Risk Group Decision

Use the decision tree to determine the risk group based on your overall rating of each of the **animal** risk factor indicators.



* Vectors are only considered if they are present in Canada

Animal Risk Group: ☐ RG1 ☐ RG2 ☐ RG3 ☐ RG4

9. References

All information provided in the risk assessment should be cited fully, using the highest quality data available.

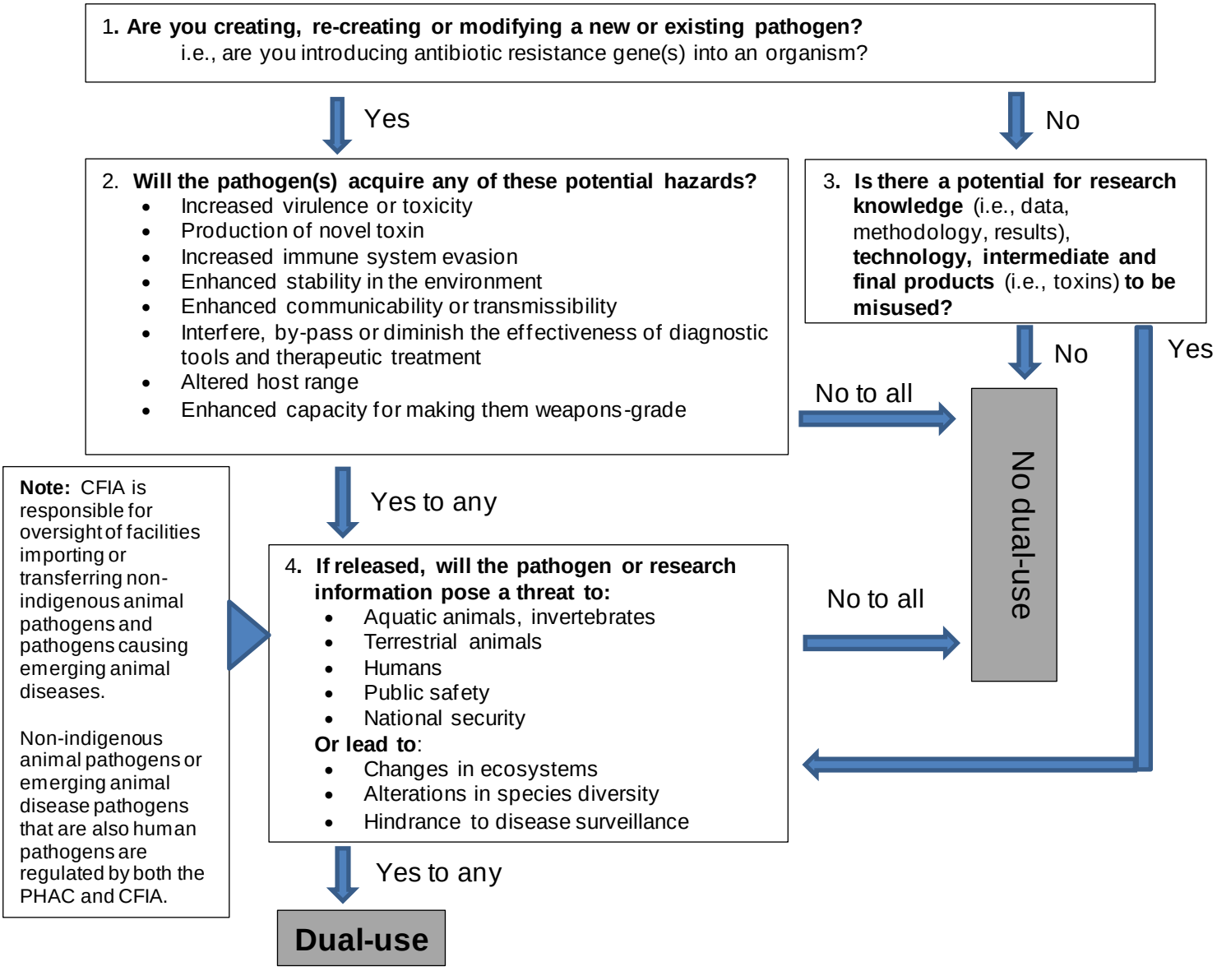
- High quality data means it was sufficient for a thorough analysis of all elements of the risk assessment. High quality data sources include information from clinical trials and standardized studies.
- Medium quality data means it was sufficient for a thorough analysis of some elements of the risk assessment but that there were some data gaps and minor assumptions were made. Medium quality data sources include peer-reviewed publish literature and edited literature.
- Low quality data means it was insufficient for a thorough risk assessment and that there were major data gaps and major assumptions were made. Low quality data sources include expert opinion, independent communications, and uncited websites.

Appendix 5: Considerations for Risk Assessment and Mitigation of Research with Dual-Use Potential

The following information has been obtained from the Public Health Agency of Canada's *Plan for Administrative Oversight for Pathogens and Toxins in a Research Setting – Required Elements and Guidance* and from *Dual-Use Webinar* (Dec. 4, 2019).

Use the "Decision Tree: Identification of Dual-use Potential in Life Sciences Research" to determine whether dual-use potential exists. Note that dual use potential extends to **knowledge** (i.e., publication of the DNA sequence for a novel microbial trait which could be stably incorporated into another organism) and **technology** (i.e., development of gene editing tools or gene drives which could be misused) developed from biological research.

Decision Tree: Identification of Dual-Use Potential in Life Sciences Research



To identify research with dual use potential ask these 4 questions:

1. Are you creating, re-creating or modifying a new or existing pathogen/toxin?
2. Will the pathogen(s) acquire any potential hazards?
3. Is there potential for generating data, knowledge or technologies that could be misused?
4. If released could the pathogen, toxin, knowledge or technologies be harmful?

If you answer "yes" for 0 or 1 of these questions, monitor the research for changes in these answers as the research progresses.

If you answer "yes" for 2 – 4 of these questions, there is the risk of dual-use potential and a **risk assessment and mitigation plan must be in place prior** to undertaking the research.

The risk assessment should assess the ways in which pathogens, knowledge, technology or products (e.g., toxin) could be misused, the ease with which they may be misused, and the scope and magnitude of the potential consequences of misuse.

- Assess the likelihood of misuse i.e., would specific training or technical skills be required for misuse.
- Assess the severity of impact misuse would have on the environment, public, economy, national security, i.e., what is the infectious dose of the pathogen? What is the availability of treatment? What types of equipment or tools would be required to disperse the agent? Could the pathogen survive and proliferate in the environment?
- Assess the ease of obtaining materials, i.e., is special equipment required to scale up?
- Assess the time frame, i.e., how fast could a harmful product be generated?

Considerations of the following questions can help when performing the risk assessment[§]:

- What types of pathogens, knowledge, technology, or products are anticipated to be generated through the research?
- How could pathogens, knowledge, technology, or products resulting from the research be misused to pose harm to public health and safety or national security?
- What type of technical skills will be required to repeat the experiment?
- Are the materials, tools and equipment expensive or difficulty to acquire?
- If released outside the laboratory, will the pathogen affect humans and/or animals?
- What is the likelihood that the knowledge, information, technology, or products from the research will be used to harm public health and safety, the environment (including animals) or national security?
- What is the scope and magnitude of the potential risk(s) identified?

An effective oversight system is based on identifying and managing the risks associated with the potential of misuse or misapplication of organisms, knowledge, technology and products of research resulting in the harm to the public health and safety, animals, or national security. Therefore, risk mitigation plans should be created and measures implemented to address the identified risks.

Considerations of the following questions can help in creating an effective risk mitigation plan[§]:

- What is the strategy or strategies being implemented by the institution/organization to address the risks (e.g., applying specific biosafety and biosecurity measures or modifying experimental design or methodology such that an attenuated strain is used or strain's ability to proliferate outside of the lab or within different hosts is limited by using a different technique)?
- Are there currently any countermeasures (i.e., treatments) to help mitigate the potential consequences? Are they readily available?

- How will the results or products of the research be shared or distributed (i.e., will the results or products be shared openly or remain within the laboratory or institutions)?
- How readily available are these results?
- Who will have access to the knowledge, information, technology, or final products?
- Will the risk change if specific information is redacted for publication?

[§]Adapted from *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern. A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern.*

Appendix 6: Biohazard spill kit instructions

BIOHAZARD SPILL CLEAN UP

1. **Clear the area** of non-essential people and items; request help if needed.
2. **Take care of injuries first**. Note eyewash station and First Aid Kit.
3. **Locate Spill Kit** (white pail) and obtain disposable gloves (in spill kit).
4. **Cover contaminated area**, including liquid, glass and Petri plates with paper towels.
5. **Soak paper towels and spill area with Bench Disinfectant** or **if a larger volume is needed, prepare and use 1% Bleach as follows:**
    - Open spill kit and remove bottle of concentrated bleach (4%) and the empty bottle labeled 'For 1% Bleach'.
    - Make up 1% bleach by following instructions on the bottle.
    - Pour 1% bleach solution on paper towels to cover area

NOTE: USE EITHER BENCH DISINFECTANT OR BLEACH, NOT BOTH!

6. **Let stand for 10 minutes**.
7. **Wearing disposable gloves and eye protection, discard wet paper towels** in the large orange autoclave bag (located in spill kit).

Broken Glass	**Petri Plates**
• Locate broom and dustpan in Biohazard Spill Kit.	• Locate broom and dustpan (if needed) in Biohazard Spill Kit
• Sweep up broken glass and place in metal bucket labelled 'infectious broken glass'.	• Pick up Petri plates and place them in the orange autoclave bag. For broken pieces of plastic use broom and dustpan, and dispose of pieces in autoclave bag.
• Put dust pan and broom into orange autoclave bag. Remove gloves by turning inside out and place in the autoclave bag.	• If used, put dust pan and broom into the autoclave bag. Remove gloves by turning inside out and place in the autoclave bag.

8. **Wash hands** thoroughly with soap and water.
9. Notify Leah, or Dr. Graham immediately and complete **Biosafety Injury/Hazardous Incident Report form** located in the Biohazard Spill Kit.

Leah Rogers lmrogers@stfx.ca; Lori Graham lgraham@stfx.ca

Appendix 7: Biohazardous Emergency Response Plan

BIOHAZARDOUS MATERIAL EMERGENCY RESPONSE PLAN

Principle Investigator:	**StFX Security**	Phone: 867-4444
Contact Info:	**Biosafety Officer**	Lori Graham: 867-2386
Room Location:	After hours Emergencies are reported to StFX Security	

Injury or Potential Exposure

- Personal injury or exposure takes priority over clean up
- For injury, contact nearest First Aid responder
- Refer to Potential Exposure flow chart and Pathogen Safety Data Sheets (PSDSs)
- For potential exposure, immediately remove contaminated clothing and PPE and place in an autoclave bag. Wash affected areas with soap and water or flush face/eyes at an eyewash station
- If medical follow up is warranted it should be sought immediately

Biological Spill Response Kit Contents

- Instructions for use
- Exposure flow chart
- Disinfectant (with instructions and container for dilution)
- Paper towels
- Forceps or tongs
- Autoclave bags
- Dust pan, brush
- Safety glasses/goggles
- Face mask
- Disposable gloves

Clean-up Procedures

SPILLS IN OPEN AREAS (i.e. LABORATORY)

- Alert people in immediate area.
- For Risk Group 2: If an aerosol is generated (or the risk exists), hold your breath and quickly leave the lab. Close the door and post a warning sign. Evacuate the area for 30 minutes to allow aerosols to settle prior to clean-up.
- For Risk Group 1: Proceed immediately to clean-up.
- Put on PPE (lab coat, gloves, and safety glasses/goggles).
- Get the Biological Spill Response Kit.
- Cover an area twice the size of the spill with paper towels.
- Cover the spill area with disinfectant. Pour disinfectant from the outside towards the inside of the spill.
- Allow 30 minutes contact time.
- Use forceps or dust pan and brush to pick up broken glass and other items.
- Discard sharps or broken glass in “contaminated broken glass” bucket.
- Collect disinfectant toweling in autoclave bag.
- Re-clean area with disinfectant allowing 30 min contact time.
- Wipe down any contaminated adjacent areas or equipment with disinfectant.
- Inform personnel and remove warning signs when clean-up is complete.
- Remove and dispose/decontaminated PPE.
- Wash hands.

SPILLS WITHIN A BIOLOGICAL SAFETY CABINET

- Leave the cabinet running.
- Spills <50ml. Cover the spill with paper towels and flood with disinfectant (70% ethanol). Let stand 30 minutes.
- Spills >50ml, or spills emptying into catch basin. Prepare a solution of 1% bleach. Cover spill with paper towels, flood with bleach. Let stand 30 min.
- Discard paper towels in autoclave bag.
- Remove broken glass using forceps and place in "contaminated broken glass" bucket.
- Wipe surfaces dry with paper towels.
- Wash cabinet walls and surfaces with distilled water.
- Wash cabinet walls and surfaces with 70% ethanol. Dry well.
- Allow cabinet fan to run for 10 minutes after clean-up is complete before resuming work.

SPILLS WITHIN A CENTRIFUGE

- Shut centrifuge off and leave lid closed for 30 minutes to allow aerosols to settle.
- Remove buckets and rotors to BSC for disinfection.
- Use a squeeze bottle to apply non-corrosive disinfectant to all contaminated surfaces of the centrifuge.
  Allow 30 minutes contact time.
- Thoroughly wipe down the inside of the centrifuge and all parts with disinfectant soaked paper towels. Dry well.
- Wash surfaces with distilled water, then with 70% ethanol. Dry.

SPILLS OUTIDE THE LABORATORY

- Biohazards transported outside the lab must be in a sealed primary container enclosed in a secondary container with a lid.
- Wipe the exterior of the secondary container with disinfectant before leaving the lab so it can be transported without gloves.
- Follow directions for spills in open areas.

Decontamination & Disposal

- Do not autoclave articles treated with bleach as this can create hazardous fumes.
- Autoclave bag containing used paper toweling and gloves may be discarded with regular waste.
- Autoclave bag containing contaminated clothing must be autoclaved prior to laundering.
- Contaminated broken glass must be autoclaved prior to disposal with non-infectious broken glass/sharps.

Reporting & Documentation

Report all spills, injuries, and potential exposures to:

- Lab Supervisor/Principal Investigator
- Biosafety Officer (BSO)

Thefts also reported to STFX Security.
Information security incidents also reported to IT Service Desk.

For all spills involving biohazardous materials complete a **StFX Biosafety Injury/Hazardous Incident Report Form** and submit to the StFX Biosafety Officer.

Appendix 8: Decision Chart to assist in the assessment of an incident to determine if exposure to a biohazardous material has occurred

(Canadian Biosafety Handbook – 2nd edition)