UNIVERSITY of GUELPH

IMPROVE LIFE.

Biosafety Manual

EDITION 3.0, JULY 2019

Table of Contents

Index of Tables

1. Introduction

Biohazardous materials are materials potentially containing infectious microorganisms that cause disease in humans, animals, or plants, and the toxins of such organisms. These materials are regulated as a workplace hazard by the Workplace Hazardous Materials Information System (WHMIS) regulation as well as the Human Pathogens and Toxins Act (HPTA) and Regulations and Transport of Dangerous Goods Act and Regulations. In addition, the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) have issued standards for working with these substances. Compliance with the Canadian Biosafety Standard is a condition of License granted to the University by PHAC under the HPTA. Guidelines issued by the National Institutes of Health and the Centers for Disease Control and Prevention in the United States are considered mandatory for researchers receiving grants from particular United States sources.

As the University endorses best practices for workplace health and safety, much of the material encompassed in this manual has been taken from the biosafety guidelines issued by Canada, the USA, and the European Community.

1.1 Biosafety policy and program

The Biosafety Policy and accompanying Program are issued under the authority of the Vice-President, Finance, Administration, and Risk and administered by the Department of Environmental Health and Safety. The Policy and Program define materials encompassed by the policy, responsibilities of various parties, and the permitting process for documenting the management of biohazardous materials.

1.2 Responsibilities

Responsibilities of various stakeholders are delineated in the Biosafety Program.

1.3 Workplace/ laboratory specific biosafety manual

The Principal Investigator is responsible for preparing the Workplace/Laboratory Specific Biosafety Manual. Although the safety manual includes protocols for working with biohazardous materials, the manual should also contain information about other workplace hazards such as hazardous materials, working with animals, electrical hazards, etc.

The Biosafety Manual contains information regarding the risk assessment process, job hazard analysis, and risk management to aid in this process.

The manual shall contain the following items as a minimum:

- Principal Investigator, designates, locations, biohazardous materials used.
- Summary of work.
- Biohazard permit.
- 24-hour emergency contacts.
- Emergency plans (spills, exposure, theft, fire, loss of power).
- Security.
- Responsibilities.
- Ordering, shipping and receiving biohazardous materials.
- Safe work practices.
- Decontamination and disinfection.
- Waste disposal.
- Use of equipment (e.g., biological safety cabinets, centrifuges, microtomes, etc.).

- Personal protective equipment.
- Medical surveillance.

1.4 Training

All persons working with or potentially exposed to biohazardous materials in the workplace must be trained at an appropriate level. The Department of Environmental Health and Safety supplies general training; the Principal Investigator is responsible for workplace-specific training. Each Principal Investigator is required to develop and regularly review a training-needs assessment for persons working with biohazards.

Training starts with orientation training and is supplemented by refresher training as well as training on new procedures, agents, and equipment when they are introduced to the work area. All workplace training must be documented.

It must be emphasized that Principal Investigators are responsible for ensuring that all persons in the workplace are aware of the hazards as well as the methods and procedures in place to control the hazards.

1.5 Medical surveillance

Medical surveillance is an integral part of the biosafety program. Occupational Health and Wellness administers the medical surveillance program. Refer to the Occupational Health Surveillance – Biosafety module for more information.

2. Legislation, standards, and guidelines

Biohazardous materials in the workplace are regulated through various legislation and standards including but not limited to:.

- Human Pathogens and Toxins Act
  - Human Pathogens and Toxins Regulations
    - Canadian Biosafety Standard
  - Canadian Biosafety Handbook, Second Edition,
  - 2016 Export and Import Permits Act
  - Health of Animals Act
  - Transportation of Dangerous Goods Act and Regulations,
- Canadian Environmental Protection Act,
  - New Substances Notification Regulations (Organisms)
- Occupational Health and Safety Act
  - Regulation 860, Workplace Hazardous Materials Information System (WHMIS)
- Ontario Environmental Protection Act
  - Regulation 347, General Waste Management
- City of Guelph By-law Number (1996)-15202 (Sewer Use),
  - Chatham Kent By-law Number 4 - 2000
  - Tri-council agreement on the administration of agency grants and awards by research institutions

    - Agreement on the Administration of Agency Grants and Awards by Research Institutions
    - Tri-Agency Framework: Responsible Conduct of Research

- Containment Standards for Facilities Handling Plant Pests, First Edition, 2007, Canadian Food Inspection Agency.

- Containment Standards for Facilities Handling Aquatic Animal Pathogens - First Edition, 2010, Canadian Food Inspection Agency.

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2016, U.S. Department of Health and Human Services, National Institutes of Health.

- Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, 2009, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health.

- Guideline C-4, The Management of Biomedical Waste in Ontario, 2009, Ontario Ministry of the Environment.

- Guideline C-17, Non-Incineration Technologies for Treatment of Biomedical Waste (Procedures for Microbiological Testing) , 2002, Ontario Ministry of the Environment.

- Guidelines for the Management of Biomedical Waste in Canada, 1992, Canadian Council of Ministers of the Environment.

3. Administration – policy, program, and responsibilities

3.1 Policy and program

The Biosafety Program is one element of the University's safety management initiatives. Biosafety program administration resides in the Department of Environmental Health and Safety.

The Biosafety Policy establishes a Biosafety Program and confirms the University's commitment to a safe work environment.

The Biosafety Program focuses on regulatory and contractual compliance issues involving the receipt, use, storage, shipment and disposal of biohazardous materials at the University and includes:

- Activities to which the policy applies.
- Definition of materials which are regulated biohazardous materials.
- Exclusions from the program.
- Requirements for registration and permitting.
- Structure and functions of the Biosafety Committee.
- Responsibilities of various entities.

3.2 Biohazard permits

All persons undertaking work with biohazardous materials must have the work approved by the Biosafety Committee and have a valid permit before obtaining the biohazardous material and commencing the work, and throughout the entire period that the biohazardous material will be manipulated or stored (including long-term storage of microbial isolates or tissues). Principal Investigators should be aware that permits are also required for work with the following:

- Human participants (see Research Ethics Board).
- Animals (see Animal Care Committee).

- Radioisotopes (see Radiation Safety Committee).

All permits must be acquired before work commences. Biohazard permits are valid for 2 years; any changes during the 2-year period must be approved via BSC-8 Change Request.

Permits may be extended once for a 2-year period by Change Request. A new application is required every four years.

3.2.1 Biohazard permit application

Risk group 1 applications

Principal Investigators whose project or course is believed to involve only Risk Group 1 biohazardous materials must complete BSC-11 - Risk Group 1 and submit to the Biosafety Officer. Registration is required to ensure appropriate risk assessment and containment levels.

Risk group 2 applications

Principal investigators whose project or course involves Risk Group 2 biohazardous materials must complete the appropriate application and submit them to the Biosafety Officer, after which they are reviewed by the Biosafety committee and approved by the Biosafety Committee Chair and Biosafety Officer. The application forms may be accessed via the EHS website.

Projects that include the use of animals must have approval from the Animal Care Committee. For the biohazard work, the BSC-7 Animal Use Involving Biohazardous Materials form must be approved by the animal housing administrator and submitted with the Biohazard Permit Application.

The source of all biohazardous materials must be indicated. Material purchased from a commercial vendor or other source must have a material transfer agreement which states the conditions under which the material may be used. Material obtained gratis from colleagues whether at the University or another institution or agency requires a Material Transfer Agreement approved by the Research Innovation Office.

Notifications regarding minor changes or amendments to the project are submitted to the Biosafety Officer via Change Request.

If the changes are considered to be substantial (e.g., addition of animal work, adding a new pathogen that carries different or increased risks), a new application may be required.

Risk group 3 and 4 applications

Principal Investigators who plan to use Risk Group 3 or 4 biohazardous materials at another institution or facility must submit an outline of the proposed work and confirmation that the work has been approved by the other institution.

The University of Guelph does not have current facilities for or licensing authorizing work with Risk Group 3 or 4 biohazardous materials.

3.3 Training

3.3.1 General requirements

Personnel directly or indirectly involved with handling, storage, and containment of biohazardous materials shall be trained at a level appropriate to their job duties.

All training shall be documented. Written records of testing shall be retained by the Principal Investigator and/or Environmental Health and Safety and shall be made available to auditors on request.

Training shall be given at the beginning of work, shall be updated as necessary to take into account new or changed risks, and shall be repeated periodically if necessary.

3.3.2 Training curriculum

Worker health and safety awareness / Supervisor health and safety awareness and due diligence

All persons who work at the University shall complete one of the above courses as appropriate shortly after commencing employment. The course is offered continuously on-line at the EHS on-line course registration system.

WHMIS 2015

All persons shall be trained in the Workplace Hazardous Materials Information System before commencing work with hazardous materials including biohazards. Such training is offered continuously on-line at the EHS on-line course registration system.

Laboratory safety

All persons who will be working in the laboratory setting shall complete the Laboratory Safety Course. The course is offered continuously on-line at the EHS on-line course registration system.

Biosafety (Principal Investigator/Supervisor)/Biosafety (Investigative Staff)

Persons who shall be directly handling biohazardous materials shall complete the applicable Biosafety course above. Such general training shall include:

- Federal, provincial, municipal, laws, regulations, and standards regarding use of biohazardous materials.
- University Biosafety Policy and Program and University requirements regarding use of biohazardous materials.
- Permits.
- Responsibilities.
- Risk assessment including potential hazards, zoonoses, and lab-acquired infections.

- Medical Surveillance.
- Biosecurity.
- Principles of containment.
- Physical facilities.
- Administrative controls.
- Engineering control.
- Operational practices.
- Personal protective equipment.
- Personal practices and hygiene.
- Disinfection and sterilization.
- Waste management.
- Emergency procedures and reporting.
- Transport of biohazardous materials: shipping, receiving, importing, exporting.

3.3.3 Workplace specific training

Principal Investigators are responsible for provision of workplace-specific training. Such training shall include but is not limited to:

- Hazards of the particular biohazardous materials in workplace.
- Laboratory standard operating procedures (SOPs) and workplace-specific safety manual.
- Laboratory-specific techniques.

- Use of departmental autoclaves, if applicable.
- Use of laboratory equipment such as centrifuges, biological safety cabinets, sonicators, microscopes, incubators, etc.
- Laboratory-specific emergency procedures and reporting.
- Location and use of emergency equipment: fire alarm pull-station, fire extinguisher, eyewash, safety shower, spill kit.
- Working with animals, if applicable.
- Field work safety, if applicable.
- Laboratory-specific recordkeeping.
- Laboratory-specific waste management.
- Packaging and transporting of biohazardous material within the work area.

3.3.4 Awareness training

Persons who do not work directly with biohazardous materials but may be required to enter or work in workplaces where biohazardous materials are handled shall receive awareness training. Such training shall include:

- Legislation regulating biohazardous materials.
- University of Guelph Biosafety Program.
- What biohazardous materials, blood-borne pathogens, and zoonoses are.
- Principles of disease transmission and potential laboratory hazards.
- Control of biohazards including containment, administrative controls, engineering controls, operational practices.

- Waste management.
- Entering workplaces where biohazardous materials are used / stored.
- Security.

3.3.5 Emergency Response Refresher Training

Emergency response training is to be refreshed annually. Refresher training is to include review of the following standard operating procedures and safety videos available through the EHS Biosafety webpage:

- Biological Spill Response Plan
- Emergency Procedure for Exposure
- Loss or Failure of Containment
- Prepare your biosafety cabinet and spill clean-up inside Biosafety cabinet
- Spill clean-up outside Biosafety cabinet
- Wash hands
- Use Eye wash

Confirmation of annual training is to be documented using the ARER - Annual Refresher Emergency Response Training form.

3.4 Medical screening and surveillance

Medical screening and surveillance programs are an integral part of the biohazard management program. By monitoring the medical status of personnel, potential problems can be spotted and appropriate treatments or work practices put in place to prevent the development of disease. The medical program also includes post-exposure treatments if exposures do occur.

The extent of medical surveillance for any individual will vary and is dependent upon:

- The nature of the research project.

- The biohazardous materials being used.
- Current and previous health status of the individual in relation to the biohazardous materials being used.

It is the responsibility of the Principal Investigator, if requested, to provide Occupational Health and Wellness with information regarding the biohazardous materials and operational parameters being used as required.

It is the responsibility of investigative staff to self-declare any medical condition that may put him/her at risk and seek medical counseling.

More information on the medical surveillance program for biohazards is available at the Occupational Health and Wellness website.

4.0 Biohazard risk assessment and control

4.1 Overview of risk assessment

Risk assessments are conducted to estimate how much damage or injury can be expected from exposures to a given hazardous agent and to assist in judging whether these consequences are great enough to require increased management.

Working with biohazardous materials suggests that there is the possibility that harm, injury, disease or environmental release may occur. A hazard is anything that can cause harm including work practices such as working at heights or with hazardous materials such as flammable liquids and biohazardous materials. Risk is the chance, high or low, that people, animals, plants, or the environment will be harmed by the hazard.

Risk assessment is measuring two quantities of the hazard to determine the level of risk:

- The magnitude of the potential loss.
- The probability that the loss will occur.

	Probability				
Severity	Frequent	Likely	Occasional	Seldom	Unlikely
Catastrophic	E	E	H	H	M
Critical	E	H	H	M	L
Marginal	H	M	M	L	L
Negligible	M	L	L	L	L

E – Extremely High Risk; H – High Risk; M – Moderate Risk; L – Low Risk

Figure 1. Example of risk assessment matrix

Classic risk assessment is often illustrated using a risk assessment matrix, which is used to define the level of risk based on the degree of severity and probability of occurrence for the hazard.

Biohazardous materials present special challenges for risk assessment as, unlike chemical hazards, microorganisms are self-replicating. Furthermore, toxins produced by microorganisms are among the most toxic materials known.

Biohazard risk assessment in simple terms is the examination in a systematic way of what, in the workplace, could cause harm to people, animals, plants, or the environment. It consists of four steps:

- Hazard Identification - the identification of the biohazardous materials capable of causing adverse health effect.

- Exposure Assessment - the qualitative and/or quantitative evaluation of the likelihood of exposure to the biohazardous material. This may include the nature and size of the population(s) exposed to the risk agent, along with the magnitude, duration, and spatial extent of the exposure.

- Hazard Characterization - (e.g., dose-response) the qualitative or quantitative evaluation of the nature of the adverse health effects associated with the hazard. For the purposes of microbiological risk assessment, the concerns relate to microorganisms and/or their toxins. Dose-response assessment is the determination of the relationship between the magnitude of exposure (dose) to the biological agent and the severity, duration, and/or frequency of associated adverse health effects (response).

- Risk Characterization - the process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment. Risk characterization results in a risk estimate.

Risk management is the process of weighing alternatives in light of the results of the risk assessment and selecting and implementing appropriate control measures

4.1.1 Purposes of biohazard risk assessment

Risk assessment is performed to determine:

- The risk group of the biohazardous material(s).

- The containment level.

- The required facilities and equipment.

- The associated work practices and administrative controls.

This information is then used to develop management plans to prevent lab-acquired infections and release of the material into the environment.

4.1.2 General principles of biohazard risk assessment

1. The conduct of the assessment shall be soundly based on science.

2. The risk assessment process shall be separated from the risk management process.

3. The assessment shall be conducted in a structured approach that includes hazard identification, exposure assessment, hazard characterization, and risk characterization.

4. The conduct of the assessment shall be transparent.

5. Constraints that impact on the risk assessment such as cost or resources shall be identified and the consequences described.

6. Uncertainties shall be minimized. In the event uncertainties arise, the risk estimate shall include a description of any uncertainties.

7. While the Principal Investigator is primarily responsible for the risk assessment, interested parties shall have input into the process.

8. The assessment shall be reviewed and re-evaluated as new information becomes available.

4.1.3 Risk factors

One of the most helpful tools available for performing a microbiological risk assessment is the risk group for the microbiological agent. A good starting point is review of the pathogen safety data sheet for the organism or toxin or review the ePATHogen: Risk Group Database. However, simple reference to the risk group for a particular agent is insufficient in the conduct of a risk assessment. Other factors that should be considered, as appropriate, include*:*

- Pathogenicity of the agent, including drug resistance. Other factors that affect pathogenicity include potency of any toxins produced, presence of enzymes that help the agent avoid host defenses, oncogenicity, and allergenicity of the agent or its by-products

- Infectious dose.

- Potential outcome of exposure including the morbidity and mortality rate.

- Host range.
- Natural route of infection, including vectors.
- Excretion of microorganisms via urine, feces, or aerosols.
- Stability of the agent in the environment.
- Origin of the agent, endemicity.
- Any genetic manipulation of the organism that may extend the host range of the agent or alter the agent's sensitivity to known, effective treatment regimens, (g*ain of function)*.
- Presence of a suitable host (human, animal, or plant).
- Local availability of effective prophylaxis or therapeutic interventions.
- Information available from animal studies and reports of laboratory-acquired infections or clinical reports.

In addition to the risk group, factors affecting the use of the organism need to be considered in order to determine a risk management plan. Such factors include:

- Concentration of the agent and volume of concentrated material to be manipulated.
- Laboratory activities planned (e.g. sonication, aerosolization, centrifugation).
- Other routes of infection, resulting from laboratory manipulations (parenteral, airborne, ingestion).
- Experience, skill level, and health status of at-risk personnel.
- Use of animals.
- Location of the activities (e.g., laboratory, field, or animal facility).

- Preventative measures available including sanitary precautions, control of animal reservoirs or arthropod vectors, and movement of people or animals.

Based on the information ascertained during the risk assessment, a risk management plan can be formulated. Appropriate engineering controls, administrative controls, and work practices can be developed. A biosafety containment level can be assigned to the planned work, appropriate personal protective equipment selected, and standard operating procedures (SOPs) developed incorporating other safety interventions to ensure the safest possible conduct of the work.

4.1.4 Categories of materials

The infectious agents whose risk is evaluated often will fall into the following discrete categories:

4.1.4.1 Materials containing known infectious agents.

The characteristics of most known infectious agents have been well identified. Information useful to risk assessment can be obtained from laboratory investigations, disease surveillance, and epidemiological studies. Reference manuals such as the American Public Health Association's manual, *Control of Communicable Diseases* are useful as well. Literature reviews on laboratory-acquired infections also may be helpful.

4.1.4.2 Materials containing unknown infectious agents.

The challenge here is to establish the most appropriate biosafety containment level with the limited information available. Often these are clinical or environmental specimens. Some questions that may help in this risk assessment include:

1. Why is an infectious agent suspected?

2. What epidemiological data are available? What route of transmission is indicated? What is the morbidity or mortality rate associated with the agent?

3. What medical data are available?

The responses to these questions may identify the agent or a surrogate agent whose existing agent summary statement can be used to determine a biosafety level. In the absence of hard data, a conservative approach is advisable.

4.1.4.3 Materials containing recombinant DNA molecules

This category of agents includes microorganisms that have been genetically modified through recombinant DNA technologies. These technologies continue to evolve rapidly such as CRISPR/Cas9 techniques. Experimental procedures designed to derive novel recombinant viruses, bacteria, yeast, and other microorganisms have become commonplace in recent years. It is highly likely that future applications of recombinant DNA technology will produce new hybrid viruses.

The National Institutes of Health publication, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, is a key reference in establishing an appropriate biosafety containment level for work involving recombinant microorganisms. In selecting an appropriate biosafety containment level for such work, perhaps the greatest challenge is to evaluate the potential increased biohazard associated with a particular genetic modification. In most such cases, the selection of an appropriate biosafety containment level begins by establishing the classification of the non-modified virus.

Among the recombinant viruses now routinely developed are adenoviruses, alpha viruses, retroviruses, vaccinia viruses, herpes viruses, and others designed to express heterologous gene products. However, the nature of the genetic modification and the quantity of virus must be carefully considered when selecting the appropriate biosafety containment level for work with a recombinant virus. Among the points to consider in work with recombinant microorganisms are:

- Does the inserted gene encode a known toxin or a relatively uncharacterized toxin?

- Does the modification have the potential to alter the host range or cell tropism of the virus?
- Does the modification have the potential to increase the replication capacity of the virus?
- Does the inserted gene encode a known oncogene?
- Does the inserted gene have the potential for altering the cell cycle?
- Does the viral DNA integrate into the host genome?
- What is the probability of generating replication-competent viruses?

This list of questions is not meant to be inclusive. Rather, it serves as an example of the information needed to judge whether a higher biosafety containment level is needed in work with genetically modified microorganisms. Since in many cases the answers to the above questions will not be definitive, it is important that the Biosafety Committee evaluate the risk assessment.

4.1.4.4 Materials that may or may not contain unknown infectious agents.

Materials that may contain infectious agents should be handled as if they do contain infectious agents. For most materials, CL2 containment is adequate, however there may be situations where enhanced practices are required as determined by the risk assessment.

4.1.5 Risk assessment of animal studies

Laboratory studies involving animals may present many kinds of physical, environmental, and biological hazards. The specific hazards present in any animal facility are unique, varying according to the species involved and the nature of the research activity. The risk assessment for biological hazards should particularly focus on the animal facility's potential for increased exposure, both to human pathogens and to zoonotic agents.

The animals themselves can introduce new biological hazards to the facility. Latent and/or sub-clinical infections are most common in field-captured animals or in animals coming from unscreened herds. Animals may shed pathogens through respiratory dissemination or dissemination in urine or feces. For example, Q-fever presents a latent risk to individuals who handle sheep. The animal routes of transmission must also be considered in the risk assessment. Animal handlers in research facilities working on infectious agents have a greater risk of exposure from the animals' commensal microbiota (which contains various opportunistic zoonotic pathogens) as well risk from bites and scratches, that can inoculate organisms from the animal or the bitten/scratched individual's skin.

4.1.6 Risk assessment of cell lines

Cell lines (cell cultures) are commonly used in diagnostic and microbiology laboratories, and in industry to produce pharmaceuticals. There have been cases of laboratory-acquired infections reported because of manipulation of primary cell cultures. Although cell lines do not inherently pose a risk to individuals manipulating them in the laboratory, because of their potential to contain pathogenic organisms – either naturally or through contamination by adventitious agents, transformation, or recombination – an assessment must be made as to the level of hazard associated with a particular line. Cell lines can be contaminated with bacteria, fungi, mycoplasma, viruses and prions.

Section 2.9 & 4.9.10 of the Canadian Biosafety Handbook, 2nd ed. Identifies factors to be considered when performing a risk assessment of cell lines.

4.1.7 Other applications of risk assessment

The described risk assessment process is also applicable to laboratory operations other than those involving the use of primary agents of human disease. It is true that microbiological studies of animal host-specific pathogens, soil, water, food, feeds, and other natural or manufactured materials, pose comparatively lower risks for the laboratory worker. Nonetheless, persons working with such materials may find practices, containment equipment,

and facilities designed for biocontainment of value in developing operational standards to meet their own assessed needs.

4.2 Risk group classification

Biohazardous materials have been traditionally placed into risk groups in order to categorize the relative hazards of infectious materials. The risk group serves as a guide to the containment level required to work safely with these materials in the laboratory setting. However, determination of the risk group is the first step towards determining the containment level and work practices.

It should be noted that there will never be a complete list of etiologic agents classified according to risk.

Four levels of risk are defined within the Canadian Biosafety Standard 2nd Ed. as provided below. These definitions closely follow the World Health Organization risk levels.

4.2.1 Risk groups

4.2.1.1 Risk group 1 (RG1), low individual and community risk

A microorganism, nucleic acid, or protein that is either a) not capable of causing human or animal disease; or b) capable of causing human or animal disease, but unlikely to do so. RG1 organisms capable of causing disease are considered pathogens that pose a low risk to the health of individuals or animals, and a low risk to public health and the animal population. RG1 pathogens can be opportunistic and may pose a threat to immunocompromised individuals.

4.2.1.2 Risk group 2 (RG2) moderate individual risk, low community risk

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

4.2.1.3 Risk group 3 (RG3), high individual risk, low community risk

A pathogen that poses a high risk to the health of individuals or animals, and a low risk to public health. These pathogens are likely to cause serious disease in a human or animal. Effective treatment and preventive measures are usually available and the risk of spread of disease caused by these pathogens is low for the public. The risk of spread to the animal population, however, can range from low to high depending on the pathogen.

4.2.1.4 Risk group 4 (RG4), high individual risk, high community risk

A pathogen that poses a high risk to the health of individuals or animals and a high risk to public health. These pathogens are likely to cause serious disease in a human or animal which can often lead to death. Effective treatment and preventive measures are not usually available and the risk of spread of disease caused by these pathogens is high for the public. The risk of spread of disease to the animal population, however, ranges from low to high depending on the pathogen.

Lists of pathogens by risk group have been developed by various agencies. These lists are general guides, based on healthy human populations; the organisms which are being used may be attenuated strains (lower risk group) or drug resistant (higher risk group). Therefore, these lists must be used with due caution.

4.2.2 Analysis of organisms for risk group.

There are many examples of organisms which require detailed analysis to determine the risk group:

- An emerging pathogen.
- A genetically-modified organism.
- A natural variant of a pathogen with apparent decreased virulence.
- An existing pathogen subject to changing conditions, e.g. drug resistance, immunity in the population; availability of prophylaxis.

4.2.3 Risk factors

Brief descriptions of the risk factors to be considered within a pathogen risk assessment are included below.

4.2.3.1 Pathogenicity and Virulence

Pathogenicity is the property of an infectious agent that determines the extent to which overt disease is produced in an infected population, or the power of an organism to produce disease.

Virulence is the ability of an infectious agent to invade and damage tissues of the host; the degree of pathogenicity of an infectious agent, often indicated by case-fatality rates.

With the risk assessment consideration must be given to the likelihood of disease spreading and the severity of the disease itself**.**

4.2.3.2 Infectious Dose

Infectious does is the number of organisms required to initiate an infection. The infectious dose can vary from one to thousands of units. It also is affected by the health and immune status of the worker. The lower the infectious dose, the greater the risk of disease.

4.2.3.3 Mode of Transmission / Route of Infection

Mode of transmission/route of infection is any mechanism by which an infectious agent is spread from a source or reservoir to a susceptible host (human, animal or plant). These mechanisms are as follows:

- Direct Transmission – Direct and immediate transfer of infectious agents to a receptive portal of entry.
    - Inhalation through the lungs via droplets.
    - Ingestion by mouth.
    - By contact through unbroken skin, broken skin, or mucous membranes.

- Injection by needle or sharp objects.
- Through the conjunctivae.
- Through the genitourinary tract.
- From animal bites and scratches.
- Transplacentally.

- Indirect Transmission – Transmission of infectious agents via vehicles or vectors.
  - Vehicle-borne – contaminated inanimate materials or objects (fomites) such as toys, eating utensils, surgical instruments, water, food, biological products such as blood or tissues or any substance serving as an intermediate means by which an infectious agent is transported and introduced into a susceptible host through a suitable portal of entry. The agent may or may not have multiplied or developed in or on the vehicle before being transmitted.
  - Vector-borne –
    - Mechanical – Includes simple mechanical carriage by a crawling or flying insect through soiling of feet or proboscis or passage of organisms through its gastro-intestinal tract.
    - Biological – Propagation and/or cyclic development in an arthropod before transmission via bite or deposition of material on the skin
    - Airborne – Dissemination of microbial aerosols to a suitable portal of entry, usually the respiratory tract.
    - Aerosols - Aerosols are suspensions of very small particles in the air consisting partially or wholly of microorganisms. Aerosols may remain suspended in the air for long periods of time. Aerosols are not to be confused with droplets which are large particles which settle out promptly. Dust from may also contain microorganisms.

4.2.3.4 Communicability

Communicability is a measure of the ability of the organism to spread. Consideration should be given to its ability to spread geographically if released as well as the ease of transmission of disease between animal species and/or between animals and humans.

4.2.3.5 Agent stability in the environment

Agent stability in the environment is ability of the organism to survive over time in the environment. This includes such factors as resistance to desiccation, exposure to sunlight or ultraviolet light, and exposure to chemical disinfectants. Other factors include whether it has a vegetative state (spore-former), whether it survives harsh environmental conditions or in lab effluent, and whether it has been modified to affect its survivability.

4.2.3.6 Host Range

The host range is the range of host species or cell types which a particular virus, bacteria, or parasite is able to infect or parasitize. Factors to consider include whether or not the organism is zoonotic or if it infects only humans or only animals or plants; whether the host is present in Canada; whether the host is of economic importance; and whether the organism has been modified to narrow or increase the scope of the host range.

4.2.3.7 Endemicity

Endemicity is the habitual presence of the agent within a given geographic area or population group. Considerations include whether or not the agent is endemic or if it is an exotic organism.

4.2.3.8 Economic aspects of introduction and/or release into the environment or Canadian public

Consider the economic impact and the clinical significance if the organism was released.

4.2.3.9 Availability of prophylactic and therapeutic treatments

Consider whether there is an effective vaccine available, if there is effective treatment for the disease, and if there has been a modification to the organism that would affect either of these responses.

4.2.3.10 Vectors

A vector is an organism (such as an insect) that transmits a pathogen from one organism or source to another. Factors to consider include whether the vector is present in Canada, whether the intermediate host is present in Canada, whether the climate or other environmental factors lower the chance of survival and whether the organism can survive in surrogate or alternate vectors.

4.2.3.11 Recombinants

Risk group assessments for recombinant organisms will require that the researcher to take into consideration the effect of the modification on all of the previous 10 risk factors. The researcher must evaluate the donor microbe and its genetic material to be used, the vector or transfer process, and the recipient microbe/cell/organism. Questions to ask include:

1. Does the inserted gene increase virulence or decrease the effectiveness of an anti-infective agent?
2. Does the inserted gene encode a known toxin or relatively uncharacterized toxin?
3. Does the inserted gene encode a known oncogene?
4. Does the modification have the potential to alter the host range or cell tropism of the virus?
5. Does the modification have the potential to increase the replication capacity of the virus?
6. Does the inserted gene encode for hormones?

7. Does the inserted gene have the potential for altering the cell cycle?

8. Does the viral DNA integrate into the host genome?

9. What is the probability of generating replication-competent viruses?

10. If the modification has resulted in a form of attenuation, how extensively has this strain been utilized without incident and/or has the attenuation been proven in animal models?

11. Does the modification have an effect of increasing or decreasing the efficacy of available treatment or prophylaxis?

4.2.4 Risk group classification

In consideration of the 11 factors described above, a risk group classification is made. If a decision does not easily present itself, consider the weight of each factor with respect to risk. For example, if there is a low geographical risk of spread if released but it is an enzootic disease under official control, go with the higher level.

4.2.5 Literature review

Unusual or new biohazardous materials will require a literature review to support assessment data. PHAC provides a pathogen risk assessment that can be used to guide and document a pathogen risk assessment.

4.3 Containment level assessment

4.3.1 Risk group vs. containment level

Risk Groups and Containment Levels are not necessarily the same as they are based on different information. Risk Groupings are based on:

- Severity of disease.
- Individual and community risk.

- Host range.
- Availability of treatment or prophylaxis.
- Endemnicity.

Containment Levels are based on:

- Information on the specific agent to be used.
- Actual work to be done.
- Worker (host) factors (training, health, etc.).

4.3.2 Purpose of containment level assessment

Containment Level assessment is performed:

- To evaluate personal or personnel safety in a laboratory workplace.
- To determine the appropriate containment practices and engineering requirements.
- To determine the appropriate personal protective equipment requirements.
- To evaluate community or environmental safety.
- To determine training needs.
- To identify biosecurity requirements.
- To comply with legislated requirements.

Generally, the containment level assessment falls in line with the risk group assessment. For example, Risk Group 2 pathogens are often used in a Containment Level 2 (CL-2) laboratory. Nevertheless, classification of a Risk Group does not in itself allow for selection of the Containment Level and appropriate operational and engineering controls.

Risk Group classification does not consider the risks associated with the experimental design and manipulation of the pathogen nor does it prescribe engineering controls and operational protocols to decrease the risk of manipulation of the pathogen.

Certain work practices or research objectives can affect the risk of working with the organism. For example:

- A third-generation lentiviral vector is fairly benign and can be utilized at CL2. However, dependent on the inserted gene, work with the vector may have to take place at CL2 with CL3 operational protocols or CL3.
- In-vivo work with an attenuated strain of an organism may have to take place at CL3 dependent on the mechanism of attenuation.
- Work with *E. coli* O157 (and other shiga-toxigenic *E. coli*) may take place in a CL2 facility but with CL3 operational protocols.

4.3.3 Containment zone and containment level definitions

Definitions included below are taken from the Canadian Biosafety Standard, 2nd Ed.

4.3.3.1 Containment zone

A containment zone is a physical area that meets the requirements for a specified containment level. This can be a single room (e.g., a laboratory) or a series of co-located rooms along a hallway (e.g., several non-adjoining but lockable CL2 laboratory work areas), or it can be comprised of several adjoining rooms of the same containment level (e.g., a suite comprised of dedicated laboratory work area and support areas, such as anterooms, change rooms, storage rooms, preparation areas, wash up rooms, centralized autoclave room). A containment zone may include one or more work areas of different types (i.e., laboratory work area, large scale area, animal work areas), if they are of the same containment level.

4.3.3.2 Animal containment zone

An animal containment zone refers to a series of co-located animal rooms or animal cubicles, as well as associated corridors and support rooms (e.g., storage and preparation areas) of equal containment level. A zone where the animals are contained in primary containment caging (i.e., filtered containment caging to prevent the release of infectious material and toxins) is termed a "small animal containment zone" (or SA zone). The room where animals are housed in primary containment caging within a SA zone is referred to as an "animal room". Alternatively, a zone where the room itself provides the primary containment is termed a "large animal containment zone" (or LA zone). The room or space within the LA zone in which animals are housed is referred to as an "animal cubicle". LA zones may also include animal postmortem rooms (PM rooms). In the context of the CBS, the term "postmortem room" is specific to rooms in LA zones where animal autopsies and dissections are conducted.

It is important to note that the designation as a SA zone or LA zone is dependent on the way in which the animal is housed (primary containment caging versus the room providing containment) rather than the actual physical size of the animal.

The Research Isolation Facility, Building 46/146, is classed as a CL2-Ag containment zone and can house both small animals (e.g., mice, rats) and large animals (e.g., chickens, cattle).

4.3.3.3 Containment levels

Containment levels provide the end-user with a description of the minimum containment system required for handling the organism safely. The containment system includes the engineering, operational, technical, and physical requirements for manipulating a particular pathogen. These containment levels are applicable to facilities such as diagnostic, research, and teaching facilities that are working at a laboratory (small) scale. Animal facilities are also classified by containment level. The four containment levels as defined in the Canadian Biosafety Standard, 2nd Edition, are described as follows:

4.3.3.4 Containment level 1 (CL1)

This applies to the basic laboratory and animal facilities where agents requiring containment level 1 are handled. CL1 requires no special design features beyond those suitable for a well-designed and functional laboratory or animal facility. Biological safety cabinets (BSCs) are not required. Work may be done on an open bench top, and containment is achieved through the use of practices normally employed in a basic microbiology laboratory.

4.3.3.5 Containment level 2 (CL2)

This applies to the laboratory and animal facilities where agents requiring containment level 2 are handled. The primary exposure hazards associated with organisms requiring CL2 by ingestion, inoculation and mucous membrane exposure. Agents requiring CL2 facilities are not generally transmitted by airborne routes, but care must be taken to avoid the generation of aerosols (aerosols can settle on bench tops and become an ingestion hazard through contamination of the hands) or splashes. Primary containment devices such as BSCs and centrifuges with sealed rotors or safety cups are to be used as well as appropriate personal protective equipment (i.e., gloves, laboratory coats, protective eyewear). As well, environmental contamination must be minimized using handwashing sinks and decontamination facilities (autoclaves).

Enhanced containment (Containment Level 2+) is a hybrid level requiring at the minimum the use of a Containment Level 2 facility with the containment equipment and the operational practices of Containment Level 3. More detailed information is available in the Enhanced Containment – CL2+ SOP.

Most standard laboratories at the University with ready access to a biological safety cabinet and designed with non-porous surfaces may be used as CL-2 laboratories.

4.3.3.6 Containment level 3 (CL3) and Containment level 4 (CL4)

Containment Level 3 and 4 are intended have additional physical and operational containment requirements. The University does not have containment level 3 or 4 facilities.

4.3.4 Assessment factors

Factors to consider for Containment Level assessment include personnel and procedures associated with the experimental design.

Agent Factors include**:**

- Risk group.
- Quantity of pathogen to manipulated (>10 L is considered “large scale”).
- Concentration of the pathogen. Clinical specimens have a lower concentration of pathogen than pure cultures.
- Origin of the pathogen:
    - Indigenous pathogens have a decreased risk.
    - Exotic pathogens require increased controls.
- New pathogen for laboratory staff.
- Unknown pathogen as may be found in a diagnostic laboratory.

Job Task Factors include**:**

1. Procedural factors:
    - Production of aerosols. Aerosols are created by a variety of operations and types of equipment: blenders, sonicators, pipets, ultrasonic cleaners, freeze-driers, shakers, stirrers, centrifuges, flaming loops with Bunsen burners or alcohol lamps, vortexing, spilling material.
    - Work with sharps - cutting, slicing, dissecting, performing injections.
    - Repetitive or boring procedures.

- Mitigating spills.
- Cleaning and decontaminating equipment.

2. Equipment factors:
    - Sharps including needles, blades, equipment with glass parts, labware made of glass.
    - Animals which may bite or scratch, produce allergens, and shed infectious agents.
    - Equipment which may fail catastrophically, e.g., ultra-centrifuges.
3. Behavioral factors:
    - Skills and experience in performing the work.
    - Safety training and ability to recognize hazards.
    - Motivation to achieve a goal or take direction.
    - Attentiveness – ability to focus, avoid distractions, work at an appropriate pace.
    - Behavioral patterns.

Experimental Design Factors include*:*

- Modification to the pathogen which may require increased physical and operational protocols as the project progresses:
    - Host range.
    - Virulence.
    - Pathogenicity.

Host Factors include*:*

- Health-related factors:

- Immune competency of individuals including deficiencies in host defenses. Deficiencies can include:
  - Skin conditions such as eczema, dermatitis, and psoriasis.
  - Compromised mucosal surfaces due to antimicrobial therapy or bowel pathology.
- Abnormalities in the immune system:
  - Antibody-mediated (B-cell) defenses.
  - Cell-mediated (T-cell) defenses).
  - Phagocytosis (macrophages).
  - Complement-mediated defenses.
- Immunization status:
  - If a vaccine is available, has the worker been immunized.
  - No vaccine available.

- Current health status
  - Persons with conditions such as asplenia, complement or antibody defects (B-cell), or decreased polymorphonuclear leukocytes are more likely to have serious infections caused by certain pathogens.
  - Persons with conditions such as T-cell defects are at increased risk of developing active tuberculosis, histoplasmosis, listeriosis, or CMV pneumonia.
  - Persons with medical conditions associated with some level of immunosuppression:

- Asthma or inflammatory bowel disease (steroid therapy).
- Acute viral infections, poorly controlled diabetes mellitus, alcoholism, pregnancy.
- Connective tissue diseases (e.g., lupus).
- Cancer.
- Radiation therapy.
- HIV-positive status.

- Genetic factors.
- Special health conditions:
  - Pregnancy with associated danger to the fetus. Agents associated with congenital or neonatal infections:
    - Rubella (German measles) – intrauterine death, congenital abnormalities, spontaneous abortion.
    - Hepatitis B virus – infant infected at birth.
    - Cytomegalovirus (CMV) – severe generalized infection of the fetus.
    - *Toxoplasma* – intrauterine death, brain damage to fetus.
    - *Chlamydia* – pre-term delivery, pneumonia.
    - *Treponema pallidum* – abortion, pre-term delivery, congenital generalized disease of the fetus.

- HIV – transmitted to the fetus in-utero; nursing infants may be infected by ingestion of breast milk.
- Enteroviruses – neonatal fever, paralysis.
- Herpes simplex virus – disseminated neonatal infections that can be fatal.
- Varicella virus – congenital varicella syndrome, severe generalized infection of neonates which can be fatal.
- Pathogenic viruses at RG-3 or RG-4 where the effect is unknown.

  - Allergies
    - Animal proteins.
    - Dust and dander.
    - Parasite.
    - Foreign proteins.
    - Constituents of vaccines.
    - Antimicrobial therapy.

- Other factors:
  - Ability to wear personal protective equipment such as respirators.

In summary, the researcher must consider that workers may have pre-existing diseases or conditions, may be taking medications for chronic conditions, and may have an altered immunization status, keeping in mind that there may be situations where vaccination provides

marginal immunity, is unavailable in Canada, or is inappropriate for medical or religious reasons.

Biosecurity Factors include:

- Regulatory requirements.
- Proprietary / forensic work.
- Dual-use research.
- Work requiring chain-of-custody procedures.

4.4 Managing risks from biohazardous materials

4.4.1 Introduction

Risk management is the second component of the risk analysis process and consists of choosing appropriate administrative, engineering, and operational controls. Decisions must be made regarding the benefit of using the biohazardous material vs. the cost of controlling the risks from such use. Risk can be managed by:

- Transferring the risk to another party.
- Avoiding the risk.
- Reducing the negative effect of the risk.
- Accepting some or all of the consequences of a particular risk.

Under the Ontario Occupational Health and Safety Act, the employer must take every precaution reasonable in the circumstances to protect the worker. Therefore, biohazard risks must be eliminated or controlled; accepting uncontrolled risk is not satisfactory.

4.4.2 Principles of risk management

The basic principles that provide a framework for implementing the risk management process are:

- Integrating risk management into work design, planning, preparation, and execution. Supervisors and workers continuously identify hazards and assess risks. Supervisors ensure that all workers understand and properly execute risk controls.
- Making risk decisions at the appropriate level. Supervisors in consultation with workers establish appropriate risk management measures; risks are continuously assessed, and personnel bring forward new information that requires a reassessment of the risk.
- Accepting no unnecessary risk. It is understood that if risk cannot be reduced to an acceptable level, then the work may not proceed.

"Acceptable risk" is a relative concept and involves consideration of different factors. Considerations in these judgments may include:

- The certainty and severity of the risk.
- The reversibility of the health effect.
- The knowledge or familiarity of the risk; whether the risk is voluntarily accepted or involuntarily imposed.
- Whether individuals are compensated for their exposure to the risk.
- The advantages of the activity.
- The risks and advantages for any alternatives.

4.4.3 Developing controls to manage risk

Risk control is performed through the definition and the adoption of adequate prevention measures such as:

- Containment levels.
- Equipment.
- Rules for conduct in the laboratory.
- General and/or personal protection measures.

Controls to manage risk can be broken down into four basic categories:

1. Avoidance**.** The most effective way of avoiding the risks of biohazardous materials is to not use them at all.
2. Engineering controls. Engineering controls are used to reduce exposure in the workplace either by removing or isolating the hazard or by isolating the worker from exposure using technology. Laboratories are equipped with devices such as biological safety cabinets and sealed centrifuge cups to contain biohazardous materials. The rooms themselves may have design features to prevent contamination of the environment such as HEPA-filtered ventilation systems and airlocks.
3. Operational controls. Procedures and work practices can be designed to mitigate risks. Operational controls reduce the likelihood of exposure by specifying the manner in which a task is performed. They are documented with standard operating procedures such as packaging and decontamination of waste, use of personal protective equipment such as gloves and goggles, and performing procedures in a biological safety cabinet rather than on an open bench. Operational controls can be vulnerable to short cuts and require diligence on the part of the worker.
4. Administrative controls. Administrative controls are changes in work procedures such as work schedules, written safety policies, rules, supervision, and training with the goal of reducing the duration, frequency, and severity of exposure to the biohazardous materials. For example, work with the biohazardous materials may be scheduled only during regular working hours.

4.4.4 Implementing controls

Supervisors are responsible for ensuring that controls are implemented in the workplace. For example, this includes disseminating the written Standard Operating Procedures, orientation, and refresher training for personnel, and holding emergency response drills. Engineering controls must be regularly inspected, maintained, and certified where appropriate.

4.4.5 Evaluating controls

Controls must be assessed to determine if they are reducing risk to an acceptable level. Controls must be carefully designed and monitored to ensure that the control measure does not cause another hazard which must be controlled. As equipment and techniques are continuously evolving, the effectiveness of controls must be continuously evaluated and corrected if necessary.

4.4.6 Controls for biohazard risks

The risk assessment process establishes a containment level for the work being performed. Both the Canadian Biosafety Standard, 2nd Edition and the Containment Standards for Facilities Handling Aquatic Animal Pathogens specify mandatory engineering controls and operational controls for working at various containment levels. The document Biosafety in Microbiological and Biomedical Laboratories (BMBL) from the United States Centers for Disease Control and Prevention, also contains control measures. These control measures are generic; the Principal Investigator will need to customize these control measures for each project and in addition create specific control measures for the various job tasks for his/her individual projects.

4.4.7 Documenting risk management initiatives

The principle of due diligence requires that control programs to mitigate or eliminate hazards be documented. For a hazardous procedure, various documents fulfill this requirement:

- Standard operating procedures.
- Laboratory-specific biosafety manual.

- Job/task hazard analysis sheets.
- Safety data sheets.

In addition, other records must be maintained:

- Training records including orientation training.
- Workplace inspections.
- Incident report forms.
- Autoclave verification records.
- Biological safety cabinet certification records.
- Records of efficacy of the control methods, e.g., disinfectants, autoclave cycles, etc.

4.4.8.1 Record Retention

The following table outlines the minimum retention periods for specific records as required by the Canadian Biosafety Standard 2nd, ed.

Table 1. Records and their corresponding retention periods

Records and documentation pertaining to:	Minimum retention period
License activities involving human pathogens and toxins (e.g. permits, imports/exports/transfers)	5 years
Animal pathogen import permit requirements for animal pathogens, toxins and other regulated infectious material	2 years following the date of disposal, transfer or inactivation of the material
Building and equipment (autoclave and biological safety cabinet) maintenance,	5 years

repair, inspection, testing or certification including performance verification in accordance with function	
Incidents involving pathogens, toxins, other regulated infectious material, infected animals or losses of containment	10 years

4.4.8 Job hazard analysis

Job hazard analysis (JHA) is a technique used to assess health and safety hazards associated with a particular job or task and to identify possible controls. JHA systematically breaks down work into its basic components and allows the hazards at each step to be thoroughly evaluated. Procedures can then be identified to eliminate or control the hazard. It is important that the persons who will actually be performing the task participate in the JHA.

Job hazard analysis is not suitable for very simple one-step tasks nor is it easily used for very complex jobs; jobs need to be broken down into manageable segments. JHA can also be used for operating equipment such as autoclaves and centrifuges.

While performing a JHA, the following should be closely observed:

- Volume of infectious material.
- Concentration of infectious material.
- Route of transmission of the agent.
- Generation of aerosols.
- Type of equipment used.
- Work flow.
- Waste disposal practices.

JHA can also be used to spot poor work practices such as improper use of the biological safety cabinet, failure to check condition of containment equipment, poor experimental set up, and the spread of contamination by poor waste practices or wearing of gloves outside the containment area. Audit checklists can also be developed by referring to the JHA.

4.5 Risk communication

Risk communication is the interactive exchange of information and opinions throughout the risk analysis process, concerning hazards and risks, risk-related factors, and risk perceptions among interested parties, including the explanation of risk assessment findings and the basis for risk management decisions. In the context of the biocontainment lab, risk communication will involve the principal investigator, laboratorians, custodians, maintenance workers, and building occupants.

5. Biosecurity

5.1 Biosecurity program

Biosecurity can be defined as a set of preventive measures designed to secure biohazardous materials from unauthorized access, loss, intentional removal (theft), misuse, diversion, or intentional release. Preventative measures are a combination of systems and practices to prevent the malicious use of pathogens and toxins. Biosecurity requires the cooperation of scientists, technicians, administrators, security experts, and law enforcement officials.

5.1.1 Laboratory biosecurity program components

Components of a laboratory biosecurity program include:

- Physical security.
- Personnel security including background checks as required.
- Purchase control and accountability.

- Inventory control and recordkeeping.
- Transport security.
- Information security.
- Program management.

5.1.2 Physical security

All areas where biohazardous materials are used and/or stored must be locked and secured against unauthorized entry.

5.1.3 Security clearances

Biosecurity is of utmost concern for Risk Group 3 and 4 biohazardous materials and certain biological toxins. Under Section 33 of the Human Pathogens and Toxins Act , any worker who enters the Containment Level 3 laboratory where a prescribed Risk Group 3 organism or biological toxin as noted in the Human Pathogens and Toxins Regulations, is being used or stored will require a security clearance acceptable to the Public Health Agency of Canada or be accompanied and supervised by a person who holds a security clearance for the facility.

5.1.4 Purchase control and accountability

All acquisitions of biohazardous materials including purchase orders must be approved by the Biosafety Officer. Purchases of biohazardous materials must be made through the University's iProcurement system as a high value purchase.

5.1.5 Inventory control and recordkeeping

Inventories of biohazardous materials including culture collections must be maintained and stored in a secure location. Inventory records may be kept as hard copies or as computer databases. Computer records must be maintained on a secure server or other system off site; they must not be maintained on a stand-alone machine. Paper copies must be maintained in a

secure location. Records must be available for inspection by the Biosafety Officer and authorized government officials.

5.1.6 Transport security

Biohazardous materials must be secured during transport from unauthorized access or theft and not left unattended in unlocked vehicles. A chain-of-custody should be established when shipping biohazardous materials, for example, using a courier service.

5.1.7 Incident reporting and response

Authorized investigators handling biohazardous materials are required to report any breaches in security in a timely fashion to Campus Community Police, x2000. Incident reports should subsequently be submitted to EHS as per the University's incident reporting process for review by the Biosafety Officer and Biosafety Committee.

5.1.8 Program management

The Principal Investigator is responsible for the day-to-day management of biosecurity in the workplace.

Detailed information on biosecurity can be obtained in the publication below:

- Canadian Biosafety Guideline: Conducting a Biosecurity Risk Assessment

5.2 Agricultural biosecurity

Agricultural biosecurity refers to management strategies that prevent the introduction of disease to a farm or control the spread of disease amongst animals within a farm. More information can be found in the following:

- Office of Research Guideline Animal Biosecurity Framework.

6. Importation, shipment and transfer of biohazardous materials

6.1 Importing and exporting biohazardous materials

Biohazardous material import and export are regulated by the Federal government to protect public health and the agricultural sector. They are designed to prevent the introduction of non-indigenous pathogens, to ensure that only qualified individuals with appropriate facilities import biohazardous materials, and to comply with international agreements to prevent the dissemination of materials that can be used as biological weapons.

The Biosafety Officer must be notified of all imports, exports or other transfers of biohazardous materials in advance of the transfer. Please refer to the Quick Reference Guide for notification procedures.

6.1.1 Export of biohazardous materials

From time to time, Principal Investigators may wish to send material to a colleague in a foreign country. Export of certain biohazardous materials, whether or not for trade or commercial purposes, is controlled by Global Affairs Canada. Biological agents are found on the Export Control List under the Export and Import Permits Act. Canada, in conjunction with others Australia Group member countries, has implemented controls with respect to biological and toxin agents. These agents include human, plant and animal pathogens, in the form of viruses, rickettsia, bacteria, toxins, fungi or genetically modified micro-organisms. These agents are specifically controlled by ECL item 7021.

There is a Guide to Canada's Export Controls and list of specific agents and toxins .

Persons wishing to export biohazardous materials are advised to review the Export Controls Handbook to determine if the material requires a permit or is exempt. The website also has instructions and forms for obtaining an export permit. Note that the receiver in the foreign country may need an import permit issued by his/her corresponding national authority.

6.1.2 Import of biohazardous materials

In order to protect public health and to prevent the introduction of non-indigenous pathogens to Canada, the importation of biohazardous materials is regulated by the Federal Government. The University has a license issued by the Public Health Agency of Canada to import risk group 2 human and terrestrial pathogens covered under the license; an import permit is not required, however a copy of the license may need to be provided to the supplier to accompany the shipment.

The Canadian Food Inspection Agency (CFIA), under the Health of Animals Act and Regulations, controls the importation of materials that may cause disease in terrestrial animals, aquatic animals, bees, and plants. This includes pure cultures, infected animal tissues, animal products such as milk and eggs, soils, and live animals. A CFIA import permit may be required for such materials.

6.1.3 CFIA import permits

6.1.3.1 General information

For materials below, an import permit from CFIA may also require for the consignment to clear Canadian Customs if the consignment contains a pathogen that causes any of the following, then the permit is obtained from the Canadian Food Inspection Agency (CFIA):

- A foreign animal disease.
- An emerging animal disease.
- A disease being monitored by the CFIA.
- A disease in aquatic animals.
- A disease in bees.
- A plant disease (includes plant pests).
- Contains or may contain infected animal tissues or fluids.

Permits are required even if the material is being obtained at no cost, for example, cultures being sent from a colleague.

Foreign animal diseases may usually only be imported to a federal government laboratory. Laboratories that work with foreign animal diseases must comply with the Foreign Animal Disease Diagnostic Laboratory Containment Standard .

6.1.3.2 Who may apply

A Principal Investigator holding a current Biohazard Permit that includes the material to be imported is authorized to apply for an import permit.

6.1.3.3 Obtaining CFIA import permits

To obtain an import permit from the CFIA for aquatic animal pathogens, plant pathogens or infected animal tissues, blood, milk, or serum, an application form must be completed by the Principal Investigator. While hardcopy CFIA import permit applications can be submitted, the University will be transitioning through 2019 to myCFIA, an electronic platform.

Note that there is a charge for the permit, payable by credit card. The charge will vary depending on the extent of the risk assessment required to be conducted by CFIA staff.

If importing aquatic animal pathogens, the requirements are more stringent; several CFIA documents must be completed, and a biosafety manual submitted. CFIA has a Containment Standards for Facilities Handling Aquatic Animal Pathogens. Aquatic import permits are issued to facilities certified to the appropriate physical and operational requirements described in the CFIA Standard. To obtain an import permit, an application form can be completed at myCFIA, an electronic platform.

Information regarding the importation of plant pests and Biocontainment for Facilities Handling Plant Pests is also available.

Once import permits have been issued to the applicant, it is the applicant's responsibility to ensure the consignor of the shipment receives the permits to attach to the package before shipment so that the consignment will clear customs. The person to whom the permit is issued is responsible for complying with all conditions on the permit upon receipt of the consignment.

Material obtained on an import permit may not be redistributed to another party without the express consent of the permitting agency. Copies of import permits are to be forwarded to the Biosafety Officer.

6.1.4 Restrictions concerning materials originating from the United States of America

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107-188 (42 U.S.C. 262a), requires the Department of Health and Human Services (DHHS) to regulate the possession, use, and transfer of certain biological agents or toxins called select agents and toxins that could pose a severe threat to public health and safety.

The United States strictly controls the export of certain biohazardous materials by means of the Export Control Regulations administered by the Department of Commerce.

Because a license may be required to export materials, some vendors may elect to not fill purchase orders from Canada for such products. Certain items may not require a license to export to Canada but may still require export notification. Consult the US Export Control Regulations to determine any requirements for a particular material.

6.2 Material transfer agreements

6.2.1 Background

A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. Biological materials, such as cultures of organisms, reagents, cell lines, plasmids, and vectors, are the most frequently transferred materials. MTAs are also used for the transfer of biohazardous materials such as bacteria, genetically-modified organisms, and recombinant DNA. MTAs are required when acquiring multicellular organisms including laboratory / research animals, for example, mice, dogs, and sheep.

6.2.2 Completing MTAs to acquire materials

6.2.2.1 Commercial transactions

When purchasing biohazardous material from a commercial vendor, the purchase documents will include a material transfer agreement. The material transfer agreement will include all restrictions on use of the material. **Please note that almost invariably the purchaser may not transfer material obtained from a commercial vendor to another user without express written permission of the vendor.**

6.2.2.2 Non-commercial external transactions.

Researchers may wish to exchange material without a transfer of funds, for example, with a colleague at another institution. In this instance an external material transfer agreement must be executed.

If supplying material to a researcher at another institution, a suitable MTA is available from the University's Research Innovation Office.

All material transfer agreements must be approved by the Research Innovation Office.

If obtaining material from another institution, the supplying institution may have its own agreement. Such agreements must be approved by the Research Innovation Office to ensure that the University can comply with all the provisions. A University of Guelph MTA is also acceptable if the supplying institution will accept it.

6.2.2.3 Non-commercial internal transactions.

Researchers may wish to obtain material from or supply material to a colleague at the University of Guelph. In this instance, the internal material transfer agreement must be executed.

The supplier must ensure that the recipient has a current biohazard permit for the material being transferred and that there are no restrictions on the transfer imposed by an import permit or supplier such as American Type Culture Collection (ATCC).

All transfers must be approved by the Biosafety Officer.

A copy of the completed internal MTA must be sent to the Biosafety Officer, Environmental Health and Safety prior to the transfer.

6.3 Shipping and receiving biohazardous materials

6.3.1 Introduction

The movement of biohazardous materials, including recombinant DNA, by motorized transport more than 1 kilometer is regulated by the Transport of Dangerous Act (TDG) and Regulations .

With certain specific exemptions, anyone moving such materials, whether or not for pay or hire, must comply with the regulations. The following examples require compliance with the regulations:

- Shipping cultures via courier to another university.
- Shipping human blood samples for testing via courier to a public health lab.
- Transporting cultures with dry ice via University vehicle to a research station.
- Transporting cultures via University vehicle to a private farm.
- Shipping cultures via airplane overseas.
- Receiving human blood samples from Africa via air.

Regulated materials cannot be placed in checked or carry-on baggage or carried in person when traveling via air, train, ship, or bus. Regulated materials may not be mailed through Canada Post.

Transport Canada may audit the University for compliance at any time and fines may be issued for non-compliance.

6.3.2 Receiving biohazardous materials

Biohazardous materials purchased from a supplier will be shipped via courier to the University. Only TDG-trained persons may receive and sign for a dangerous goods consignment (as defined by the TDG regulations) including biohazardous materials. Each Department where dangerous goods are received and/or shipped is required to have an adequate number of trained personnel. On-line training can be obtained by contacting Environmental Health and Safety .

After the consignment has been received, WHMIS regulations come into force.

6.3.3 Shipping via courier

Shipping biohazardous materials requires advance planning and careful attention to the regulations in order to avoid delayed or returned packages. The consignment will require appropriate shipping papers, packaging materials, and labeling. If the package requires dry ice or liquid nitrogen for refrigeration, other TDG requirements must be met. Dangerous goods regulations are slightly different depending on whether the shipment is going via air or ground transport.

Anyone shipping biohazardous materials must contact the Dangerous Goods Shipping Coordinator in Mail Services, x52264, for instructions.

6.3.4 Transporting via University-owned or University-leased vehicle

Persons transporting biohazardous materials via University-owned or University-leased vehicles may require dangerous goods paperwork and regulation packaging. If the shipment is within the confines of the campus, then the regulations do not apply. If the package needs to be transported off campus, then the regulations may apply depending on the nature of the goods. Consult the Dangerous Goods Shipping Coordinator, x52264, or the Biosafety Officer, to determine if the regulations apply and to obtain appropriate paperwork and packaging instructions.

Persons driving the vehicle and in charge of the shipment must be TDG-trained and carry a certificate issued by the University of Guelph. Training can be obtained by contacting Environmental Health and Safety.

6.3.5 Shipping via private vehicle

Materials considered dangerous goods as per Transportation of Dangerous Goods regulations are not to be shipped using privately-owned vehicles.

7.0 Operational requirements

7.1 Standard operating procedures (SOPs)

7.1.1 Introduction

In a general sense, a standard operating procedure is a set of instructions covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. For the purposes of laboratory work, an SOP is a written document detailing all steps and activities of a process or procedure. These must be carried out without any deviation or modification to guarantee the expected outcome.

SOPs include not only how to perform a certain task to end up with a consistent endpoint such as making cell culture media or donning personal protective, but also include how to perform the task safely. For example, an SOP will specify the amount of media to be weighed out (consistency) and that a fume hood is used to protect the worker (how to perform the task safely).

SOPs should be reviewed regularly. It is recommended that reviews are conducted at least every two years, sooner if there is an incident or inconsistency involving the SOP.

7.1.2 Elements

Standard operating procedures should include the following sections as applicable:

- Purpose - a short summary of the objective of the procedure.

- Glossary - a list of acronyms, abbreviations, and workplace-specific terms with definitions.
- Personnel responsibilities - overview of roles and responsibilities for personnel involved in the procedure.
- Training requirements.
- Hazards and their controls - location, containment, ventilation, personal protective equipment, guarding.
- Equipment and materials requirements.
- Maintenance and inspection procedures.
- Detailed step-by-step instructions.
- Repair procedures.
- Emergency response procedures.
- Documentation and recordkeeping requirements.
- References - a list of information sources cited in the procedure including SDSs, equipment manuals, regulatory requirements, and standard methods.
- Approvals and dates including review dates.

Note that safe procedures are an integral part of the SOP and are not listed as a separate section.

7.2 Operational practices

Following good laboratory practices meticulously will minimize the risk of exposure of laboratory workers. The following are the basics of good microbiological laboratory practices:

- Do not work alone when working with biohazardous materials.
- Do not eat or drink, apply cosmetics, store food or drink, personal belongings, or street clothing in the workplace.
- Restrain long hair, scarves, sleeves, and other pieces of clothing that may contact lab materials.
- Wear personal protective equipment, properly fastened. Store reusable equipment away from street clothing. Do not wear PPE in public places such as the cafeteria, library, or washrooms. Disinfect contaminated laboratory coats before laundering.
- Keep doors closed to maintain inward directional air flow.
- Do not allow unauthorized persons into the workplace. Question the presence of unknown persons.
- Plan the work and confirm that all materials are ready and at hand.
- Eliminate clutter.
- Review material and pathogen safety data sheets and Standard operating procedures before commencing new work.
- Work carefully and methodically. Practice new, unfamiliar procedures before using the biohazardous materials.
- Do not mouth-pipette at any time, use pipette aids.
- Wash hands regularly.
- Avoid the use of sharps and glass.
- Use safety-engineered syringes.

- Avoid the use of Bunsen burners; use electric incinerators instead.
- Use the biological safety cabinet for all procedures that produce aerosols.
- Disinfect the area regularly and at the end of every workday. Use the least hazardous disinfectant that is effective.
- Use absorbent bench cover; clean up spills promptly.
- Handle waste as specified in the standard operating procedures.
- Transport materials in closed leak-proof containers using carts.
- Be aware of other workers around you.
- Maintain doors locked at all times when the workplace is unoccupied. Lock storage freezers.
- Allow time at the end of the day to clean up and disinfect.
- Report all incidents to the Principal Investigator or designate.

7.3 Sharps

7.3.1 Introduction

Incorrect use and disposal of sharps places laboratory staff and other people at risk of a potentially serious infection. Sharps are defined as anything that could puncture the skin and include hypodermic needles, scalpels, glass pipettes, tubes and bottles, dissection instruments, scissors, wire loops that are not closed circles, glass microscope slides, coverslips, plastic pipette tips, and broken glass. This document describes simple and practical measures to minimize the risk of a sharps injury.

7.3.2 Minimize exposure to sharps

Sharps should not be used unless there is no alternative. This is extremely important at all times, but vital when working with material (e.g., human blood) that could contain infectious agents. In these cases, if sharps must be used, cut-resistant gloves can be worn to protect against cuts from knives, scalpels and microtome blades.

7.3.3 Handling of sharps

7.3.3.1 Hypodermic needles.

- Use Safety-engineered needles wherever practical.
- Fit the needle onto the syringe while still in its sheath.
- Ensure the needle is not bent or broken before use.
- Always keep your hand behind the needle tip.
- Minimize manual handling, do not pass the needle from hand to hand.
- Do not disconnect the needle from the syringe before disposal, discard as a single unit whenever possible.
- Never re-cap a needle unless it is essential for the procedure (e.g., pre-loading syringes for drug delivery).
- Never re-cap a needle by hand; only re-cap a needle if a device is available to allow this to be done using one hand.
- Never remove a needle from a syringe unless it is essential for the procedure, e.g., when transferring blood to a container. Re-cap before removal using a device designed for the purpose.
- Place used needles immediately and directly into an approved sharps disposal container. Do not leave the needle on work surfaces.

- Retrieve dropped needles immediately. If it cannot be found, inform people of the danger, and search the area until it is found and discarded appropriately.
- Use tongs to retrieve needles that have been dropped; never use your bare hand.

7.3.3.2 Blades

- Do not use a blade without its handle.
- Take care when attaching the guard to blades and handles with guards.
- Place used blades immediately and directly into a sharps disposal container.
- Do not leave blades on work surfaces or in drawers.

7.3.3.3 Glassware

- Check for damage before use; never use damaged glassware.
- Never store glassware above shoulder height.
- Store tall vessels at the back of shelves with smaller ones in front.
- Store heavy glassware at bench height.
- Carry large glass bottles in specially designed carriers; do not hold them by the neck, or even with two hands.
- Sweep up broken glass or pick up with forceps.

7.3.3.4 Pipette holders

- Lubricate pipettes with detergent solution to make insertion into bulb easier.
- Hold glass pipette and capillary tubes in a cloth close to end being inserted into bulb or syringe.

7.3.4 Sharps disposal

- Only use properly assembled plastic containers that comply with the CSA standard. Cardboard containers must not be used since they disintegrate when sharps that are wet are placed in the bins. Cardboard containers are not puncture-resistant.
- Never put fingers into a sharps disposal container; use tongs if something must be retrieved.
- Do not fill sharps disposal containers more than 2/3 full or above the fill line.
- Send sharps disposal containers for incineration via the hazardous waste system.
- Always carry sharps disposal containers by the handle.

7.3.5 Accident procedure

Following an injury with a contaminated sharp follow this procedure:

7.3.5.1 Immediate first aid treatment

1. Encourage the wound to bleed.
2. Wash with soap and warm running water for a few minutes.
3. Cover with suitable dressing.

7.3.5.2 Follow up treatment

1. Contact Occupational Health and Wellness, x52647 (employees) or Student Health Services, x52131 (students) during normal working hours or Campus Community Police dispatch, x2000, after hours. A risk assessment will be conducted to determine further treatment, if any.

2. Retain the source of contamination for testing if necessary. The sample must be transferred to a suitable container that is labeled and stored in a refrigerator.

3. Laboratory personnel involved in the cleanup and disinfection of the spill must be informed of the risks and trained in safe working procedures. They must not place themselves at risk, especially if the accident involves broken glass or other sharp objects.

7.3.5.3 Incident Reporting

Incidents are to be reporting using the standard University incident reporting procedures and the Incident Report Form. Once completed, send a copy via fax to Occupational Health and Wellness, 519-780-1796. Do not delay sending the form for lack of signatures; these can be obtained later.

7.4 Blood-borne pathogens

Human blood products, tissues, and other bodily fluids present a risk for transmission of serious diseases, primarily Hepatitis A, Hepatitis B, Hepatitis C, and Human Immunodeficiency Virus (HIV).

All activities using human and non-human primate-derived materials shall be undertaken in compliance with the Blood-borne Pathogen (BBP) Policy. All work shall be performed using universal precautions as stipulated in the BBP program.

8.0 Personal protective equipment

8.1 Introduction

Use of personal protective equipment (PPE) is one of several strategies employed to minimize the exposure of workers to biohazardous materials. Any such PPE must be carefully chosen and be appropriate for the procedures being used in the laboratory.

Examples of PPE include gloves, gowns, masks, boot covers and respiratory equipment.

8.2 Hand protection

The use of well-fitting gloves is basic for work in any laboratory where biohazardous materials are manipulated. Glove materials differ in permeability depending on the substance to which they are exposed and must be carefully chosen. Glove charts published by the glove manufacturers are readily available on the web, for example Grainger and Ansell .

While latex gloves may effectively prevent exposure to blood and fluids, they are not approved for use because many persons develop very serious allergies to them. Latex-free gloves and nitrile gloves are suitable alternatives. Cloth gloves are not appropriate as they absorb contaminants.

Gloves should be relatively tight-fitting to maintain manual dexterity. Double-gloving provides an extra measure of protection.

8.3 Clothing

The most common protective garment worn in the laboratory is the classic button-front clinician coat, available from any scientific supply house. While this design of lab coat is suitable for some types of lab work, there are better choices for work with biohazards.

Coats suitable for work with biohazards should have the following:

- Knitted cuffs to reduce turbulence when working at the biological safety cabinet and to simplify the donning of gloves over the sleeves.

- Full coverage to the neckline.
- Snap closures on the front or, if wrap-around, ties for quick removal.
- Below-the-knee length for coverage while sitting.
- Fabric which is impermeable to bodily fluid spills.
- Well-fitting, not baggy, to prevent snagging on equipment.

The clothing can disposable (one-time use) or re-usable. Re-usable coats must be able to withstand autoclaving.

Lab coats should fit appropriately so that there are no loose pockets to catch on furniture. Sleeves should be the appropriate length to avoid rolling up excess material. Special consideration must be made for pregnant laboratorians as conventional lab coats may not fit properly off-the-shelf. Maternity lab coats and scrubs are available from various suppliers.

8.4 Eye and face protection

Appropriate eye and face protection must be worn when working in areas where there is a hazard to the eyes and face. Hazards include dusts, aerosols, vapours and airborne materials. All safety eyewear must be certified by the Canadian Standards Association. Regular prescription glasses are not suitable.

Splash goggles are the best protection for most lab work. These fit tightly to the face and protect the eyes from dusts, mists, and splashes of hazardous liquids such as acids. Safety glasses are rarely suitable for lab work as they protect only against impact hazards such as flying objects. They do NOT protect against splashes, the most common hazard to be encountered in the lab. However, safety glasses do prevent laboratorians from touching their eyes with potentially contaminated fingers. Face shields provide full face and mouth protection. Face shields are always used as a supplement to splash goggles or safety glasses; a face shield is not worn as a sole piece of protective equipment.

While not likely to be encountered during routine lab work, a full-face respirator also supplies eye and face protection as an integral part of its design.

The most common reason laboratorians do not wear protective eyewear is that the item chosen does not fit. There are many styles manufactured that are sold through laboratory supply houses and safety equipment vendors. It is recommended that several styles be tried to find the best fit.

8.5 Respiratory protection

Infective materials that are spread via aerosols or are airborne are of special concern. The primary method of containment of such materials is the use of a biological safety cabinet and specially designed equipment such as centrifuges with sealed cups. Work at Containment Level 2 rarely, if ever, requires the use of respiratory protection such as half-face respirators as all work is to be performed in proper containment devices. Persons working in the field or in large animal containment may require respiratory protection.

In rare instances, individuals with specific medical conditions may also require the extra safeguard of respiratory protection even at Containment Level 2. The requirement for respirators is determined when conducting a risk assessment for the work and in consultation with Occupational Health and Wellness.

All persons who require respiratory protection must be enrolled in the Environmental Health and Safety Respiratory Protection Program for assessment and fit-testing of the respirator.

8.6 Foot protection

Persons working in laboratories must wear closed-toed, closed heeled shoes that are non-absorbent and without ventilation holes (no cloth shoes or ventilated plastic clogs) and that provide coverage of the foot. Sandals are prohibited in laboratories and areas where hazardous materials are used or stored. When working in animal areas, safety shoes may be required.

Footwear can be protected by use of disposable boot covers as it can be difficult if not impossible to disinfect footwear without ruining it.

8.7 Contaminated personal protective equipment

From time to time, spills may occur that contaminate PPE. Disposable goods such as gloves may be placed in biohazard waste bags and treated or incineration. Reusable items such as lab coats may be decontaminated by soaking in disinfectant or by autoclaving before being laundered. If shoes become contaminated from spills, the shoes will require decontamination by autoclaving before reuse. Alternatively, the shoes can be sent for incineration.

9.0 Decontamination and disposal

9.1 Disinfection and sterilization

9.1.1 Definition of terms

The words disinfectant, antiseptic, sanitizer, and sterilant are terms that have been used loosely but have specific meanings to microbiologists. All four terms are used in the context of decontamination.

Decontamination is the use of physical or chemical means to remove, inactivate, or destroy microorganisms on a surface or item to the point where the microorganisms are no longer capable of transmission and the surface or item is rendered safe for handling and disposal. While the term is usually used in the context of pathogenic organisms in a clinical setting, it is just as important in the modern molecular biology research laboratory.

Sterilization is the process of treating an object or material to remove or kill all living organisms.

Disinfection is the process of killing microorganisms by chemical or physical means directly applied. It does not necessarily kill all organisms nor does it always result in sterile conditions.

A disinfectant is an agent, either chemical or physical (e.g., x-ray or UV radiation), used for disinfection. A "low-level" disinfectant destroys vegetative bacteria except tubercle bacilli, lipid viruses, some nonlipid viruses and some fungal spores, but not bacterial spores. A "high-level" disinfectant can kill bacterial spores when used in sufficient concentration under suitable conditions. Disinfectants generally are used on inanimate objects. They are called antimicrobial agents in the Food and Drugs Act and regulations.

Health Canada has published several Guidance Documents and monographs concerning disinfectants and their uses.

A list of currently registered disinfectants with DIN numbers may be found by entering "disinfectant" in the "product name" field at the Health Canada Drug Product Database (DPD).

An antiseptic is a substance that prevents or arrests the growth or action of microorganisms either by inhibiting their growth or by destroying them. The term antiseptic is generally used for substances applied to living tissue.

A sanitizer is an agent that reduces the number of contaminants to a safe level as judged by public health requirements. Sanitizers are generally used on food contact surfaces.

A sterilant is an agent that destroys or eliminates all forms of microbial life in the inanimate environment including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses. It is important to understand that only sterile environments are free of living microorganisms.

The effectiveness of a decontamination process depends on several factors:

- Types and numbers of microorganisms.
- Concentration of the agent.
- Length of contact time with the agent.
- Presence of organic matter and dirt.

- Presence of biofilms.
- Temperature.
- Condition and nature of the surfaces being treated.

9.1.2 Microbial resistance

9.1.2.1 Relative resistance of microorganisms

Microorganisms have variable susceptibility to disinfectant agents as described in the table below (Table 15-1 in the Canadian Biosafety Handbook). Vegetative bacteria and enveloped viruses are usually the most sensitive, and bacterial spores and protozoan cysts the most resistant. Some pathogens (e.g., *Pseudomonas aeruginosa*) have been shown to be significantly more resistant than their laboratory grown counterparts to a variety of disinfectants in their "naturally occurring" state, (e.g.., in body fluids and tissues).

Table 2: Pathogens ranked according to relative susceptibility to chemical disinfectants, reproduced from the Canadian Biosafety Handbook, 2nd Ed

Susceptibility	Pathogen	Disinfectants reported to be effective
Extremely resistant	Prions	• High concentrations of sodium hypochlorite (NaOCl) or heated strong solutions of sodium hydroxide (NaOH)
Highly resistant	Protozoal oocysts	• Ammonium hydroxide, halogens (high concentrations), halogenated phenols.
	Bacterial endospores	• Some acids, aldehydes, halogens (high concentrations), peroxygen compounds.
Resistant	Mycobacteria	• Alcohols, aldehydes, some alkalis, halogens, some peroxygen compounds, some phenols.
	Non-enveloped viruses	• Aldehydes, halogens, peroxygen compounds.
Susceptible	Fungal spores	• Some alcohols, aldehydes, biguanides, halogens, peroxygen compounds, some phenols.
	Gram-negative bacteria	• Alcohols, aldehydes, alkalis, biguanides, halogens, peroxygen compounds, some phenols, some quaternary ammonium compounds (QACs).
	Gram-positive bacteria	
	Enveloped viruses	
Highly susceptible	*Mycoplasma*	• Acids, alcohols, aldehydes, alkalis, biguanides, halogens, peroxygen compounds, phenols, QACs.

9.1.3 Disinfectants

Disinfectants are used to clean surfaces such as lab benches, to clean heat-sensitive devices that cannot be autoclaved, and to decontaminate spills. They are occasionally used to decontaminate liquids but this is not the preferred method. Disinfectants are registered with Health Canada and are issued a DIN number. Disinfectants currently registered can be reviewed at the Health Canada Drug Product Database (DPD).

Major classes of disinfectant chemicals and their relative advantages and disadvantages are summarized in Table 3. The manufacturer of the chemical disinfectant will provide instructions for use, including the recommended exposure time. Manufacturers' recommendations regarding exposure time must be followed.

Table 3. Classes of chemical disinfectants and their advantages and disadvantages, adapted from Table 6, Infection Control Guidelines, Canada Communicable Disease Report Vol. 24S8, Health Canada, December 1998 and Table 15-3, from the Canadian Biosafety Handbook 2nd Ed.

Disinfectant	Uses	Advantages	Disadvantages
Alcohol	Intermediate level disinfectant. Disinfect surfaces of some equipment. Used as a skin antiseptic	Fast acting. No residue. Non-staining	Not recommended to disinfect large areas as it could be fire hazard. Longer contact times difficult to achieve due to evaporation. May harden rubber or cause deterioration of glues.
Chlorine	Intermediate level disinfectant. Disinfect environmental surfaces. Effective disinfectant following blood spills; aqueous solutions (5,000 parts per million) used to decontaminate area after blood has been removed; sodium dichloroisocyanurate powder sprinkled directly on blood spills for decontamination and subsequent cleanup.	Low cost. Fast acting. Readily available.	Corrosive to metals. Neutralized by organic material. Reaction of chlorine with some organics may produce carcinogens. Irritant to skin and mucous membranes. Use in well-ventilated areas. Shelf life shortens when diluted; should be prepared fresh. Solutions sensitive to light. Not suitable for autoclaving.
Formaldehyde	Very limited use as chemisterilant. Gaseous form used to decontaminate biological safety cabinets.	Active in presence of organic materials	Carcinogenic. Toxic. Strong irritant. Pungent odour.
Glutaraldehyde	2% formulations — high level disinfection for heat sensitive equipment. Most used for endoscopes, respiratory therapy equipment and anesthesia equipment.	Noncorrosive to metal. Active in presence of organic material. Compatible with lensed instruments Sterilization may be accomplished in 6-10 hours.	Extremely irritating to skin and mucous membranes. Limited shelf life (effective for 14-30 days depending on formulation). High cost. Fixative.

Disinfectant	Uses	Advantages	Disadvantages
Hydrogen peroxide	3% — low level disinfectant. Cleans floors, walls, and furnishings. 6% — high level disinfectant. Higher concentrations used as chemisterilants in specially designed machines for decontamination of heat sensitive medical devices	Strong oxidant. Fast acting. Breaks down into water and oxygen.	Can be corrosive to aluminum, copper, brass or zinc. May be unstable when exposed to heat and light. High concentrations can cause skin burns, irritation or damage to mucous membranes and can pose risk of explosion. Equipment used may be expensive compared to other methods.
Iodine	Intermediate level disinfectant for some equipment. Low level disinfectant for hard surfaces and equipment that does not touch mucous membranes.	Rapid action. Relatively free of toxicity and irritancy.	Note: Antiseptic iodophors are NOT suitable for use as hard surface disinfectant. Corrosive to metal unless combined with inhibitors. Disinfectant may burn tissue. Neutralized by organic materials. May stain treated objects.
Phenolics	Low/intermediate level disinfectants. Clean floors, walls and furnishings. Clean hard surfaces and equipment that does not touch mucous membranes.	Leaves residual film on environmental surfaces. Commercially available with added detergents to provide one-step cleaning and disinfecting.	Toxic. Pungent odour. Neutralized by hard water. Not recommended for use on food contact surfaces. May be absorbed through skin or by rubber. Some synthetic flooring may become sticky with repetitive use.
Quaternary ammonium compounds	Low level disinfectant. Clean floors, walls and furnishings clean blood spills.	Generally nonirritating to hands. Usually have detergent properties.	DO NOT use to disinfect instruments. Decreased activity in hard water and in presence of organic matter Limited use as disinfectant because of narrow microbicidal spectrum. May make surfaces slippery due to detergent-like properties.

Table 4. Susceptibility of microorganisms to chemical disinfectants, as adapted from Table 15-2 in the Canadian Biosafety Handbook, 2nd Ed.

Chemical Disinfectant	Commonly Available Form	Effective Against							Contact Time
		Bacteria			Viruses		Fungi		
		Vegetative	Mycobacteria	Spores	Enveloped	Non-enveloped	Fungi	Fungal Spores	
✓: effective; L: limited activity; V: variable activity; ✗: no activity * Effective against Gram-positive bacteria; limited activity against Gram-negative bacteria.									
Chlorine	Liquid, powder and tablet	✓	✓	✓	✓	✓	✓	✓	Generally short; longer for bacterial spores (≥ 30 min)
Iodine	Aqueous solutions, tinctures and iodophors	✓	L	L	✓	L	✓	L	Generally short for vegetative bacteria and enveloped viruses; contact time for other organisms is product-specific
Alcohol	Ethyl or isopropyl alcohol; 70% in water is most effective	✓	✓	✗	✓	L	✓	L	Generally short for vegetative bacteria and enveloped viruses; longer for fungi and mycobacteria
Phenolics	Wide variety; generally used as substituted phenols in combination with detergents	✓	V	✗	✓	✗	V	V	

Chemical Disinfectant	Commonly Available Form	Effective Against							Contact Time
		Bacteria			Viruses		Fungi		
		Vegetative	Mycobacteria	Spores	Enveloped	Non-enveloped	Fungi	Fungal Spores	
Quaternary ammonium compounds	Wide variety available with built-in detergent action	✓	×	×	✓	×	✓	×	
Glutaraldehyde	2% acidic solution supplied with a bicarbonate compound	✓	✓	✓	✓	✓	✓	✓	≥ 20 min required for non-enveloped viruses and mycobacteria; >3 hours required for bacterial spores
Formaldehyde	Available as solid paraformaldehyde and liquid formalin	✓	✓	✓	✓	✓	✓	✓	
Hydrogen peroxide (H_2O_2)	Accelerated formulations and 30% solutions in water	✓	✓	✓	✓	✓	✓	✓	Short contact time with 6% H_2O_2, for all viruses, vegetative bacteria, fungi, mycobacteria, and some bacterial spores; higher concentrations and longer contact times required for sporicidal activity
Chlorhexidine	4% solution of chlorhexidine gluconate in a detergent base and	✓/L*	×	×	✓	×	L	×	

Chemical Disinfectant	Commonly Available Form	Effective Against							Contact Time
		Bacteria			Viruses		Fungi		
		Vegetative	Mycobacteria	Spores	Enveloped	Non-enveloped	Fungi	Fungal Spores	
	concentrated alcohol-based solutions								

✓: effective; L: limited activity; V: variable activity; ✗: no activity

* Effective against Gram-positive bacteria; limited activity against Gram-negative bacteria.

Table 5 outlines preparation and use of chlorine-based disinfectants.

Table 5. Directions for preparing and using chlorine-based disinfectants, adapted from Infection Control Guidelines, Canada Communicable Disease Report Vol. 24S8, Health Canada, December 1998

Product	Intended Use	Recommended dilution	Level of available chlorine
Household bleach (5% sodium hypochlorite solution with 50,000 ppm available chlorine)	Cleanup of blood spills	Use concentrations ranging from 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 organic material (e.g., blood or mucus) present on the surface to be cleaned and disinfected.	0.05% or 500 ppm 0.5% or 5,000 ppm
	To add to laundry water	One part of bleach to be mixed with about 500 parts of tap water	0.01% or 100 ppm
	Surface cleaning Soaking of glassware or plastic items	One part to be mixed with about 50 parts of tap water	0.1% or 1,000 ppm
NaDCC (Sodium dichloroisocyanurate) powder with 60% available chlorine	Cleanup of blood spills	Dissolve 8.5 g in one litre of tap water	0.85% or 5,000 ppm
Chloramine-T powder with 25% available chlorine	Cleanup of blood spills	Dissolve 20 g in one litre of tap water	2.0% or 5,000 ppm

9.1.4.1 Factors that affect disinfectant action

Several physical and chemical factors influence disinfectant action, including temperature, pH, relative humidity, water hardness and the presence of organic debris. Extremes of acidity or alkalinity can effectively limit growth of microorganisms. Moreover, the activity of antimicrobial agents may be profoundly influenced by relatively small changes in the pH of the medium. An increase in pH improves the antimicrobial activity of some disinfectants (e.g., glutaraldehyde, quaternary ammonium compounds) but decreases the antimicrobial activity of others (e.g., phenols, hypochlorites, iodine). The pH influences the antimicrobial activity by altering the disinfectant molecule or the cell surface.

Many chemical disinfectants require dilution prior to use. It is mandatory that users follow exactly the manufacturer's directions regarding dilution and mixing. If the concentration of the disinfectant is too low the efficacy will be decreased. If the concentration is too high the risk of the chemical damaging the instrument or surface or causing toxic effects on the user increases.

Once diluted, some disinfectants may be used (if handled properly) for a period of days or weeks. Dilutions are inherently unstable once mixed and the manufacturer's directions as to duration of use must be followed.

Glutaraldehydes require special discussion. Glutaraldehydes may be in acidic or alkaline formulations, and are usually purchased in concentrated forms and diluted for use. These dilutions are time limited. During reuse, the concentration of active ingredient(s) in the product may drop as dilution of the product occurs (incomplete drying), and while organic impurities accumulate (incomplete cleaning). Chemical test strips are available for determining whether an effective concentration of active ingredients (e.g., glutaraldehyde) is present despite repeated use and dilution. The frequency of testing should be based on how frequently the solutions are used (e.g., used daily, test daily). The strips should not be considered a way of extending the use of a disinfectant solution beyond the expiration date. The glutaraldehyde solution should be considered unsafe when the concentration of glutaraldehyde falls below the

minimum effective concentration (MEC) for the product, or the dilution falls below 1% glutaraldehyde.

9.1.5 Antiseptics

An antiseptic is defined as a germicide that is used on skin or living tissue for the purpose of inhibiting or destroying microorganisms. Although some germicides contain active chemicals that are used as both antiseptics and disinfectants (i.e., iodophors and alcohols), adequacy for one purpose does not ensure adequacy for the other. The concentrations of the active ingredients differ significantly, as does the compatibility with inanimate objects and surfaces compared to skin and tissues. Therefore, an antiseptic formulation should never be used to disinfect surfaces such as lab benches or instruments nor should a disinfectant be used on skin or tissues.

9.1.6 Physical methods of decontamination

In addition to the dry heat and moist heat methods of sterilization, ultraviolet (UV) radiation and ionizing radiation can be employed to sterilize inanimate objects. Both UV radiation and ionizing radiation kill microorganisms by causing DNA damage although the damage differs between the two.

UV radiation is most effective at 260 nm, the wavelength of peak absorption for DNA. UV has poor penetrating power and therefore is compromised by the presence of dirt or shadows. It is best used in water-sterilizing systems and to reduce the air-borne bacterial load in TB patients' rooms. It is not recommended for use in biological safety cabinets.

Ionizing radiation such as x-rays and gamma rays are effective in inactivating most microorganisms although some spores are resistant. Due to the extra precautions that must be employed and licensing requirements, it is generally impractical for routine sterilization.

Filtration using high-efficiency particulate air filters is an effective means of removing microbes from the air. This is the means used to sterilize air in biological safety cabinets and clean benches. These filters will remove particles down to 0.3 microns from the air stream.

9.1.7 Toxins

While biological toxins are not "alive" and do not self-replicate, toxin-contaminated materials require treatment before re-use or disposal. There is no one protocol that is suitable for all biological toxins; each toxin must be assessed for appropriate destruction methods.

9.2 Waste management and disposal

9.2.1 What is biohazardous waste?

Biohazardous waste can be considered any material to be discarded that has been contaminated by biohazardous materials. This includes but is not limited to disposable labware, needles, blades, disposable bench cover, and animal carcasses. Reusable materials such as culture flasks and lab coats are not considered "waste" as they are not to be discarded but rather are decontaminated for reuse.

9.2.2 Regulations and guidelines

Hazardous waste is managed by the province as an environmental initiative.

Biohazardous waste may appear in government documents under several names – "pathological waste", "biomedical waste", or "biohazardous waste".

Pathological waste is defined in R.R.O. 1990, Reg. 347: General - Waste Management of the Ontario Environmental Protection Act, as,

a) any part of the human body, including tissues and bodily fluids, but excluding fluids, extracted teeth, hair, nail clippings and the like, that are not infectious,
b) any part of the carcass of an animal infected with a communicable disease or suspected by a licensed veterinary practitioner to be infected with a communicable disease,
c) non-anatomical waste infected with communicable disease,
d) a mixture of a waste referred to in clause (a), (b) or (c) and any other waste or material, or

e) a waste derived from a waste referred to in clause (a), (b) or (c), unless the waste that is derived from the waste referred to in clause (a), (b) or (c) is produced in accordance with a certificate of approval that states that, in the opinion of the Section 39 Director, the waste that is produced in accordance with the certificate of approval does not have characteristics similar to the characteristics of pathological waste referred to in clause (a), (b) or (c).

The Ontario government also has issued Guideline C-4, The Management of Biomedical Waste in Ontario. At the University, this guideline pertains to the veterinary teaching facility and the associated veterinary research laboratories and mobile clinics. The wastes covered by this guideline are those contaminated with primarily Risk Group 3 and 4 organisms. It also pertains to wastes generated from human health care and testing facilities, e.g., Student Health Services, Occupational Health and Wellness, and the Human Nutraceutical Research Unit. Cytotoxic wastes (cancer drugs) are included in this guideline.

Animal-derived infectious waste may be decontaminated in campus facilities including the Animal Health Laboratories alkaline digester. Human-derived bodily fluids and tissues are removed from campus via an authorized biohazardous waste contractor. Such wastes are required to be incinerated.

9.2.3 Storage, treatment and disposal

All waste containers that contain biohazard-contaminated material must be labeled with the biohazard symbol until decontaminated.

Storage of waste until it is treated varies depending on the type of waste:

1. Liquids. Store in leakproof containers with lids. Allow the container to vent if there is continuing microbial growth.

2. Solid debris such as paper towels, gloves, and bench cover. Store in leakproof plastic bags marked with the biohazard symbol. If the material is to be autoclaved, use bags designed to withstand autoclave temperatures. Bags are manufactured in different

thicknesses; choose bags appropriate to the weight of the material.

Figure 2. Typical biohazard bag, Wikimedia commons, September 14, 2016.

3. Plates**.** Store in leakproof plastic bags marked with the biohazard symbol. If the material is to be autoclaved, use bags designed to withstand autoclaving.

4. Putrifiable wastes such as animal carcasses must be refrigerated or frozen until the carcasses are shipped to an incineration facility or treated via the University's alkaline digester (currently for Animal Health Laboratories only). Contact the Laboratory Safety Officer, x54270, for further information regarding scheduling of carcass waste removal.

5. Sharps. All sharps, e.g., needles and blades, must be discarded in a CSA-approved sharps collector. These containers are designed to resist punctures and to prevent the sharps from falling out if the container tips over. Generators are responsible for purchasing their own sharps collectors. Sharps are then disposed of using the electronic process - Chemical/Sharps waste disposal request.

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Figure 3. Sharps container, Wikimedia Commons, September 14, 2016

6. Human bodily fluids and tissues. Waste material contaminated with human bodily fluids such as blood products and tissue samples must be collected for off-campus incineration at an approved waste management facility. At the Guelph campus, there are collection facilities with approved containers at the Ontario Veterinary College Health Sciences Centre, Human Health and Nutritional Sciences, and Student Health Services. Pickups can be arranged at other departments through the Laboratory Safety Officer. The regional campus at Ridgetown will need to arrange for local pickup by the waste management contractor through the Laboratory Safety Officer.

7. Plant wastes. Plants, seeds, and soils may be decontaminated by autoclaving as long as the waste does not contain other material such as radioisotopes or hazardous materials such as solvents. Decontaminated waste may be discarded in the regular dumpster.

8. Outdated vaccines and reagents such as immune-globulins from human serum can be autoclaved and then discarded in the regular dumpster. Alternatively, these materials can be sent for off-campus incineration via the waste contractor.

9. Biological toxins. Biological toxins may or may not be inactivated by autoclaving depending on its chemical structure. Consult the Safety Data Sheet or contact the manufacturer regarding the inactivation of such materials. Toxins can also be deactivated via incineration at the approved off-campus waste management facility.

10. Prions. Prions are not inactivated by conventional methods. Rather, they require special treatment using an alkaline solution. Consult the Biosafety Officer for further information regarding the treatment of prions.

Bagged waste must be transported from the place of generation to the disposal site using carts and/or secondary means of containment such as plastic bins with lids. Biohazardous waste is not to be carried by hand in bags down hallways. Liquid wastes must be placed in a secondary

means of containment such as a plastic bin and transported on a cart. Sharps containers must be transported with the lid snapped closed.

Treatment methods

Waste is generally treated in one of four ways:

- Steam sterilization (autoclave) at sufficient temperature, time and pressure to destroy the biohazardous materials.
- Chemical disinfection using an appropriate verified disinfectant allowing adequate contact time of all contaminated surfaces.
- Incineration at an approved incinerator facility.
- Off-campus waste management contractor.

9.2.3 Steam sterilization

Steam sterilization is suitable for bags of debris, plates, culture flasks, and liquids. It cannot be used if it is mixed waste, e.g., contains radioisotopes or hazardous materials such as phenol, untreated bleach solutions, formaldehyde solutions, or solvents. Waste should never be processed in an autoclave that is used to sterilize instruments or devices that are used in a clinical setting. Please note that waste is rarely rendered completely “sterile”; rather, the microbial load is reduced to a very low level that renders the waste harmless. Steam sterilization is not suitable for carcasses.

Autoclaves must only be operated by trained personnel. Further information regarding autoclaves can be found in the Lab Safety Manual.

Any use of an autoclave for waste must be verified using a biological indicator (spore strips) to ensure that the steam penetrates the load. As waste is rarely the same from load to load, it is important to package it carefully to allow the steam to penetrate to all the contaminated

After the waste has been autoclaved, it can be discarded in the regular dumpster. Place any bags that display the biohazard symbol into a black garbage bag before disposal.

Records to be maintained for autoclaving should include the following information:

- The results of performance indicators.
- Daily use log, with the cycle used, exposure times, dates, user and nature of the load.
- Maintenance and troubleshooting records.

Records are to be retained for a minimum of 5 years.

9.2.4 Chemical disinfection

Chemical disinfection is used on items that may be difficult to autoclave because of size or properties of the material, e.g., shapes that are difficult for steam to penetrate such a long, thin tubes (lumens). Bleach solutions are inexpensive and readily available; be sure to check that bleach is an effective disinfectant for the organism of interest and verify its effectiveness on your material. If bleach has been used before autoclaving items, add sodium thiosulfate to the bleach to prevent the release of chlorine in the autoclave.

9.2.5 Alkaline digestion

Alkaline digestion is used for animal carcasses and tissues generated in the Animal Health/ Pathobiology Building by postmortem activities. Paper, bedding, plastic, and other extraneous materials must be excluded from the digester.

9.2.6 Off-campus waste contractor services

Off-campus contractors are available for material that cannot be decontaminated using the above methods. The waste contractor can handle all contaminated materials including sharps containers, carcasses, debris, and bedding. For occasional generators, waste can be transferred to the campus collection points by EHS using the regular hazardous waste transportation system. For areas that generate waste on a regular basis, direct pickup on site by the off-campus contractor can be arranged by contacting the Laboratory Safety Officer in EHS, x54270. There is no charge to the generator for this service.

10. Emergency response

All persons working with biohazardous materials must be prepared to handle unforeseen incidents that could result in exposure or release if not properly handled.

In all cases of serious personal injury or fire, call Campus Community Police Dispatch at extension 2000.

10.1 Spills

Spill prevention. The best way to manage a spills mitigation program is to eliminate or reduce the possibility of their occurrence.

- Plan and prepare your work.
- Practice the protocol with non-hazardous materials until comfortable with the procedures.
- Eliminate clutter.
- Check all glassware and equipment for defects before commencing work.
- Allow adequate time to perform the procedures including cleanup. Incidents occur when people are tired, rushed, or distracted.

Minimizing the consequence of spills. If spills do occur, you can minimize the aggravation and time by organizing the work and the work area.

- Eliminate all extra materials that are not immediately required.
- Eliminate all porous materials. Materials such as cardboard boxes and cloth chairs cannot be decontaminated and will need to be discarded if contaminated.
- Do NOT use the lab for storage of supplies. If there is no other area for storage, keep supplies in impervious containers such as plastic totes that can be easily

decontaminated or in cupboards with doors that can be disinfected. Do not keep supplies in cardboard boxes in the biocontainment laboratory.

- Use benchcoat (absorbent plastic-backed material) when manipulating biohazardous materials.
- Ensure that there is a biological spill kit available. See Appendix 1 for contents of a biological spill kit.

Refer to the Biological Spill Response Plan on biosafety page for spill cleanup procedures. Each Principal Investigator is responsible for completing a Biological Spill Response Plan and posting in the lab.

10.2 Exposure to potentially infectious material

Intact skin is an excellent barrier to microorganisms. However, exposures to potentially infectious materials can occur via spills resulting in splashes to mucous membranes, including the eye if not wearing eye protection, cuts with sharp objects such as broken glass or scalpel blades, or needlesticks. For this reason, use of sharps in a laboratory using biohazardous materials should be eliminated or minimized.

Exposures via aerosols are potentially hazardous as the respiratory system can serve as a portal for the entry and growth of pathogenic organisms.

Any worker who believes he/she has been exposed to an infectious agent or biological toxin should seek medical assistance as soon as possible. Student Health Services, Powell Building, and Occupational Health and Wellness, Alexander Hall, have knowledgeable personnel on staff and can supply assistance.

10.3 Procedure following exposure

If a worker is exposed via splashes or cuts,

1. Wash the affected area immediately with soap and water. Allow small cuts to bleed but do not squeeze the wound.
2. If there is a splash to the eye, rinse the eye in an eyewash fountain for 15 minutes.
3. Seek medical assistance as soon as possible. Bring a Pathogen Safety Data sheet with you to assist medical personnel.
4. Report the incident to the Principal Investigator as soon as reasonably practical.

10.4 Exposure to bodily fluids or tissue

Persons exposed to human bodily fluids or material derived from non-human primates may be at significant risk, however there is still risk to persons if the source of the material is an animal. If the worker has received a needlestick or other subcutaneous injury, medical attention should be sought immediately as prophylactic measures, if recommended, are most effective if initiated within one to two hours.

10.5 Building evacuation

Various incidents may require the evacuation of the building in which the laboratory is located. Incidents include but are not limited to fires, floods, gas leaks, and loss of power.

10.5.1 Procedure for building evacuation.

When the building evacuation alarm is activated, and it is safe to do so, quickly:

1. Stop work.
2. Cover all containers, extinguish any open flames, and shut down any equipment.
3. Lower the sash of the biological safety cabinet.
4. Remove personal protective equipment and lab clothing taking care not to contaminate the work area and wash your hands.

5. Leave the building by the shortest safe route and proceed to the prearranged assembly point.

6. Provide information to emergency response personnel if you have knowledge of the emergency.

Do not delay leaving the building to try to “save” an experiment.

10.5.2 Procedure for building evacuation when working with animals.

If the procedure with the biohazardous materials involves working with animals, consult Animal Care Services for developing a work-specific emergency management protocol that includes consideration of the welfare of the animals.

10.6 Incident reporting

All incidents that result in a potential exposure to biohazardous materials shall be reported as per the Injury and Incident Reporting process using the Injury/Incident Report form .

Incidents that must be reported include but are not limited to:

- Needlesticks.
- Any injuries with sharps.
- Any spill of biohazardous material outside of the biological safety cabinet.
- Bites or scratches caused by animals.
- Any spill in a centrifuge or incubator.
- Exposure to aerosols.
- Unplanned events involving biohazardous waste.
- Any fever or illness that may be caused by exposure to the biohazardous material.

- Any infection or disease known or suspected to be lab-acquired.
- Any release of the biohazardous material that may cause harm to persons, animals, or the environment.

Incidents shall be reported as soon as possible and in any event within 24 hours. Do not delay submitting the form; missing signatures can be obtained later. Forms are to be submitted as directed on the form and to the Principal Investigator in charge of the project.

11. Biohazards associated with the use of animals

11.1 Introduction

All work that utilizes animals whether for research or teaching must be approved by the Animal Care Committee.

(See Animal Care Policy and Procedures)

All persons handling animals must be trained for the specific species to be used; such training must be documented. Detailed written standard operating procedures specific to the animal use are required.

In addition, all work that involves the infection of animals with a biohazardous substance must be covered by a current biohazard permit.

11.2 Infecting live animals

Projects that involve the infection of live animals with pathogens or use of biological toxins require special precautions. Procedures must be developed to deal with the hazards such as:

- Use of sharps with live pathogens
- Aerosols created during animal challenges

- Live organisms in bedding
- Infected carcasses
- Transport of live pathogens to animal colonies

Animals that have been infected with pathogens must be housed in facilities with the appropriate level of containment as determined by the risk assessment. The Research Isolation Unit at Building 46/146 is designed for Containment Level 2-Ag and has facilities for small and large animals.

There are no Level 3 animal containment facilities at the University of Guelph.

12. References and resources

12.1 References

The following are useful resources that were referenced in the preparation of this manual:

- Biosafety in Microbiological and Biomedical Laboratories, Fifth Edition, Center for Disease Control and Prevention and National Institutes of Health, 2007.
- Block, Seymour S. *Disinfection, Sterilization, and Preservation,* 5th Edition, Lippincott Williams & Wilkins, Philadelphia, 2001.
- Canadian Biosafety Standard, 2nd Edition, Public Health Agency of Canada, Biosafety Division, Office of Laboratory Security, Centre for Emergency Preparedness and Response.
- Canadian Food Inspection Agency, Biohazard Containment and Safety.
- Fraise, Adam P., Maillard, Jean-Yves, and Sattar, Sayed, *Principles and Practice of Disinfection, Preservation and Sterilization*, 5th Edition, Wiley Blackwell, 2013.

- Identifying and Evaluating Hazards in Research Laboratories, American Chemical Society, 2013.
- Infection Control Guidelines, Canada Communicable Disease Report Vol. 24S8, Health Canada, December 1998.
- Laboratory Biosafety Manual**,** Fourth Edition**,** 2019, World Health Organization.
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules Department of Health and Human Services, National Institutes of Health.
- Principles and Guidelines for the Conduct of Microbiological Risk Assessment CAC/GL30 (1999) , Codex Alimentarius Committee, Food and Agricultural Organization / World Health Organization.
- Risk Management, Field Manual No. 100-14, *Risk Management, Field Manual No. 100-14*, Department of the Army, Washington, D.C.
- Taylor, D.M., *Inactivation of Transmissible Degenerative Encephalopathy Agents: A Review.,* The Veterinary Journal, 2000, Vol. 159, pp 10-17.

12.2 Additional web-based resources

12.2.1 Canadian sites

- Canadian Immunization Guide
- Guide on respiratory protection against bioaerosols: Recommendations on its selection and use
- Pathogen Safety Data Sheets – Public Health Agency of Canada

12.2.2 International sites

- ABSA International

- Belgian Biosafety Server

12.3 Resource publications

- *Biological Safety: Principles and Practices, 4th Edition,* Fleming, Diane and Debra Long Hunt, eds. ASM Press, American Society for Microbiology, Washington, D.C., 2006.

- *Control of Communicable Diseases Manual,* Heymann, David L., ed., American Public Health Association, Washington, D.C.

13. Appendix

Appendix 1. Sample spill kit for biohazardous materials

- Container, 20-litre plastic pail with lid, labelled
- Absorbent pads, polypropylene
- Forceps and/or tongs
- Disposable scoop or pancake turner
- Biohazard waste bags
- Disposable non-latex gloves (e.g., nitrile), various sizes
- Disposable Tyvek® coveralls, apron, and/or gown
- Disposable boot covers
- Goggles
- Disinfectant (check expiration date) – concentrated bleach (or suitable substitute)
- Solidifying gel

Biohazard spill kits are also available ready-made from lab supply houses