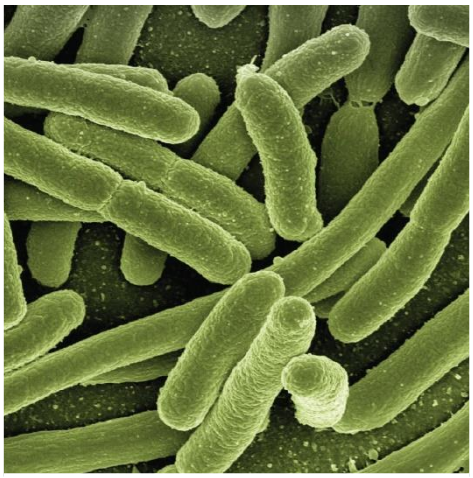
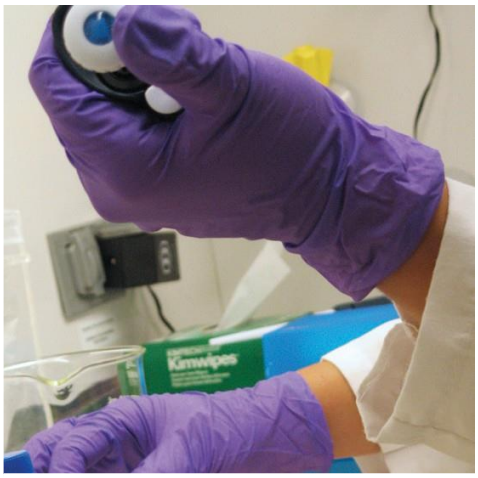
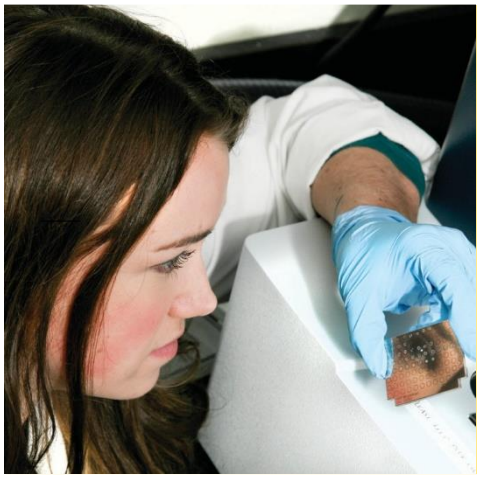
THOMPSON RIVERS UNIVERSITY

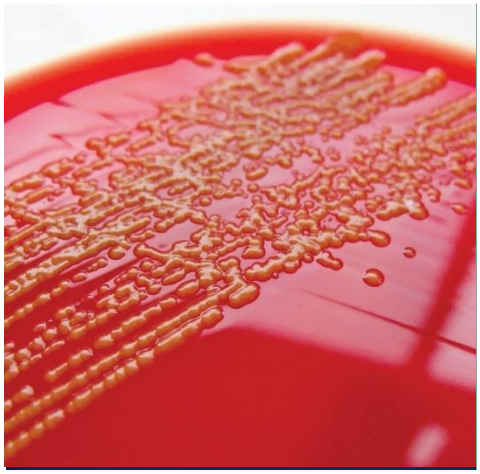
Safety & Emergency Management

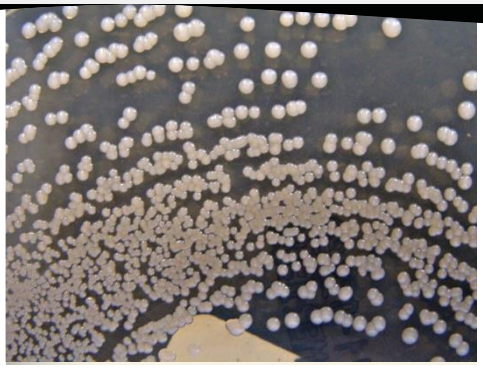






Bio Safety Manual





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i. List of Abbreviations

BBP	Blood Borne Pathogen
BSC	Biological Safety Cabinet
BSO	Biological Safety Officer
CBS	Canadian Biosafety Standard
CBH	Canadian Biosafety Handbook
CCAC	Canadian Council on Animal Care
CDC	Center for Disease Control
CFIA	Canadian Food Inspection Agency
CL	Containment Level
DGR	Dangerous Goods Regulations
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HEPA	High Efficiency Particulate Air
HIV	Human Immunodeficiency Virus
HPIR	Human Pathogen Importation Regulations
HPTA	Human Pathogens and Toxins Act
HPTR	Human Pathogens and Toxins Regulations
IATA	International Air Transport Association
IBSC	Institutional Biosafety Committee
OSEM	Office of Safety and Emergency Management
PEP	Post-Exposure Prophylaxis
PHAC	Public Health Agency of Canada
PI	Principal Investigator
PPE	Personal Protective Equipment
PSDS	Pathogen Safety Data Sheet
rDNA	Recombinant DNA
RG	Risk Group
SDS	Safety Data Sheet
SOP	Standard Operating Procedure
SSBA	Security Sensitive Biological Agent
TDGA	Transportation of Dangerous Goods Act
TDGR	Transportation of Dangerous Goods Regulations
TIMT	TRU Incident Management Team
UACC	University Animal Care Committee
UV	Ultra-Violet

ii. Glossary of Terms/Definitions

Note: clicking on underlined text will redirect you to the term in the glossary or to the related chapter in the manual

Accident: An unplanned event that results in injury, harm or damage.

Aerosol: A suspension of particulates or liquid droplets in a gaseous medium, such as air.

Airborne pathogen: A pathogen that is capable of moving through or being carried by the air.

Animal pathogen: Any pathogen that causes disease in terrestrial, avian, and amphibian animals; including those derived from biotechnology.

Animal room: A room designed to house small-sized animals (e.g. mice, rats, rabbits) in primary containment caging.

Biohazardous material: material of biological origin that may be potentially harmful to humans, animals, plants, the economy or the environment. Biohazardous materials include:

- Pathogenic microorganisms such as viruses, fungi, parasites and bacteria;
- Biological toxins from microorganisms, plants and animals;
- Materials that may contain the above-mentioned agents (e.g. cell cultures; tissue, blood and body fluids from humans and animals; environmental samples);
- Certain proteins, nucleic acids (siRNA, miRNA, DNA from pathogenic organisms, oncogenes);
- Genetically modified organisms (GMO) that may be hazardous to the environment if released

Biological material: pathogenic and non-pathogenic microorganisms, proteins and nucleic acids, as well as any biological material that may contain them. Biological material that contains human or animal pathogens is referred to as "Infectious material".

Biological toxins: poisonous substances naturally produced by living organisms (microorganisms, plants and animals).

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

Biological safety officer (BSO): A specific individual designated for overseeing facility biosafety and biosecurity practices.

Biosafety: The application of containment principles, technologies and practices to prevent unintentional exposure to infectious material or toxins, or their accidental release. See also: Microbial toxins.

Biosafety Manual: A facility-specific manual that describes the necessary core elements of a biosafety program (e.g. biosecurity plan, training, personal protective equipment).

Biosecurity: measures implemented to prevent the loss, theft, misuse, diversion or intentional release of infectious materials or toxins.

Biosecurity risk assessment: A risk assessment in which relevant pathogens, toxins, infectious material, and other related assets (e.g. equipment, animals, information) are identified and prioritized. Associated threats and risks of these materials are identified, and suitable mitigation strategies are determined to protect against any potential theft, misuse, diversion, or intentional release of these materials.

Blood Borne pathogen: infectious microorganisms in human blood that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV).

Center for Disease Control (CDC): The leading federal public health agency in the United States of America.

Community: That area which encompasses relevant human and animal populations.

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

Containment level (CL): The minimum required physical containment and operational practices for safely handling infectious material or toxins in laboratory, large scale production, and animal work environments. As defined by the CBS, there are four containment levels ranging from a basic laboratory (containment level 1 [CL1]) to the highest level of containment (containment level 4 [CL4]).

Containment system: Equipment dedicated to providing and maintaining containment. This includes, but is not limited to, primary containment devices (e.g. biological safety cabinets), decontamination apparatus (e.g. autoclaves), heating, ventilation and air conditioning (HVAC), and control systems.

Contamination: Unwanted infectious material/toxins within laboratory materials (e.g. laboratory samples, cell cultures) or laboratory surfaces (e.g. benchtop, hands, gloves).

Controlled activities: Any of the following activities referred to in Section 7(1) of the Human Pathogens and Toxins Act: possessing, handling or using a human pathogen or toxin; producing a human pathogen or toxin, storing a human pathogen or toxin; permitting any person access to a human pathogen or toxin; transferring a human pathogen or toxin; importing or exporting a human pathogen; releasing or otherwise abandoning a human pathogen or toxin; or disposing of a human pathogen or toxin.

Culture: The *in vitro* propagation of tissue cells, microorganisms, or other living matter under controlled conditions (e.g., temperature, humidity, nutrients).

Decontamination: process by which materials and surfaces are made reasonably free of microorganisms or toxins, and thus are safe to handle. Decontamination may be achieved through disinfection, inactivation or sterilization.

Disease: A structural and/or functional disorder in a living human or animal, or one of its parts, resultant of infection or intoxication. Disease typically manifests via distinguishing signs and symptoms.

Disinfection: A process used to eliminate most forms of living microorganisms.

Emergency Response Plan: A document that outlines the procedures to be taken and the parties responsible in emergencies such as spills, exposure, release of infectious material or toxins, personnel injury or illness, power failure, fire, explosion or other emergency situations (e.g. severe weather, hurricane, armed intruder).

Endemic: Naturally present in or limited to a particular geographic area.

Enzootic: Relating to a disease or pathogen that is regularly present in an animal population in a particular geographic area.

Exotic Pathogen: A pathogen not naturally present in a specific geographic area.

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

Facility (plural: facilities): Structures or buildings, or defined areas within structures or buildings, where infectious material or toxins are handled or stored. This could include individual research and diagnostic laboratories, large scale production areas, or animal housing zones. A facility could also be a suite or building containing more than one of these areas.

Genetically Modified Organism (GMO): A microbe, plant or animal whose genetic material has been altered through the use of natural selection, crossbreeding, conjugation, transformation or genetic engineering (e.g. insertion or deletion of genes or gene segments).

Good Microbiological Laboratory Practices (GMLP): Basic laboratory practices applicable to all types of activities with biological material.

Handling or storing: "Handling or storing" pathogens, toxins, or infectious material includes possessing, handling, using, producing, storing, permitting access to, transferring, importing, exporting, releasing, disposing of, or abandoning such material. This includes all controlled activities involving human pathogens and toxins specific in Section 7(1) of the Human Pathogens and Toxins Act.

High concentration: Infectious material or toxins that are concentrated to a degree that increases the risks associated with manipulating the material (i.e., increases the likelihood or consequences of exposure).

High efficiency particulate air filter (HEPA): A device capable of filtering 99.97% of airborne particles 0.3µm in diameter, the most penetrating particle size. Due to the effects of impaction, diffusion, and interception, HEPA filters are even more efficient at trapping and retaining particles that are either smaller or larger than 0.3µm in diameter.

Incident: An event or occurrence with the potential of causing injury, harm, infection, intoxication, disease, or damage. Incidents can involve infectious material, infected animals, or toxins, including a spill exposure, release of infectious material or toxins, animal escape, personnel injury or illness, missing infectious material or toxins, unauthorized entry into the containment zone, power failure, fire, explosion, flood, or other crisis situation (e.g. earthquake, hurricane). Incidents include accidents and near misses.

Infectious material: Any isolate of a pathogen or any biological material that contains human or animal pathogens.

Injury: The occurrence of a sudden and unforeseen event, arising out of, or in the course of a University Sanctioned Activity, attributable to any factor that caused an injury or an occupational disease (an exposure to conditions or substances that resulted in a disease).

Intoxication: A disorder or disease caused by exposure (ingestion, inhalation, inoculation, absorption) to a microbial toxin.

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

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

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

Inward directional airflow (IDA): Air that always flows from areas of lower containment or lower contamination risk areas to areas of higher containment or higher contamination risk, as a result of a negative air pressure differential within the containment zone created by a ventilation system.

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

Laboratory work area: Area inside a containment zone designed and equipped for in vitro research,

diagnostics, and teaching purposes.

Large scale: Activities generally involving volumes of toxins or the in vitro culture of infectious material on a scale of 10 litres or greater. This could be a single vessel with a volume of 10 litres or greater, or based on the processes and pathogen used, could be multiple vessels with a total volume of 10 litres or greater. It is determined in consultation with the Public Health Agency of Canada and/or the Canadian Food Inspection Agency on a case-by-case basis, whether or not particular activities conducted in a containment zone are required to follow the increased or unique requirements for large scale production areas.

Large volume: A volume of infectious material or toxins that is sufficiently large to increase the risk associated with the manipulation of the material (i.e., increases the likelihood or consequences of exposure or release).

Local Risk Assessment (LRA): Site-specific risk assessment that identifies hazards based on the infectious material or toxins in use and the procedures being performed.

Medical surveillance program: A program for prevention and detection of illness related to laboratory exposure to infectious material or toxins. The program emphasizes prevention, but also provides a process through which potential infections are identified and treated before disease occurs.

Microbial toxins: A subcategory of biological toxins. Microbial toxins are poisonous substances produced by microorganisms (bacteria, viruses, fungi).

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

Movement: The action of moving people, material or animals from one physical location to another in the same building. This can include movement within the same containment zone, to a difference containment zone, or to another location within the same building.

Near-Miss: The occurrence of event on University Property, arising out of, or in the course of a University Sanctioned Activity attributable to any factor that could have caused an injury or material damage.

Operational practice requirements: Administrative controls and procedures used in the laboratory to protect personnel, the environment and the community from biohazards.

Overarching risk assessment: A broad risk assessment that supports the biosafety program as a whole and may encompass multiple containment zones within an institution or organization. Mitigation and management strategies reflect the type of biosafety program needed to protect personnel from exposure and to prevent the release of pathogens and toxins.

Pathogen: An agent (e.g., a microorganism, nucleic acid or protein) that can cause disease or infection in humans and/or animals.

Pathogen risk assessment: The determination of the risk group and appropriate physical containment and operational practice requirements needed to safely handle the infectious material or toxins in question.

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

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

masks, and respirators.

Physical containment requirements: Physical barriers, *i.e.* engineering controls and facility design that protect personnel, the environment and the community from biohazards.

Post-Exposure Prophylaxis: Is a short-term antiretroviral treatment aimed at reducing the likelihood of viral infection after potential exposure.

Post mortem room (PM room): A room within the containment zone where animal necropsies and dissections are conducted.

Primary containment: Protection of workers and laboratory from exposure to infectious material and toxins by provision of a physical barrier between the individual and/or the work environment and the biological material.

Primary containment caging: Animal caging serving as a primary containment device to prevent the release of infectious material and toxins. Examples include ventilated filter-top cages and ventilated micro-isolator cage rack system, with or without highly particulate air (HEPA) filters.

Primary containment device: Apparatus or equipment that is designed to prevent the release of infectious material or toxins and to provide primary containment (i.e., provide a physical barrier between the individual and/or the work environment and the biological material). Examples of primary containment devices include biological safety cabinets, isolators, centrifuges with sealable cups, process equipment, fementers, microisolator cages, and ventilated cage racks.

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

Process equipment: Specific equipment used to carry out a manufacturing procedure involving biological material. This term is generally used to describe equipment used in large scale processes (e.g., industrial fermentation equipment).

Puff-back: Reversal of airflow from the face of a Class II type B2 biological safety cabinet.

Release: The discharge of infectious material or toxins from a containment system.

Restricted Access: Access that is strictly controlled to authorized personnel only by means of a physical barrier (i.e. a controlled access device or system, such as an electronic access card, access code, etc.).

Risk: The probability that a person will be harmed or experience an adverse health effect if exposed to a hazard.

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

Scientific Research: As defined in Section 1 of the Human Pathogens and Toxins Regulation: the following types of systematic investigation or research that are carried out in a field of science or technology by means of controlled activities:

a) Basic research: when the controlled activities are conducted for the advancement of scientific knowledge without a specific practical application.

b) Applied research: when the controlled activities are conducted for the advancement of scientific knowledge with a specific practical application.

c) Experimental development: when the controlled activities are conducted to achieve scientific or technological advancement for the purpose of creating new – or improving existing – materials, products, processes, or devices.

Small-sized animal: Refers to the physical size of the animal; small-sized animals are small enough to be housed in primary containment caging. Examples include rodents, rabbits, ferrets, chickens, and nonhuman primates. Small-sized animals may also be housed in an animal cubicle (e.g., when open caging is used).

Standard operating procedure (SOP): A document that identifies the hazards associated with a project and describes safe work practices and procedures to minimize or eliminate risk.

Sterilization: A process that completely eliminates (destroys) living microorganisms, including bacterial spores.

Terrestrial animal pathogen: An agent that causes disease in terrestrial animals, including avian and amphibian animals, but excluding invertebrates and aquatic animals.

Thimble connection: An air gap type connection used to exhaust BSC air to the outside atmosphere; the air gap allows for exhaust system fluctuations without affecting cabinet performance.

Toxins:

- Biological Toxins: poisonous substances naturally produced by living organisms such as microorganisms, plants and animals.
- Microbial Toxins: a subcategory of biological toxins. Microbial toxins are poisonous substances produced by microorganisms (bacteria, viruses, fungi).

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

Transportation: Shipping of infectious material or toxins to another building or location, within Canada or abroad, in accordance with the *Transportation of Dangerous Goods Act* and *Regulations*.

Trigger quantity: The minimum quantity above which a toxin regulated by the Human Pathogens and Toxins Act is considered a "prescribed toxin" and, therefore, a security sensitive biological agent, as described by Section 10(2) of the Human Pathogens and Toxins Regulations.

TRU Romeo: TRU's research administration tool that allows researchers and administrators to work collaboratively to manage internal and external grant applications throughout the life span of the research application.

University Sanctioned Activities: Sanctioned activities include, but are not limited to: working, conducting research, studying, working as an intern, visiting or volunteering.

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

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

Zoonoses: Diseases transmissible between animals and humans. This includes anthropozoonoses, which are diseases that are transmitted from animals to humans, and Zooanthroponoses ("reverse zoonoses"), which are transmitted from humans to animals.

1. Introduction

The Laboratory Biosafety Manual was developed for individuals who handle or work in proximity to potentially infectious material and toxins, and is based on an overarching risk assessment of the protocols in use at Thompson Rivers University.

For information related to general safety roles and responsibilities please refer to the TRU Safety Policy or contact the Office of Safety and Emergency Management at safetyofficer@tru.ca

The Biosafety Program and Biosafety Officer position at Thompson Rivers University are under the portfolio of the Office of Safety and Emergency Management (OSEM), which is responsible for Occupational Health & Safety including WorkSafe BC Regulations and Emergency Management. This Biosafety Manual is based on the 2nd editions of both the *Canadian Biosafety Standard* (CBS) [released in 2015]) and the *Canadian Biosafety Handbook* (CBH [released in 2016]) by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA). The CBS covers work with human and terrestrial animal pathogens, toxins and prions and replaces the following:

- Canadian Biosafety Standards and Guidelines (parts 1 and 2), 1st edition 2013 (PHAC and CFIA)
- Human pathogens and toxins: Laboratory Biosafety Guidelines, 3rd edition, 2004 (PHAC);
- Terrestrial animal pathogens: Containment Standards for Veterinary Facilities, 1st edition 1996 (CFIA); and
- Prions: Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents, 1st edition 2005 (CFIA).

1.1 Definition of Biohazardous Material

Biohazardous materials are defined as material of biological origin that may be potentially harmful to humans, animals, plants, the economy or the environment. Biohazardous materials include (but are not limited to):

- Pathogenic microorganisms such as certain viruses, fungi, parasites, and bacteria;
- Biological toxins from microorganisms, plants and animals;
- Materials that may contain the above-mentioned agents (e.g. cell cultures; tissue, blood and body fluids from humans and animals; environmental samples);
- Certain proteins, nucleic acids (prions, siRNA, miRNA, DNA from pathogenic organisms, oncogenes);
- Genetically modified organisms (GMO) that may be hazardous to the environment if released.

2. Legislation, Standards and Guidelines

Activities involving human and animal pathogens and toxins are regulated by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA), in accordance with the *Human Pathogens and Toxins Act* (HPTA), Human Pathogens and Toxin *Human Pathogens and Toxins Regulations* (HPTR), *Health of Animals Act* (HAA) and *Health of Animals Regulations* (HAR).

2.1. Human Pathogens and Toxins Act (HPTA) and Regulations (HPTR)

The HPTA was developed to protect the health and safety of the public from the risks posed by human

pathogens and toxins, and establishes basic biosafety requirements for handling human pathogens and toxins in Canada. The HPTR support the Act and establish National standards for the safe handling of human pathogens and toxins, as well as a licensing process for facilities engaged in Controlled Activities.

The HPTA and HPTR apply to all activities with Risk Groups 2, 3, and 4 human pathogens and microbial toxins, whether imported or domestically acquired. It should be noted that TRU only works with Risk Groups 1 and 2. Administration and enforcement of the Act and Regulations are overseen by PHAC's Centre for Biosecurity.

2.2. Standards and Guidelines

2.2.1 Canadian Biosafety Standard (CBS)

The second edition of the *Canadian Biosafety Standard* (CBS) was released in 2015, by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) and supports full implementation of the HPTA and HPTR. The CBS is a harmonized national standard for Controlled Activities with human and terrestrial animal pathogens, toxins and prions. The CBS also describes the physical containment and operational practice requirements for facilities that fall under the HPTA and HPTR, the HAA and HAR.

2.2.2 Canadian Biosafety Handbook (CBH)

The second edition of the *Canadian Biosafety Handbook* (CBH), released in 2016, is a companion document to the CBS, and provides core information and guidance on how to achieve the physical containment and operational practice requirements outlined in the CBS.

2.3. Containment Standards for Facilities Handling Aquatic Animal Pathogens

The animal pathogens covered under the CBS refer to those that cause disease in terrestrial animals, including avian and amphibian animals; however, they exclude aquatic animals and invertebrates. Facilities in which imported aquatic animal pathogens are handled or stored must follow CFIA's *Containment Standards for Facilities Handling Aquatic Animal Pathogens*, 1st edition, 2010. Facilities that handle or store both aquatic and terrestrial animal pathogens must adhere to the aquatic standards, as well as the CBS.

2.4. Containment Standards for Facilities Handling Plant Pests

Plant pests rarely infect healthy people, and pose little risk to laboratory workers. They may, however, pose a substantial threat to agriculture or to the environment. In order to prevent accidental release into the environment, facilities handling plant pests (i.e. microorganisms, insects and non-indigenous plants) must conform to the CFIA Containment Standards for Facilities Handling Plant Pests 1st edition, 2007. The required level of containment depends on the risk of the plant pest escaping and becoming established in the environment and on the consequences of such an introduction.

2.5. TRU Policies and Procedures

2.5.1 Health and Safety Policy ADM-05

The University's Health and Safety Policy outlines institutional obligations and line supervision and/or management responsibilities for health and safety throughout the University.

2.5.2 Biosafety Policy

The University's Biosafety Policy (in development) outlines the framework for the biosafety program and provides details regarding:

- Management of the Biosafety Program
- Disposal of Biohazardous Waste
- Operational Responsibilities.

2.5.3 Hazardous Biological Material Spill Response Procedure (SEM 20.07-09.1)

The Hazardous Materials Spill Response Procedure at Thompson Rivers University, outlines facility-specific procedures used to manage accidental spills or the release of hazardous materials, of varying magnitudes.

2.5.4 Personal Protective Equipment and Lab Safety Protocols (OH&S 18.06.2)

Thompson Rivers University's policy on personal protective equipment, describes conditions for the required use of personal protective equipment (PPE) by members of the University community, in the course of university sanctioned activities.

3. Institutional Biosafety Committee (IBSC)

The IBSC is mandated to fulfil the responsibilities of the Institutional Biosafety Committee as described in the CBH. The IBSC is an advisory committee that operates within regulatory and institutional policies to protect faculty, staff, students, research subjects and the general public from exposure to biohazardous materials. The responsibilities, mandate and membership of the Committee are outlined in the TRU IBSC Terms of Reference.

4. Project Registration and Approval

4.1. Biohazard Permits

Local risk assessments for all work with biohazardous materials are conducted by OSEM (via the Biosafety Officer), in conjunction with the IBSC. All projects, whether funded or not, involving biological material must be registered with OSEM to ensure that the work is compliant with internal policies and the CBS. Before beginning any activities with biological materials, or if there are significant changes (e.g. new biological materials or procedures) to a previously approved Biohazard Permit, Principal Investigators or their delegates must:

1. Submit a *Biohazard Permit Application & Certificate (SEM 20.03)*
   Note: Biohazard Permits are required for all risk groups (RG1 and RG2) agents, and for all University Sanctioned Activities, including teaching.
2. Include the SOPs (or in the case of teaching labs, the course lab manual) related to the project/activity for risk assessment and review by OSEM/BSO. SOPs for RG 1 and RG2 work will also be reviewed by the IBSC.
3. Include an updated inventory of biological materials (used and stored).

The Biohazard Permit approval process is summarized below:

- The Biohazard Permit Application and supporting documents (SOPs and inventory) and training records are reviewed by the BSO and the IBSC;
- As assessment of the medical surveillance requirements is conducted by the BSO, in consultation

with TRU Health Services as required.

- A local biosecurity risk assessment is carried out by the BSO to determine if special security measures are required;
- A Biohazard Permit & Certificate is issued by the BSO on behalf of the IBSC.

4.2. Laboratory-specific Standard Operating Procedures (SOPs)

Project- or laboratory-specific guidelines for work with biohazardous materials are not addressed in this manual; they are available as Standard Operating Procedures (SOPs), which are specific to each laboratory. These SOPs are developed by the Principal Investigator or laboratory supervisor, and include:

- A list of locations where the biohazardous material will be used and stored;
- Training requirements;
- Entry/exit procedures for lab workers, animals and equipment;
- PPE requirements;
- Identification of the hazards associated with the work, including signs and symptoms of disease caused by the infectious agents in use;
- Step-by-step description of the procedures involving biohazards;
- Injury, exposure and spill response procedures[1]
- Use of engineering controls, e.g.:
    - Biological safety cabinet;
    - Chemical fume hood;
    - Sealed rotors/safety cups for centrifuges
- Procedures for movement and transportation of biohazardous materials;
- Decontamination and waste disposal procedures;
- Procedures to follow for unattended experiments.

SOPs for work with RG 2 materials are reviewed by the BSO as part of the application process and approved by the IBSC. The SOP(s) must be made available to everyone conducting the procedures outlined in the SOP(s); all lab workers must demonstrate knowledge of, and proficiency in, the SOP(s) before commencing work. Please consult the BSO for assistance in preparing research-specific SOP(s).

4.3. Safety & Emergency Management Research Approval Certificate

For funded projects, an approved Biosafety Certificate is required before the AVP Research and Graduate Studies (AVP-RGS) will release research funds. This document is part of the Biohazard Permit that is submitted to ROMEO during project proposal. OSEM Biosafety Certificates are issued by OSEM, once approval of the Permit is granted and following review and assessment of all hazardous materials and controlled products that are used in the laboratory.

5. Biosafety Training

It is the responsibility of PIs, faculty members, researchers, instructors, teaching assistants and technicians (in their capacity as supervisor of a class, laboratory or university-sponsored activity) to ensure that all individuals involved with biohazardous materials receive the necessary biosafety training.

[1] see also section 8.1 on Emergency Response Procedures

The OSEM training courses described below provide general and theoretical knowledge, and are valid for 3 years. Practical and hands-on training are the responsibility of the PI. All practical, hands-on, laboratory or project-specific training must be documented using the Training Attendance/Compliance Record (SEM 22.04.1) and a copy of the completed form must be submitted to OSEM for inclusion in the official training repository.

The following biosafety training courses are available through OSEM, and are valid for 3 years.

5.1. General Biosafety

This training is mandatory for all students, faculty, staff, volunteers and visitors working with biohazardous materials, as well as for anyone who oversees spaces where these materials are used or stored. The course provides an overview of biosafety in order to promote awareness in research and teaching labs where biohazardous materials are handled or stored, in order to protect faculty, staff, students, the public and the environment from potential exposure to biohazardous materials.

Topics include: definition and classification of biological agents; elements of risk assessment; policies, guidelines and regulations; laboratory management and operations; good microbiological laboratory practices; biosecurity; safety equipment; principles of sterilization and disinfection; waste disposal and spill response procedures.

5.2. Biosafety Refresher

This training is offered in lieu of repeating the Biosafety training after its expiration: it is mandatory for all students, faculty, staff, volunteers and visitors working with biohazardous materials, and for everyone who oversees spaces where these materials are used or stored.

Topics include: definition and classification of biological agents, elements of risk assessment, policies, guideline and regulatory updates, safety equipment, laboratory management and operations, and biosecurity.

5.3. Safe Use of Biological Safety Cabinets

This training is required for anyone who uses a biological safety cabinet. The course provides information on HEPA filtration and cabinet airflow characteristics, types of cabinets and safe work practices related to the use of biological safety cabinets.

5.4. Safe Handling of Blood

This in class and hands-on training is required for all individuals who work with human blood, blood products, body fluids, unfixed human tissues, or unscreened human cell lines.

Topics include Universal Precautions, transmission of blood-borne pathogens (e.g., Human Immunodeficiency Virus, Hepatitis B and C Viruses), exposure control principles and procedures.

5.5. Transportation of Dangerous Goods Class 6.2 – Infectious Substances

This training provides an overview of the Transportation of Dangerous Goods (TDG) regulations for Class 6.2 – Infectious Substances and is required for any individual who ships, transports or receives Risk Group 2 biological materials.

Topics include: classification; documentation; labeling; preparation of biological substances, including

dry ice shipments; training; and emergency response.

6. Biosecurity Plan

6.1. Definitions: Biosafety vs Biosecurity

While biosafety refers to the application of containment principles, technologies and practices to prevent unintentional exposure to infectious material or toxins, biosecurity refers to measures taken to prevent the loss, theft, misuse, diversion or intentional release of these materials. Potential consequences of a biosecurity lapse include:

- Infection, poisoning or death of humans or animals;
- Undesirable social, economic, or environmental impact;
- Negative impact on research due to the loss of material.

6.2. Local Biosecurity Plan Requirements

TRU's biosecurity plan (SEM 20.05) was developed in collaboration with PIs, lab personnel, IBSC and OSEM. A biosecurity risk assessment is conducted by OSEM during the Biohazard Permit review process (refer to Section 4, Project Registration and Approval). Any special biosecurity requirements are included as conditions to a Biohazards Permit and communicated directly to the applicant. The TRU Biosecurity Form SEM 20.05.1 is to be read, signed and posted in CL2 areas.

PIs and lab supervisors are responsible for the local biosecurity plan for their facilities. Basic elements of this plan include:

- **Physical security:**
    - Strategies that prevent unauthorized removal of biohazardous material from laboratories, for example:
        - Restrict access to authorized individuals;
        - Keep doors closed and lock them when the laboratory is not occupied;
        - Lock freezers, refrigerators, and other storage devices located outside the laboratory;
        - Do not copy keys or give keys/electronic security devices to unauthorized individuals;
        - Ensure that keys/electronic security devices are returned by those who no longer need lab access;
        - Report suspicious behavior, or unauthorized individuals loitering in laboratory areas to the Security at extension 5033 or 250-828-5033.
- **Personnel suitability and reliability:**
    - Ensure that individuals have the appropriate training, experience, competency and personality traits to carry out the work.
- **Infectious material and toxin accountability:**
    - Maintain an inventory tracking system so that missing material is readily identified; report any loss/theft of biohazardous material to the supervisor and OSEM.
    - An annual audit of inventory is mandatory.
- **Incident and emergency response:**
    - Report incidents, including missing infectious material/toxins or signs of forced entry, to

OSEM and Security for follow-up investigation.

- **Information security:**
    - Protect sensitive information (e.g. information-sensitive SOPs and results, inventories, storage locations of biohazardous materials) from unauthorized access. Do not share usernames and passwords, as specified in TRU's Information Security Policy.

7. Risk Groups, Containment Levels and Risk Assessments

7.1. Pathogen Risk Assessments and Risk Group Classification:

Risk: is the probability that a person will be harmed or experience an adverse health effect if exposed to a hazard?

Pathogen risk assessments evaluate the consequences and likelihood of exposure to infectious material, based on the following risk factors:

- **Pathogenicity/virulence** – does the agent cause disease in humans, animals or plants? What is the degree of disease severity?
- **Route of infection** – how does the pathogen enter the body (ingestion, inhalation, mucous membrane, inoculation, etc.)?
- **Mode of transmission** – is the agent transmitted by direct contact, indirect contact, airborne, vectors or zoonosis?
- **Survival in the environment** – does the pathogen survive outside the host?
- **Infectious dose** – how many organisms are required to cause infection?
- **Availability of effective preventive and therapeutic treatments –** are effective vaccines, antibiotics or antivirals available?
- **Host range** - does the pathogen have a narrow host range, or does it cause disease in a wide range of species?
- **Natural distribution** – is the pathogen indigenous to Canada or prevalent in one particular area?
- **Impact of introduction/release into the environment** – what would be the economic, clinical and biosecurity impact if released/introduced into the environment?

PHAC has conducted risk assessments on almost 200 well-characterized human pathogens and produced Pathogen Safety Data Sheets (PSDS); these technical documents describe the hazardous properties of pathogens and provide recommendations for working with them in a laboratory setting.

The CFIA has developed Fact Sheets for federally reportable diseases affecting terrestrial animals. Safety Data Sheets (SDS) are available from commercial suppliers for biological toxins, cell lines and serum-derived products.

Pathogen risk assessments for uncharacterized or modified agents are conducted on a case-by-case basis (Refer to the Local Risk Assessment Matrix, SEM 20.04), and must be updated regularly. Please contact the Biosafety Officer for assistance in risk classification.

7.1.1. Classification of Biological Material by Risk Group

The following summarizes the four risk group categories for human and animal pathogens, based on risk to individuals/animals, public health, livestock or poultry. Note that as of 1 Jan 2016, only RG1 and RG2 are in use at TRU.

7.1.1.1. Risk Group 1 (RG1): Low Individual, Low Community Risk.

Risk group 1 agents are unlikely to cause disease in healthy humans or animals and pose a low risk to public health, livestock or poultry. Nevertheless, good microbiological laboratory practices must be followed when handling these agents, as some RG1 organisms are opportunistic and can pose a threat to immune-compromised or immunosuppressed individuals (e.g., due to medical therapy, pregnancy, diabetes, or other conditions).

7.1.1.2. Risk Group 2 (RG2): Moderate Individual Risk, Low Community Risk.

These pathogens are unlikely to be a serious hazard to laboratory workers, the community, livestock or poultry. Effective treatments and preventive measures are available and the risk of spread is limited. Examples of RG 2 human pathogens are included in Schedule 2 of the HPTA.

7.1.1.3. Risk Group 3 (RG3): High Individual Risk, Low Community Risk.

These pathogens can cause serious human or animal disease but do not ordinarily spread by casual contact. Effective treatment and prevention are usually available. The risk of spread to livestock or poultry ranges from low to high, depending on the agent. Examples of RG 3 human pathogens are listed in Schedule 3 of the HPTA.

7.1.1.4. Risk Group 4 (RG4): High Individual Risk, High Community Risk.

These pathogens cause very serious human or animal disease. Effective prevention and treatment are generally not available and the risk of spread to the public is high. The risk of spread to livestock or poultry ranges from low to high, depending on the agent. Examples of RG 4 human pathogens are included in Schedule 4 of the HPTA.

7.2. Inventory

Inventory records are maintained by the PI. The Microbiology Laboratory Technician will ensure a complete inventory for organisms used for teaching is updated annually and forwarded to the BSO.
The Biosafety Committee will review the list of registered materials annually. Inventory shall include material from commercial, university or private institutions regardless of whether it is a gift or purchased.

The Principal Investigator (PI) or Supervisor will be responsible for properly providing the BSO with information regarding biological materials acquired from outside sources. All new organisms must be registered with the Biosafety Officer before they are introduced to TRU.

Anyone ordering organisms needs to advise the BSO of their request to ensure approval is given to the TRU purchasing department before the order can be processed. Registration assists the Biosafety Officer in developing a catalogue/inventory of biohazardous materials on campus, and registration is used by the Biosafety Committee to assist in assigning biological safety levels (Risk Group category) to each agent. It also helps to ensure that research teams are working with these materials in a manner that is safe for everyone's protection and that appropriate permits are obtained. Such inventories will be used in the development of the TRU Bio Security Plan.

Importation requirements and forms may be obtained from:
The Public Health Agency of Canada
The Canadian Food Inspection Agency

7.3. Principles of Containment and Containment Levels

Containment: refers to physical design parameters and operational practices that serve to protect lab workers, the immediate work environment, the community and the external environment from exposure to potentially hazardous biological material.

Primary containment: protects personnel and the immediate laboratory environment from exposure to infectious agents and toxins, and is established through the provision of physical barriers between individuals and/or the work environment and infectious materials or toxins. Examples of primary containment devices include:

- Biological safety cabinets and glove boxes;
- PPE (lab coats, gloves, eye protection);
- Centrifuges with sealable cups/rotors;
- Animal micro-isolators;

Secondary containment protects protection of the environment external to the laboratory, and is provided by a combination of facility design and operational practices. Examples of secondary containment include:

- Physical separation from laboratories and animal facilities from public areas;
- Negative airflow into laboratories;
- Hand-washing sinks available and located near lab exits;
- Self-closing doors;
- Technology for decontamination available.

7.3.1 Containment Level Categories

Risk group classifications do not take into account the procedures and manipulations occurring in a laboratory or animal work environment. The term "**containment"** refers to the combination of physical design parameters and operational practices that protect personnel, the immediate work environment and the community from exposure to biological material. The Agencies have developed a system of **containment levels** to describe the minimum physical containment and operational practices required for safe handling of infectious material or toxins in laboratory and animal work environments. There are 4 containment levels, ranging from a basic laboratory (CL1) to the highest level of containment (CL4).

The containment level and risk group of a pathogen are generally the same; however, containment levels may change when a pathogen has been modified or the original conditions of use have changed. The following factors are considered when determining the appropriate containment level:

- Potential for **aerosol generation** by equipment or procedures. Increased containment may be required if there is potential of exposure to infectious aerosols;

- **Quantity**: Large scale processes may have different containment requirements than laboratory scale work with the same pathogen;

- **Pathogen concentration varies** with the work being done, e.g. diagnostic specimens may contain lower pathogen concentrations than pure cultures;

- **Nature of work**: (e.g., in vivo versus in vitro studies). For in vivo procedures, the risks associated with specific animals may affect containment level requirements;

- **Shedding** (animal work) – the potential for pathogen shedding via breath, saliva, urine or feces must be taken into consideration when working with infected animals.

7.3.1.1. Containment Level 1 (CL1): Basic Laboratories

CL1 labs do not require special design features beyond being well-designed and functional. Work can be conducted on an open benchtop; containment is achieved through the use of Good Microbiological Laboratory Practices (GMLP; SEM 20.06). Although Biological Safety Cabinets (BSCs) are not required for CL1 work, they are often used to maintain product sterility.

7.3.1.2. Containment Level 2 (CL2):

CL2 builds upon the basic requirements for CL1. Biosafety and biosecurity requirements are met through a combination of physical containment features and operational practices appropriate for Risk Group 2 material. Refer to Chapter 3 and Chapter 4 of the CBS for details regarding CL2 physical and operational requirements.

7.3.1.3. Containment Level 3 (CL3):

In addition to the requirements for CL2, strict facility design and engineering controls and specialized biosafety equipment are required to minimize the release of infectious agents into laboratory work areas, animal rooms and the environment. At present, TRU does not have a CL3 facility.

7.3.1.4. Containment Level 4 (CL4):

CL4 adds to the physical and operational requirements for CL3, and provides maximum containment. Requirements include a highly complex facility, maximum engineering controls, specialized biosafety equipment and the highest level of operational practices. CL4 is not feasible at TRU.

7.4. Special Considerations

7.4.1. Biological Toxins

Biological toxins are non-replicating, non-infectious, poisonous substances produced by or derived from certain microorganisms, plants and animals. Many are capable of causing adverse health effects in humans and/or animals at relatively low concentrations. An additional risk associated with working with toxins, includes the potential for buildup of static electricity and release of aerosolized toxin when handling dried/lyophilized toxins.

Routes of exposure to biological toxins in the laboratory include:

- Accidental inoculation
- Absorption through skin or mucous membranes
- Ingestion
- Inhalation of aerosols

The biological toxins currently being used at TRU can safely be handled in Containment Level 2 laboratories, without the need for security clearances (Refer to Schedule 1 of the HPTA for a list of regulated microbial toxins and trigger quantities). All projects involving biological toxins require a Biohazards Permit issued by OSEM (refer to Section 4.1).

7.4.2. Human Blood, Body Fluids and Primary Tissue

The primary hazards associated with handling human blood, body fluids or tissues in the laboratory setting are:

- Percutaneous exposure, e.g., from a needle injury or through skin breaks (dermatitis, acne, cuts, etc.);
- Exposure of mucous membrane (eye, nose, mouth) to aerosols, splashes or sprays of contaminated material.

Although the HPTA does not regulate pathogens in their natural environment, TRU requires that a Biohazards Permit (refer to Section 4.1) be obtained prior to initiating work involving human tissue, blood and body fluids. Laboratory practices should be based on the assumption that all human blood, body fluids and tissues are potentially infectious for blood borne pathogens such as Hepatitis B, Hepatitis C or human immunodeficiency virus (HIV), regardless of their source. These precautions also apply to work with human cells in culture and human serum-derived reagents.

Under TRU's Medical Surveillance Program (refer to Section 12.2), everyone working with human-derived material should be immunized against Hepatitis B Virus. Anyone who refuses the immunization must complete a Declination Form, available from the Manager of Safety & Emergency Management (OSEM).

7.4.3. Recombinant DNA: Genetically Modified Organisms and Viral Vectors

Natural or synthetic genetic material from more than one source can be combined to create new recombinant DNA (rDNA). The genetic material of microorganisms, animals and plants can be modified by the insertion or deletion of genes or gene segments to create a genetically modified organism (GMO). Viral vectors (e.g., lentivirus, retrovirus, adenovirus, herpesvirus vector systems) can be used to deliver genetic material into host cells for subsequent gene expression.

Genetic manipulation may increase or decrease the risk group and containment level, depending on:

- The gene(s) being transferred;
- Modification of genes (point mutations, deletions) already present in the organism;
- Properties of the gene(s) expressed in the recombinant;
- Risk Group of the host organism;
- Interaction between the gene(s) being transferred and the host vector system(s);
- Viability of the host vector system.

Work with recombinant DNA (rDNA) must include an assessment of the host, vector and insert; the work should be carried out at the highest containment level of any of the individual components. In general, when the source of the DNA being transferred, the vector and host are all innocuous, the possibility of

hazard is remote. An approved Biohazard Permit must be obtained before starting any project involving rDNA technology (refer to Section 4.1).

7.4.4. Cell Lines and Cell Culture

Cell cultures may contain unsuspected oncogenic, allergenic or infectious particles, and even well-characterized cell lines with no inherent risk have the potential to acquire pathogenic organisms, either naturally or through contamination by adventitious organisms, transformation or recombination. Cell lines that contain a known pathogen should be handled using the containment level appropriate for the agent.

Many commercially-available eukaryotic cell lines of human or animal origin are classified as Risk Group 2 due to presence of pathogenic viruses in the original cells or introduced during their immortalization. Since it is not feasible to test for all conceivable human pathogens, it is prudent to use CL2 facilities and operational practices when handling human or non-human primate sourced cell lines.

The potential hazards associated with human primary cell cultures include blood borne pathogens (e.g. HBV, HCV, HIV) as well as agents such as Mycobacterium tuberculosis that may be present in lung tissue. All projects involving cell culture require a Biohazard Permit issued by OSEM (refer to Section 4.1).

7.4.5. Environmental Samples

Environmental samples, such as water, sediment or soil may contain pathogens that present a hazard to people, animals or the environment, and should be collected using the appropriate PPE.

In keeping with best biosafety practices, CL2 facilities and operational procedures are recommended when handling samples that contain unknown microbes/pathogens. If the purpose of a study is to investigate the presence of a specific Risk Group 2 pathogen, the samples are classified as Risk Group 2.

In all cases, a risk assessment must be carried out in collaboration with OSEM when determining risk group and containment level requirements for environmental specimens.

7.4.6. Autologous Cells, Tissues and Specimens (Self-Experimentation)

Experimental infection of cells or other specimens derived from the person conducting the experiment poses a risk to the individual. *In vitro* transformation or other genetic modification of autologous cells puts the individual at risk, since any innate immune protection that would normally destroy foreign cells is bypassed. Laboratory workers must not donate or collect their own blood specimens or tissues, or those of others, for procedures carried out within the same laboratory.

7.4.7. Large-scale

Activities involving volumes of 10 litres or more, whether in a single or in multiple vessels, are generally considered to be large scale by PHAC and CFIA. Large-scale work may pose an increased risk to lab workers and the environment.

Please contact OSEM prior to initiating any large-scale project. OSEM will consult with PHAC and /or the CFIA to determine whether the work is considered laboratory or large scale.

7.4.8. Animal Work

All aspects related to the use of animals in research, including operational procedures for the care and maintenance of animals must follow the *Guide for the Care and Use of Experimental Animals* of the Canadian Council on Animal Care (CCAC).

Anyone (PI, staff and students) who intends to conduct research, testing or teaching projects involving animals must obtain approval of the University Animal Care Committee (UACC) **before** commencing the project. Questions regarding this are to be directed to the UACC via email: TRUacc@tru.ca

7.4.8.1. Zoonoses

Zoonoses are diseases that are communicable between animals and humans; zoonotic diseases may be acquired as a result of:

- Animal bites and scratches;
- Contact with animal tissues and cultures, body fluids and excreta;
- Exposure to aerosols produced as a result of activities such as cleaning of cages.

The risk of exposure to a zoonosis while handling commercially-available common small laboratory animals is very small; the risk is greater for those who handle experimental animals from random sources and for field researchers working with wild animals.

7.4.8.2. Laboratory Animal Allergy

It is estimated that up to 44% of people working with laboratory animals develop allergies to one or more species, usually within 3 years after first exposure[2]. Allergies can develop following inhalation of airborne animal allergens or after eye or skin contact with animal serum, tissues, saliva, urine and skin dander of laboratory animals. Most species of laboratory animals can trigger an allergic reaction, with allergies to rats, rabbits, mice, guinea pigs, cats and dogs being the most common. Symptoms of allergy may be mild (itchy eyes, runny nose and eyes, sneezing, skin reaction) to severe (wheezing, chest tightness, shortness of breath).

The following measures have been shown to be effective in reducing individual exposure to laboratory animal allergens:

- Ensure that adequate room ventilation and humidity (50-65% for dust control) are provided in rooms where animals are housed or handled;
- Manipulate animals in ventilated hoods or biological safety cabinets;
- Use filtered cages and ventilated cage racks;
- Use low-dust bedding material;
- Reduce exposure to potential allergens by wearing dedicated lab coats or scrubs, particulate mask, gloves, and shoe covers;
- Good personal hygiene practices, such as regular hand washing;
- Keep the area clean and free of dust.

8. Emergency Response Plan (ERP)

8.1. Emergency Response Procedures

Emergencies are generally unpredictable and occur with little or no warning. Prevention and mitigation measures must be developed, and emergency response procedures included in lab-specific SOPs. Examples of biosafety-related emergencies include:

- Spills of biohazardous material refer to: SEM 20.15, 20.16, 20.17and 20.18;

[2] *Allergies to Laboratory Animals, CCAC training module on: occupational health and safety, Module 16.* www.ccac.ca/en_/training/niaut/stream/cs-ohs

- Exposure to blood borne pathogen (BBP) refer to: SEM 20.07, 20.25, 20.26, and 20.27;
- BSC Power failure refer to: SEM 20.19;
- Discrepancy or violation of inventory of agents;

In addition, everyone at TRU is expected to know how to respond to general emergencies, and is encouraged to consult the Emergency Management website for details on various emergency procedures.

In order to ensure that personnel are capable of responding immediately and effectively to emergencies, the CBS requires annual ERP training for everyone who works in a CL2 (and higher) facility. Reminders to comply with this requirement will be incorporated into the message sent to PIs during the annual Biohazard Permit review process conducted by OSEM.

8.2. Injury and Near-Miss Reporting Procedure

As per TRU's Incident Reporting procedures, members of the University Community are required to report all injuries, occupational disease and near-misses. Detailed reporting instructions are available on the TRU OSEM website.

Biosafety-related injuries and near-misses include confirmed or suspected laboratory acquired infections/intoxications, exposure to infectious material or toxins, and containment system failure that may have resulted in exposure to biohazardous material. Injury reports assist TRU OSEM in determining the root cause(s), corrective actions and in developing measures for preventing recurrence; reporting of near-miss events allows OSEM to investigate in order to prevent future injuries. Injury and Near-Miss Reports involving biohazardous materials are reviewed by the BSO and IBSC, investigated, and reported to the appropriate government agencies including PHAC and/or CFIA, if required.

PIs are responsible for ensuring that everyone working in the laboratory is aware of the reporting requirements for incidents and near misses.

8.3. Spills of Biological Material

The *Hazardous Material Spill Response Procedure* exists for the management of spills or accidental release of hazardous materials, and outlines procedures and guidelines for the handling of spills of potentially hazardous materials, including spills of biohazardous material.

8.3.1 Spill Response Plan

Spills involving infectious materials or toxins must be addressed as soon as they occur; lab workers must always be prepared for the possibility of a spill of biohazardous material. The appropriate spill response depends on the nature of the spilled material and on the size of the spill. Spills may be **minor** ("incidental") or **major** ("emergency"):

Incidental spills:

- Limited in quantity, exposure potential and toxicity;
- May be safely cleaned up by those who are familiar with the hazards of the material and have the knowledge and training to address the spill.
- Follow either the SEM 20.15 (BSC Biological Spill Clean Up), or SEM 20.16 (Small Biological Spill outside of BSC Clean Up Protocols), or SEM 20.18 (Biological Spill in a Centrifuge), depending on the situation.

Emergency spills:

- Pose significant risk to persons in the immediate vicinity or to the environment;
- Follow SEM 20.17 (Large Biological Spill outside of BSC Clean Up Protocols) if the spill, while large, can still be contained.
- If full room decontamination is necessary, this is at the discretion of the PI and the BSO.

Due to the nature and quantity of biohazardous materials used at the University, Emergency spills are unlikely to occur. Procedures for Incidental and Emergency spills are outlined below.

8.3.1.1. Incidental (Minor) Spills

The necessary cleanup materials should be readily available and response procedures established before a spill occurs. Incidental spill response procedures are specific for the pathogen(s) being used, and are included in the laboratory standard operating procedures (SOPs) SEM 20.15 and SEM 20.16.

The proper procedure for handling biological spills will vary depending on the agent(s), quantity and location of the spill. To deal with a minor biohazardous material spill, laboratories must have ready access to biological spill kits.

- **Spill Response Kit**

As per SEM 20.15 and SEM 20.16, spill kits must contain the appropriate clean-up materials, protective clothing and equipment. They must be labeled and kept in a visible and accessible location inside the lab or in an alternate space designated by the Department. Biological spill kits should include:

- Autoclave bags for collecting contaminated waste during the cleanup;
- Disposable PPE:
  - Chemical splash goggles;
  - Several pairs of disposable gloves (latex, vinyl, or nitrile) in multiple sizes;
  - Chemical resistant shoe covers;
  - Disposable N95 masks, to protect from direct (splash) and indirect (accidental transfer via hands) exposure to infectious material or toxins during spill clean-up. If fit-tested, N95 masks also provide aerosol protection.
- Appropriate absorbent material, e.g.:
  - Paper towels or absorbent pads;
- Autoclavable polypropylene plastic tweezers, forceps, dustpan or scoop for collecting contaminated materials such as broken glass/sharps;
- Sharps container;
- Concentrated chemical disinfectant, such as a 1/10 dilution of household bleach (~10% sodium hypochlorite) or other disinfectant appropriate for the spilled material (replace yearly to ensure efficacy);
- A copy of applicable biological spill procedures or SOPs.

9. Ventilation and Laboratory Safety Equipment

9.1. General Ventilation

Heating, ventilation and air conditioning (HVAC) systems dilute indoor air contaminants and maintain comfort parameters of temperature, humidity and air circulation. The laboratories are equipped with dedicated HVAC systems, which are separate from the ventilation of offices and public spaces, and

which exhaust 100% of the air extracted from the laboratory. Laboratory ventilation systems are balanced to maintain negative pressure (inward directional airflow) relative to adjacent areas, reducing the potential for release of aerosolized infectious materials or toxins from the work area.

A laboratory's HVAC system is not designed to control or exhaust biohazards or volatile or toxic chemicals; these must be handled in biological safety cabinets, chemical fume hoods or other containment enclosures.

9.2. Personal Protective Equipment (PPE)

When properly used, personal protective equipment (PPE) protects individuals and adjacent non-laboratory areas from contamination. PPE is required for work with all hazardous substances, including biohazards, and is provided by principal investigators (PI)/lab supervisors to personnel and students who handle potentially harmful materials.

Good PPE practices include:

- Post signage to indicate the PPE requirements;
- Ensure that everyone entering the laboratory wears laboratory coats and safety glasses;
- Never reuse PPE meant for single use;
- Decontaminate reusable PPE that has come into contact with infectious materials or toxins;
- To prevent contamination of non-laboratory areas and negative public perception, never wear PPE in public areas outside the laboratory;
- Remove PPE in a manner that minimizes the spread of contamination to the skin, hair and underlying clothing.

9.2.1. Eye and Face Protection

Eye and face protection must be used whenever there is a risk of exposure to flying objects or splashes of infectious liquids or toxins. Eye and face protection prevent this material from entering eyes, nose or mouth. Note that:

- Regular prescription eyeglasses do not provide adequate eye protection.
- Safety glasses provide basic eye protection; they are sturdier than regular prescription eyeglasses, impact-resistant and available in prescription and non-prescription forms.
- Safety goggles provide a higher level of splash protection than safety glasses due to the snug fit over and around the eyes.
- Face shields cover the eyes, nose, mouth and skin; however, they provide adequate eye protection only when worn in combination with safety glasses or goggles.

9.2.2. Laboratory Coats, Gloves and Other Protective Equipment

Fastened knee-length long-sleeved laboratory coats and closed non-slip footwear with no or low heels must be worn at all times in laboratory areas. Capri pants, short skirts, etc. do not provide adequate skin coverage and are not permitted.

Gloves are required for all procedures that could involve direct skin contact with chemicals (e.g. concentrated disinfectants), blood, animals, infectious materials and toxins and when using a BSC; they must be replaced immediately when contaminated or torn. They should be selected for their degradation and permeation characteristics to provide proper protection for the specific project (refer to Table 1 in Section 5.5 of the TRU Microbiology Lab Safety Manual (SEM 20.10) for guidance on glove selection, use

and removal. Always wash hands after removing gloves and before leaving the lab.

Surgical and dust masks offer little protection from infectious aerosols or aerosolized toxins, but do protect mucous membranes of the eyes and nose from spills and splashes, as well as from accidental touching. Masks are rarely required for work with biohazardous materials, as infectious aerosols can be generally controlled at the source by using BSCs. Anyone who intends to use a full-face or half-face respirator or disposable N-95 mask must first contact TRU's Biosafety Officer (safetyofficer@tru.ca), as fit-testing is required to ensure that full respiratory protection can be achieved.

9.3. Biological Safety Cabinets

Biological safety cabinets (BSCs) provide effective primary containment for work with pathogens and toxins when properly maintained and used in combination with good microbiological practices (GMLP). BSCs reduce the risk of airborne exposure by preventing the escape of aerosolized biohazardous agents into the laboratory environment. They should be used for procedures that have the potential to produce infectious aerosols and for work involving high concentrations or large volumes of infectious material. Ideally, BSCs should be provided with emergency power to ensure containment during power outages.

9.3.1. HEPA filters

HEPA (High Efficiency Particulate Air) filters are essential components of BSCs, with particle removal efficiencies of 99.97% or better for 0.3 µm diameter particles. A particle size of 0.3µm is used as the basis for filter definition because it is the most difficult size to remove; particles that are larger or smaller are removed with greater efficiency.

A HEPA filter is comprised of a single sheet of fiber paper, which is pleated over rigid corrugated separators (to prevent the pleats from collapsing in the airstream) and glued onto a wood, metal or plastic frame. HEPA filters are easily damaged if mishandled; thus, biological safety cabinets must be tested and certified whenever they are moved.

Although HEPA filters effectively remove particulates from an airstream, they do not capture chemical gases or vapors. Thus, recirculating Class II BSCs must not be used with hazardous volatile or radioactive materials.

9.3.2. Classes of Biological Safety Cabinets

There are three classes of BSCs, operating under the same basic principles. **Personnel protection** is provided by means of a continuous stream of inward air, which helps to prevent aerosols from escaping through the front opening. HEPA-filtered exhaust air provides **environmental** protection. In addition to protecting workers and the environment, some BSCs (Classes II and III) provide **product protection** from airborne contamination by sending HEPA-filtered air across the work surface.

Horizontal or laminar flow clean benches are not BSCs; they provide product protection but do not protect the ambient environment or the user from exposure to the materials being handled. Clean benches must never be used for handling infectious, toxic or sensitizing materials: they are appropriate for non-hazardous activities that require a clean environment, such as the assembly of sterile apparatus or electronic devices.

Refer to Appendix IV: Characteristics of Different Classes and Types of BSCs, and Comparison with Chemical Fume Hoods for a summary of BSC characteristics by Class and Type.

9.3.2.1. Class I cabinets

Class I cabinets provide personnel and environmental protection, but do not protect the product: thus, they are suitable only for work where sterility is not required. Examples include:

- Animal cage changing stations
- Enclosure of equipment such as homogenizers and fermenters
- Handling of specimens in diagnostic labs

9.3.2.2. Class II cabinets

There are 4 types of Class II BSCs (A1, A2, B1 and B2); all provide personnel, environmental and product protection. The majority of BSCs at TRU are Class II Type A2.

9.3.2.3. Class III cabinets

Class III cabinets provide personnel, environmental and product protection, and are intended for work with Risk Group 4 pathogens. A Class III BSC is completely enclosed and airtight, and kept under negative pressure by a dedicated exhaust. Work is carried out via attached heavy-duty long-sleeved gloves.

9.3.3. Placement of Biological Safety Cabinets in the Laboratory

In order to ensure that the protective curtain of inward directional airflow is maintained, BSCs should be located away from interfering room air currents, such as those caused by:

- Pedestrian traffic;
- Room ventilation, e.g. overhead supply diffusers, fans, heating and air conditioning registers;
- Equipment that generates air currents, e.g. centrifuges, chemical fume hoods;
- Opening and closing of doors.

The ideal placement is in a “dead end” area of the lab, away from doors, throughways, windows, supply air diffusers, fume hoods and other equipment that could interfere with cabinet airflow. BSCs should not be located directly opposite seated work stations, other BSCs or fume hoods, and there should be adequate clearance on each side to allow access Please contact the BSO before relocating a BSC or installing a new one.

9.3.4. Safe use of the Biological Safety Cabinet (BSC)

BSCs provide effective primary containment only if properly maintained and used in conjunction with good microbiological laboratory practices. Everyone who uses a BSC must attend the “Safe Use of Biological Safety Cabinets” training course in order to understand how these cabinets work and how to use them safely.

Practices and procedures for working in a BSC are summarized in the following sections:

9.4. Chemical fume hoods

Chemical fume hoods are designed to capture and exhaust gases, vapours, mists, aerosols and particulates generated during manipulation of chemical substances. The user is protected by an inward stream of room air, which flows across the work surface and is exhausted directly outdoors. Chemical fume hoods are not equipped with HEPA filters; they provide personnel protection, but no product or environmental protection. Thus, chemical fume hoods are not suitable for manipulation of infectious materials.

9.5. Autoclaves

Steam autoclaves combine high temperature, pressure and moisture to kill infectious agents and denature proteins. Efficacy is dependent on temperature, the length of the exposure time, and direct steam contact with the material being autoclaved. Autoclaves are effective for the decontamination of biohazardous waste and for sterilization of equipment, glassware, media and liquids. Note that antineoplastic agents, toxic chemicals, volatile chemicals and radioisotopes must ***never*** be autoclaved.

Not all materials can withstand autoclaving conditions. The table below explains what are recommended materials for primary containers (flasks, bottles, vials, tubes, waste bags) and secondary containers (for capture of accidental spills or meltdown).

Recommended Materials	Poor Choices For Containers
• Borosilicate glass (e.g. Pyrex, Kimax); • Polypropylene (PP) and polycarbonate (PC) plastic; • Stainless steel.	• Soda lime glassware; • Polystyrene (PS), Polyethylene (PE), High Density Polyethylene (HDPE) and Low Density Polyethylene (LDPE) plastics.

9.5.1. Safe Use of Autoclaves

First-time users must receive hands-on training prior to using an autoclave; this training must be documented by completing and forwarding the ***Training Attendance/Compliance Record SEM 22.04.1*** form to OSEM.

Autoclaves must be loaded so that steam is able to penetrate into the innermost areas of autoclave bags, containers or equipment. Longer processing times are required for larger loads, larger volumes of liquids and denser materials.

Please refer to the following Sections for guidelines on autoclave use:

9.5.1.1. Preparing to Load the Autoclave
9.5.1.2. Loading the Autoclave
9.5.1.3. Unloading the Autoclave

9.5.2. Efficacy Monitoring for Autoclave Decontamination of Biological Waste

The markings that appear on temperature-sensitive indicator tape (“autoclave tape”) after autoclaving indicates that the proper temperature was reached; however, this change is not time-dependent and does not prove successful decontamination of the contents of the bag/container.

Effective operating parameters must be established through the use of appropriate biological indicators (e.g. heat-resistant Bacillus stearothermophilus spores). Test indicators are placed in areas least likely to reach sterilizing conditions, such as in the centre of a load, while a positive growth control from the same lot number is set aside without being autoclaved. After processing, test and control indicators are incubated for a specified length of time and examined for bacterial growth. Growth is expected in the control; however, growth in test indicators shows that the load was not exposed to effective operating parameters. Failure may be due to insufficient sterilization time, improper loading, or overloading of the autoclave

The efficacy monitoring program for autoclaves used to decontaminated biohazardous waste is overseen by Microbiology Laboratory Technical staff or the BSO.

10. Other Laboratory Equipment Used for Biological Work

10.1. Centrifuges

Spills, leaks, tube breakage or improper use of safety cups/rotors can result in generation of biohazardous aerosols during centrifugation. Refer to Appendix IX: Safe Use of Centrifuges for recommendations for safe centrifugation of infectious material or toxins.

10.2. Mixing apparatus

The operation of blenders, sonicators, homogenizers, shaking incubators, tissue grinders and mixers can generate significant amounts of infectious aerosols. Procedures for safe operation of aerosol-generating equipment must be documented in the lab-specific SOP. Please refer to Appendix X: Safe Use of Mixing Apparatus for recommendations on using mixing apparatus.

10.3. Vacuum pumps and aspirating systems

The use of vacuum to aspirate infectious liquids can result in generation of infectious materials or toxins and subsequent contamination of vacuum lines, pumps and centralized vacuum systems. These systems must be protected by liquid disinfectant traps and an in-line HEPA or 0.2 µm filter placed between the secondary flask and the vacuum source.

11. Movement and Transportation

The term **movement** is used when moving biohazardous materials within a laboratory or building, while **transportation** refers to transporting this material to another building or location in Canada or abroad. Transportation of infectious materials and toxins falls under the TDGA[3], the TDGR[4] and the Dangerous Goods Regulations issued by IATA[5]. Infectious material and toxins must be documented and packaged appropriately in order to protect against their release during movement or transport, and in accordance with TDGR when applicable.

11.1. Movement within Laboratories or Buildings

Procedures must be in place to prevent leaks, drops and spills: containers must be closed, labeled, leak-proof and impact resistant, and placed inside secondary containers. A cart with raised rails or edges

[3] Transportation of Dangerous Goods Act
[4] Transport of Dangerous Goods Regulations
[5] International Air Transport Association

must be used for moving multiple samples, large volumes or heavy items.

11.2. Transportation between buildings

Note that transportation falls under the Transport of Dangerous Goods Act and Regulations whenever infectious materials or toxins are transported across public roads used by the general public, and that TDG training is required. The appropriate training ("Transportation of Dangerous Goods Class 6.2 – Infectious Substances") can be scheduled via the OSEM Department.

When transporting biohazardous materials between buildings, the following precautions will reduce the risk of breakage and contain the materials in the event of a leak or spill:

- Place materials in a leak-proof and impact-resistant labeled primary container, using screw-cap containers whenever feasible;
- Use a secondary container that is large enough to hold the volume of the material being transported;
- Transport the materials on a cart that has rails or raised edges and is lined with absorbent material, or in a handheld carrier bucket;
- Never use passenger elevators to transport biohazardous materials; use the freight elevator instead.

11.3. Shipping

The transportation of infectious substances within Canada is administered through Transport Canada and regulated by the TDGA and TDGR. Infectious materials and toxins fall under *Class 6, Division 6.2 Infectious Substances* of the Regulations, which define the labelling, packaging and documentation requirements.

Import, export, purchase, or transfer of biological materials at TRU requires strict adherence to the National Standard of Canada: Packaging of Category A and Category B infectious substances (Class 6.2) and clinical, (bio) medical or regulated medical waste (2016).

International and national regulations stipulate that everyone involved in the transport (shipping, handling, transporting or receiving) of biohazardous materials must be trained, tested and certified. TDG training can be arranged by contacting OSEM.

Certain biological materials or samples are fully or partially exempt from TDG regulations: please contact OSEM (biosafetyofficer@tru.ca) before shipping any biological substances. Biological material should not be sent until arrangements have been made with the sender, carrier and recipient. ***The sender must keep records of the shipping documents (electronic and/or paper), including the waybill and completed transfer documents, for at least 2 years.***

For a more detailed explanation of packing and labelling requirements and some examples, see the Thompson Rivers University Packing and Labelling Biological Materials for Transport SOP: SEM 20.30.

12. Medical Surveillance Program

The purpose of medical surveillance is to help prevent and detect illness or disease related to exposure to infectious material or toxins. While the focus is on prevention, medical surveillance also provides a response mechanism through which a potential infection or intoxication can be identified and treated before serious disease occurs.

12.1 Medical Surveillance for Work with Infectious Materials and Toxins

Depending on the biohazardous materials used, TRU recommends, at minimum, current immunizations as part of the medical surveillance program. Including:

- Tetanus
- Hepatitis A Virus (HAV) when dealing with sewage
- Hepatitis B Virus (HBV) for work involving blood, body fluids or tissues
- Rabies as required

The medical surveillance requirements for individuals working with biohazardous materials are assessed on a case-by-case basis as part of the Biohazard Permit application process (details in Section 4.1), and are indicated on the Permits. The recommendations apply to all Authorized Users listed on the Permit.

12.2 Medical Surveillance for Work with Human Blood, Body Fluids or Tissues

The majority of people identified during the Biohazard Permit application review as needing medical surveillance are working with human blood, body fluids or unfixed primary tissue. Hepatitis B Virus (HBV) immunization is strongly encouraged for everyone who handles these materials, and is offered at Public Health and travel immunization centers. Individuals who have already been vaccinated for Hepatitis B, but were never tested to ensure that the immunization was effective, can request Hepatitis B surface antibody titre testing through Public Health.

Principal Investigators whose projects involve human blood, body fluids, or unfixed tissue, will receive a letter from OSEM outlining the requirements for Hepatitis B immunization for the Authorized Users listed on the Biohazard Permit.

Anyone who refuses the immunization is required to email their respective department or complete a Declination Form (for rabies only), available from the Office of Emergency Management through either the Associate Director or the BSO. All other declinations are presented to the applicable department on a case-by-case basis.

The emergency response procedure following accidental exposure to material of human origin is summarized in Appendix XI: What to do if exposed to human blood, body fluids or tissue? A memo and an information sheet will be provided to everyone who has reported an exposure to human blood, body fluids or tissue (refer to Appendix XII: BBP Exposure Memo, SEM 20.26 and Appendix XIII: Blood Borne Pathogen Post Exposure Information, SEM 20.27).

12.3 Medical Surveillance for Work with Research Animals

The animal facility houses disease-free mice and rats acquired from commercial suppliers of laboratory animals; no infectious agents or biological toxins are handled inside the facility. Everyone who plans to work with the mice and rats should update their tetanus immunization through Public Health before starting their projects.

Anyone who is bitten or scratched by a rat or mouse from the facility should clean the injured area with warm soapy water and seek medical attention from Health Services where they will be evaluated and sent for further testing if required. Individuals should go to a medical clinic if the injury occurs outside regular working hours.

13. Decontamination and Waste Management

It is good laboratory practice to decontaminate all biological waste generated by a laboratory, whether or not it is known to be infectious. Examples of such waste include human and animal tissues, blood and blood products or body fluids; spent culture medium; microorganisms and toxins. Decontamination helps to prevent occupational exposure to, and/or the unintentional release of, infectious materials or toxins, and refers to procedures that render materials and surfaces safe to handle and relatively free of infectious microorganisms or toxins.

Decontamination can be achieved through disinfection, inactivation (prions, biological toxins) or sterilization. **Disinfection** eliminates most forms of living microorganisms and is less lethal than **sterilization**, which completely eliminates all living microorganisms, including bacterial spores. The choice of decontamination method will depend on the nature of the material to be processed. Decontamination procedures must be included in all laboratory SOPs; laboratory staff and students must be trained in these procedures. Each laboratory must ensure that the appropriate materials required for decontamination are readily available and that equipment, specimen/sample containers, surfaces, rooms and spills are properly decontaminated before disposal.

13.1 Chemical Disinfection

Liquid chemical disinfectants are suitable for spill cleanup and the decontamination of surfaces and equipment that cannot be autoclaved. Many chemical disinfectants are toxic; thus, it is important to

read Safety Data Sheets (SDS), follow manufacturers' recommendations and wear the appropriate PPE when handling them. The choice of disinfectant will depend on a number of factors, including:

1. Resistance of the specific microorganism or toxin;
2. Application (e.g. whether a liquid or gaseous chemical is required);
3. Nature of the material to be disinfected (e.g. hard surface vs porous material);
4. The organic load. Organic material such as tissue, blood, animal bedding and feces may
    - Physically shield microorganisms/toxins, or
    - Inactivate certain disinfectants (e.g. bleach).
5. Concentration;
6. Contact time;
7. Temperature, relative humidity and pH
    - High temperature may enhance efficacy, but may increase evaporation of disinfectant
    - Lower temperature may reduce efficacy
8. Stability (e.g. diluted bleach has a short shelf-life, and must be prepared more frequently).

Refer to Chapter 15, Section 15.3.1 of the 2nd edition of the CBS for a summary of microorganism susceptibility to chemical disinfectants (including prions) (Table 15.1), characteristics and contact times of chemical disinfectants (Table 15.2), and disadvantages of chemical disinfectants (Table 15.3).

13.2 Autoclaving

As discussed in Section 9.5 above, autoclaves are effective in decontaminating biohazardous waste. Please refer to Appendix VIII Safe Use of Autoclaves and SEM 20.10 Microbiology Lab Safety for detailed instructions on using an autoclave.

13.3 Biohazardous Waste Disposal Procedures

13.3.1 Biological Toxins

There are no standard procedures for inactivation and disposal of biological toxins, due to their wide variability in physical properties and susceptibility to inactivation. OSEM can provide assistance to individual PIs in determining the optimum inactivation and disposal protocols for the toxins in use. An overview of thermal and chemical inactivation of toxins is available in Chapter 15, *Section 15.11.* of the current CBH.

13.3.2 Other: Sharps, Anatomical Waste, Non-anatomical Waste, Liquid Waste, Autoclaved Waste

Please refer to the Office of Safety & Emergency Management for detailed instructions on the procedures to follow when disposing of biohazardous sharps, anatomical and non-anatomical waste, liquids and autoclaved waste.

13.4 Equipment Decontamination

Laboratory equipment that has been in contact with hazardous materials, including biohazardous material/toxins, must be decontaminated prior to repair or removal from the lab. A Certificate of Equipment Decommissioning (SEM 20.09) form must be completed by the responsible individual (PI or delegate), signed and attached to the equipment/part before servicing, transfer or disposal. A copy of the Certificate should also be kept by the PI for at least 5 years; alternatively, the document can be sent to OSEM for inclusion in the official repository.

14. Laboratory Decommissioning

Investigators working with biological materials should notify the BSO prior to ceasing operation in order to ensure that the laboratory is decontaminated and that all biological materials have been secured or properly disposed of. A walk-through of the lab can be performed by the BSO and the PI to provide recommendations on the termination of the biohazardous work in the lab. The BSO will advise the IBSC and a final lab decommissioning inspection can then be scheduled accordingly.

General lab close-out procedures are as follows:

- Empty storage freezers and incubators and dispose of the contents according to waste procedures;
- Ensure that all equipment used for manipulation of biological agents has been properly decontaminated and tagged as such;
- Clean and decontaminate all work surfaces (e.g. floors, bench tops, sinks, drawers) with a suitable disinfectant;
- Ensure that the BSC(s) are decontaminated by an NSF-certified professional prior to being relocated and recertified afterward and,
- Remove all biohazard warning labels and signage from surfaces.

15. References and Resources

1. *Allergies to Laboratory Animals*, CCAC training module on: occupational health and safety, Module 16. < http://www.ccac.ca/en_/training/niaut/stream/cs-ohs>.
2. Canadian Biosafety Standards and Guidelines 2nd edition, Public Health Agency of Canada and Canadian Food Inspection Agency. < http://canadianbiosafetystandards.collaboration.gc.ca/cbs-ncb/index-eng.php>.
3. Containment Standards for Facilities Handling Aquatic Animal Pathogens, Canadian Food Inspection Agency,1st edition,<http://www.inspection.gc.ca/animals/aquatic-animals/imports/pathogens/facilities/eng/1377962925061/1377963021283.
4. Containment Standards for Facilities Handling Plant Pests 1st edition, Canadian Food Inspection Agency, http://www.inspection.gc.ca/plants/plant-protection/biocontainment/containment-standards/eng/1412353866032/1412354048442
5. Corradi M, Ferdenzi E, and A. Mutti. The characteristics, treatment, and prevention of laboratory animal allergy, Lab Animal 42(1): 26-33, 2013. http://labanimal.com/laban/journal/v42/n1/index.html.
6. Gmuender F. (2010) Tips for the Biosafety Practitioner: Placement of biosafety cabinets. APBA *Newsletter* **3(2**) 1-10. http://www.a-pba.org/System/Storage/file/APBA_NewsletterVol3- No2.pdf.
7. *Human Pathogens and Toxins Act* (S.C. 2009). http://laws.justice.gc.ca/eng/acts/H-5.67/.
8. Human Pathogens Import Regulations, Public Health Agency of Canada <http://www.phac-aspc.gc.ca/lab-bio/regul/reg-imp/index-eng.php>.
9. PHAC (Centre for Biosecurity) and CFIA (Office of Biohazard Containment and Safety) e-learning portal: https://training-formation.phac-aspc.gc.ca/course/index.php?categoryid=2&lang=en
10. Questions and Answers – Containment Standards for Facilities Handling Aquatic Animal Pathogens, CFIA,http://www.inspection.gc.ca/animals/aquatic-animals/imports/pathogens/questions-and-answers/eng/1377953768057/1377953941773>
11. Questions and Answers – Containment Standards for Facilities Handling Plant Pests, CFIA <http://www.inspection.gc.ca/plants/plant-protection/biocontainment/questions-and-answers/eng/1392497209673/1392497407493>.
12. Standards, Policies & Guidelines, National Institutes of Health (2010). *Placement of a Biological Safety Cabinet in the Laboratory,* <http://orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/Pages/News_to_Use_June_2010.aspx>
13. Division of Technical Resources, National Institutes of Health (2010). *Biosafety Cabinet (BSC) Placement Requirements for new Buildings and Renovations,* <http://orf.od.nih.gov/PoliciesAndGuidelines/Bioenvironmental/Documents/BiosafetyCabinetBSCPlacementRequirements_508.pdf>.
14. CCAC Guide to the Care and Use of Experimental Animals Volume 1, Appendix VII, *Zoonoses—Experimental Animals to Man,* <http://www.ccac.ca/Documents/Standards/Guidelines/Experimental_Animals_Vol1.pdf>.
15. Canadian Food Inspection Agency: *Invasive Plants – Fact Sheets*. <http://www.inspection.gc.ca/plants/plant-protection/invasive-plants/fact-sheets/eng/1331614724083/1331614823132>

16. Useful Contact Information

Canadian Food Inspection Agency (CIFA) Regional Office
2001 University Street, Room 671
Montreal, Quebec, H3A 3N2
514-283-8888

PHAC Pathogen Regulation Directorate
613-957-1779
Biosafety.biosecurite@phac-aspc.gc.ca
http://www.phac-aspc.gc.ca/lab-bio/index-eng.php

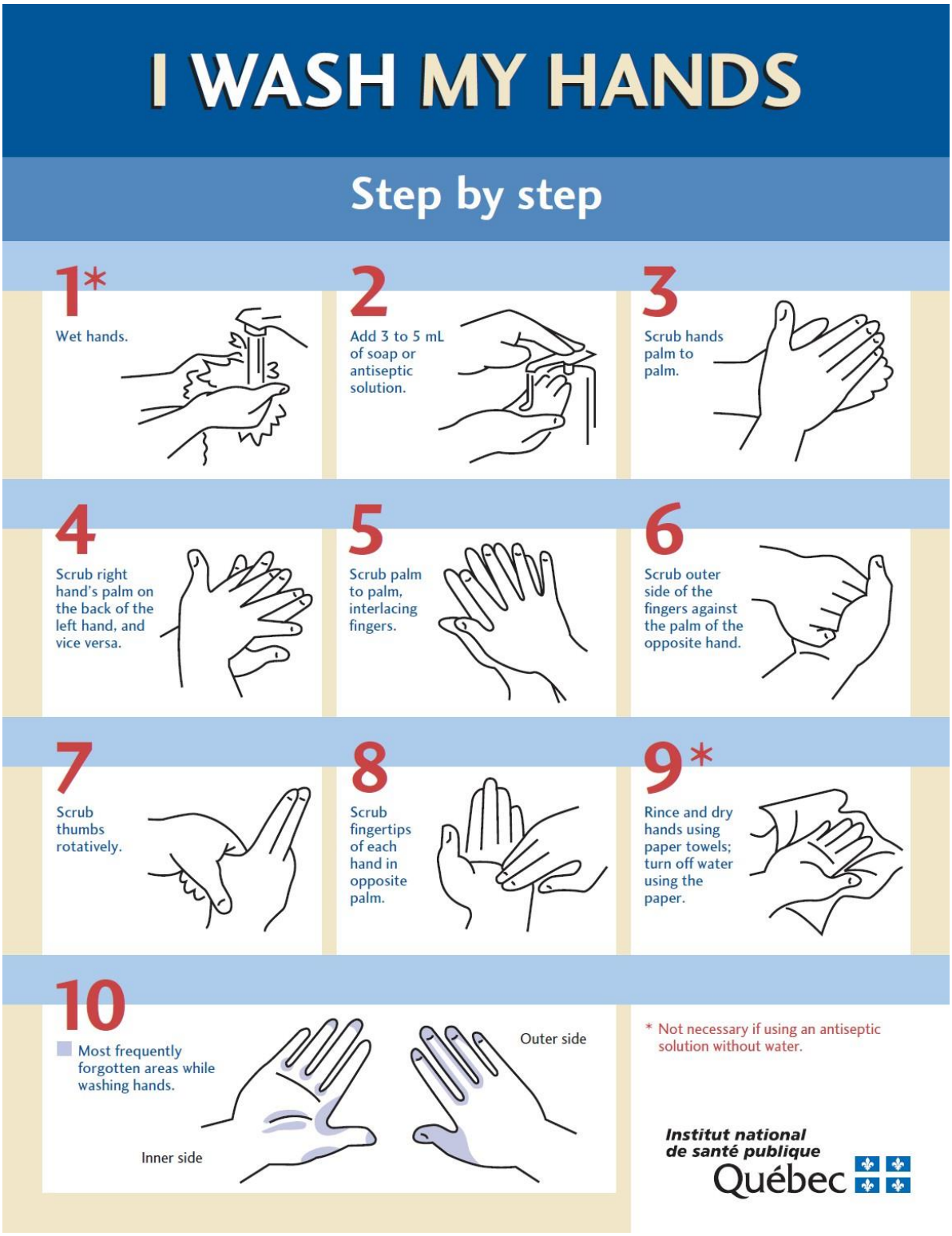
Transportation of Dangerous Goods, Transport Canada
514-283-5722
TMD-TDG.Quebec@tc.gc.ca

Appendix I: Good Microbiological Laboratory Practices (GMLP) – SEM 20.06.

- Post a Department Emergency Information sign at the laboratory entrance. Include the name and contact information of the laboratory supervisor or other responsible person.
- Restrict laboratory access; keep doors locked when the laboratory is unattended.
- Ensure that everyone entering the laboratory understands the hazards associated with the lab.
- Keep the lab clean and free of clutter.
- Ensure that emergency safety equipment (e.g., fire extinguishers, eyewashes, showers) are accessible and in working order.
- Wear appropriate lab attire:
    - Fastened knee-length lab coats, never worn outside the laboratory;
    - Gloves: when deemed necessary; remove and dispose of them before leaving the laboratory; wash hands before and after use;
    - Eye and face protection if necessary;
    - Footwear with closed toes and heels;
    - Covered legs: shorts, Capri pants, short skirts, etc., do not provide adequate skin coverage and are not permitted.
- Never perform experiments using your own cells.
- Never eat, drink, store food or drinks and related utensils, apply cosmetics or lip balm, handle contact lenses or take medication in the laboratory.
- Perform all procedures to minimize splashes, spills and generation of aerosols.
- Never pipet any substance by mouth.
- Avoid touching mouth or eyes.
- Tie back long hair.
- Restrict the use of needles and other sharps to those procedures for which there are no alternatives. Do not bend, break, shear or recap used needles or remove them from disposal syringes. Dispose of all sharps in labeled, leak- and puncture-proof sharps containers.
- Substitute plastic ware for glassware whenever possible. Avoid direct handling of broken glassware; pick up using a brush and dustpan, tongs, or forceps.
- Avoid bringing items (e.g. books, cell phone) that cannot easily be decontaminated into the lab.
- Store personal items such as purses, backpacks and street clothing separately from PPE and away from areas where biological material is handled.
- Cover any open wound, cut, scratch or graze with a waterproof dressing and gloves.
- Use disinfectant traps and in-line filters to protect vacuum lines from contamination.
- Wash hands after removing gloves and other personal protective equipment, after handling viable materials and animals, and before leaving the laboratory.
- Follow appropriate cleanup and disposal procedures:
    - Decontaminate work surfaces with an appropriate disinfectant at the end of every experiment and following any spill;
    - Ensure that all cultures and stocks are decontaminated before disposal;
    - Decontaminate glassware, instruments and lab coats before reuse, recycling or disposal;
    - Dispose of broken glassware in a puncture-proof container;
    - Ensure that contaminated clothing is decontaminated before laundering.
- Report all spills and accidents/incidents to your supervisor and OSEM, using the University online Incident Report Form.

Return to Section 7.1.1.1, Risk Group 1
Return to Section 7.2.1.1, Containment Level 1

Appendix II: GMLP – Effective Hand Washing Poster



Appendix III: GMLP – Laboratory-Acquired Infection Prevention Poster

Appendix IV: Characteristics of Different Classes and Types of BSCs, and Comparison with Chemical Fume Hoods

Class & Type	Inflow Velocity m/s (ft./min)	Characteristics	Suitable for Work with Volatile Toxic Chemicals/Radionuclides?	Can be used for work with:	Product Protection?	Personnel Protection?	Environmental Protection?
Class I	0.38 (75)	Room air enters through front opening and flows across work surface No recirculation of air within BSC HEPA-filtered exhaust to lab or outdoors via hard duct	Yes, minute quantities of volatile toxic chemicals ***if exhausted outdoors via hard duct***	RG 1, 2, 3	No	Yes	Yes
Class II Type A1	0.38 (75)	70% of air is HEPA-filtered and recirculated in BSC 30% of air is HEPA-filtered and exhausted to lab or outdoors through air-gap type (thimble) connection	No	RG 1, 2, 3 RG 4 if positive pressure suit worn	Yes	Yes	Yes
Class II Type A2	0.51 (100)	70% of air is HEPA filtered and recirculated into BSC 30% of air is HEPA-filtered and exhausted to lab or outdoors via thimble connection	Yes, minute amounts of volatile chemicals, trace amounts of radionuclides ***if exhausted outdoors via thimble connection***	RG 1, 2, 3 RG 4 if positive pressure suit worn	Yes	Yes	Yes
Class II Type B1	0.51 (100)	Hard-ducted ≤50% of air is HEPA-filtered and recirculated in BSC ≥50% of air is HEPA-filtered and exhausted outdoors through dedicated plenum	Low levels of volatile chemicals, trace amounts radionuclides	RG 1, 2, 3 RG 4 if positive pressure suit worn	Yes	Yes	Yes
Class II Type B2	0.51 (100)	Hard-ducted No recirculation within BSC 100% air exhausted outdoors through dedicated plenum Potential for airflow reversal (“puff-back”) through BSC face if exhaust fan fails	Yes	RG 1, 2, 3 RG 4 if positive pressure suit worn	Yes	Yes	Yes
Class III	N/A	Totally enclosed, air-tight Under negative pressure Work performed through attached long-sleeved gloves HEPA-filtered supply Dedicated exhaust through 2 HEPA filters ***or*** through 1 HEPA filter	Yes	RG 4	Yes	Yes	Yes
Chemical Fume Hood	0.43-0.51 (85-100)	Room air enters through front opening and flows across work surface No HEPA filters Hard-ducted No recirculation, 100 % air exhausted outdoors	Yes	RG 1, RG 2 if non-infectious by aerosol	No	Yes	No

Return to Section 9.3.2;

Appendix V: Safe Use of Biological Safety Cabinets (BSC) – SEM 20.10

Preparing to use the BSC

1. Ensure that opening and closing of lab doors and pedestrian traffic into the work area will be kept to a minimum;
2. Turn off the UV lamp (if used) and turn on the fluorescent lighting;
3. Confirm that the drain valve for the catch basin below the work surface is closed;
4. Adjust the chair height so that the bottom of the sash is level with your armpits;
5. Check pressure gauges to ensure the cabinet is functioning properly; confirm that air is flowing inward by holding a tissue at the middle of the lower edge of the sash;
6. Ensure that the airflow alarm (if present) is on;
7. Don appropriate PPE: gloves, lab coat with long sleeves, and closed toed shoes at minimum;
8. Wipe down the interior with a disinfectant effective for the material in use. If a corrosive such as bleach is used, rinse with 70% ethanol or sterile water after disinfecting;
9. Place all materials needed for the experiment, including appropriate disinfectant and waste receptacle, inside the cabinet without obstructing the grilles. Do not bring non-essential equipment and supplies into the cabinet;
10. Plan work ahead of time to avoid sweeping arm movements;
11. Line the work area with a plastic-backed absorbent pad if there is potential for splatter or splashes of infectious agents or toxins;
12. Place aerosol-generating equipment, such as sonicators or vortexes, toward the rear of the cabinet, without blocking the rear grille;
13. When aspirating liquids, install a secondary flask to collect any overflow, as well as an in-line HEPA or 0.2 µm filter between the secondary flask and the vacuum source;
14. Allow the blower to run for at least five minutes before starting work.

Return to Section 9.3.4

Working safely in the BSC

1. Wear the appropriate PPE (gloves and lab coat minimum at TRU);
2. Work toward the rear of the cabinet, without resting elbows and arms on the front grille;
3. To prevent disruption of the air current at the front of the cabinet, avoid excessive movement of arms and hands through the front opening;
4. Do not place waste containers outside the cabinet; position them inside the BSC, near the rear;
5. Separate the work surface into contaminated and non-contaminated areas; ensure that work flows from clean to dirty areas and limit movement of dirty materials over clean;
6. Unless the cabinet has been certified for simultaneous use by 2 users, ensure that only one person at a time works in the BSC;
7. Do not use open flame inside the cabinet;
8. Do not operate vacuum pumps and centrifuges in the BSC. Their use can disrupt airflow and eject particulates at velocities that are too high to be captured by the cabinet.

Return to Section 9.3.4

Preparing to shut down the BSC

1. Close/cover open containers;
2. Leave the blower on for at least 5 minutes to allow the cabinet to purge before removing material

from the BSC;
3. Surface-decontaminate and remove equipment and materials;
4. Wipe down interior surfaces with an appropriate disinfectant; rinse with water or ethanol if a corrosive such as bleach is used;
5. Turn off the blower and fluorescent lamp, and turn on the UV lamp (if used)

Return to Section 9.3.4

Ultraviolet (UV) Light

The use of UV germicidal lamps is not recommended for decontamination of BSC surfaces. UV light 1) does not penetrate particulates such as accumulations of dust, dirt, grease or clumps of microorganisms; 2) is harmful to skin and eyes; and 3) may not deliver the appropriate wavelength due to age or reduced performance, while continuing to emit blue light. Lab workers who use UV light in BSCs should keep in mind the following:

- UV light must never be utilized as the sole method for decontaminating the interior of a BSC: use a liquid chemical disinfectant as the main method of decontamination.
- The UV lamp must be wiped frequently (at least every 2 weeks) with an appropriate disinfectant to remove dust, dirt, oil and organic matter.
- UV irradiation does not penetrate cracks or through cabinet grilles.
- Some plastics and tubing may be damaged by UV irradiation.
- The radiation output of the lamp must be measured routinely (at least twice yearly) with a UV meter to ensure that the proper intensity (40 µW/cm2) and wavelength (254 nm) are being delivered to the work area.
- Warning signs should be posted to discourage personnel from entering areas where there is risk of UV light exposure.

Return to Section 9.3.4

Open flame

Open flames contribute to the heat load, create turbulence that disrupts airflow patterns, may ignite disinfectants, and may damage the HEPA filter. Gas escaping from loose connections or damaged tubing may present additional hazards. Pre-sterilized supplies such as loops and needles, or a micro-incinerator (located toward the rear of the BSC to minimize disruption of the air curtain at the front of the BSC) should be used instead of a flame.

Return to Section 9.3.4

Maintenance and Certification

Biological safety cabinets must be tested and certified in accordance with NSF/ANSI 49. Cabinet performance must be verified:

- Upon initial installation in the laboratory
- Annually
- After any repairs or modifications
- Whenever relocated
- Whenever filters are changed
- Before disposal

Return to Section 9.3.4

Appendix VI Safe Use of Autoclaves – SEM 20.10

Preparing to Load the Autoclave:

- Ensure that the strainer, located over the drain at the front of the autoclave, is not clogged;
- Make sure that plastic bags, containers and trays can withstand the high heat and pressure;
- Do not fill bottles of liquid or autoclave bags more than 3/4 full);
- Immediately before loading, loosen the caps of liquid containers to prevent bottles from shattering during pressurization. Alternatively, use vented caps;
- Use suitable wrapping when sterilizing clean equipment for re-use. For example, steam will not penetrate objects that are tightly covered with aluminum foil;
- Close autoclave bags loosely to allow for steam penetration.

Return to Section 9.5.1
Return to Section 13.2

Loading the autoclave:

- To allow for steam penetration around all items, do not overload the chamber or stack containers. Items must not touch the top or sides of the autoclave;
- To prevent spills inside the autoclave, place bags and containers in autoclavable rigid, leak-proof secondary containers. Shallow tubs are preferable to buckets because the air can be displaced more efficiently;
- Avoid placing containers and bags directly on the floor of the autoclave;
- Make sure the door of the autoclave is fully closed and that the correct cycle has been selected;
- Never autoclave volatile/toxic chemicals or radioisotopes.

Return to Section 9.5.1
Return to Section 13.2

Unloading the autoclave:

- Verify the autoclave cycle log to ascertain that decontamination conditions were achieved;
- Ensure that the chamber pressure gauge reads zero psi;
- Wear eye protection and insulated gloves or mitts. Add a rubber apron and rubber sleeve protectors for large volumes of liquids;
- Open the door slightly to allow the steam to escape before unloading;
- Allow the autoclaved waste to cool and place inside a dark garbage bag in the designated area.

Return to Section 9.5.1
Return to Section 13.2

Appendix VII: Safe Use of Centrifuges – SEM 20.10

Spills, leaks, tube breakage or improper use of safety cups/rotors can result in generation of biohazardous aerosols during centrifugation. Recommendations for safe centrifugation of biohazardous material:

- Use the centrifuge according to the manufacturer's instructions and laboratory SOP:
- Ensure that the centrifuge is properly balanced;
- Use tubes intended for centrifugation, e.g. plastic thick-walled tubes with exterior thread screw caps;
- Check tubes for stress lines, hairline cracks and chipped rims before use;
- Never fill tubes to the rim;
- Use sealed centrifuge cups/rotors:
- Inspect cup/rotor seal integrity regularly and replace if cracked or dry;
- Load and unload infectious materials or toxins inside a BSC;
- Allow time for aerosols to settle before opening cups/rotors;
- Decontaminate the outside of the cups/rotors before and after centrifugation;
- Do not open the centrifuge lid during or immediately after operation, attempt to stop a spinning rotor by hand or with an object, or interfere with the interlock safety device;
- Clean spills promptly;
- Prohibit the use of centrifuges in a BSC.

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Appendix VIII: Safe Use of Mixing Apparatus

The operation of blenders, sonicators, homogenizers, shaking incubators, tissue grinders and mixers can generate significant amounts of infectious aerosols. Recommendations for using mixing apparatus include:

- Select equipment designed to prevent the release of aerosols – for example, cup horn sonicators allow processing of sealed vials or tubes;
- Use the equipment inside a primary containment enclosure. A biological safety cabinet can be used if airflow patterns will not be disrupted;
- Check the condition of gaskets, caps and containers before use;
- Allow at least one minute for aerosols to settle before opening or removing covers; open them in a biological safety cabinet if possible;
- Disinfect contaminated surfaces after use.

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Appendix IX: What to do if exposed to human blood, body fluids or tissue?

What to do if exposed to human blood, body fluids or tissue?

1. FIRST AID Procedure:

Skin injury/exposure (needle stick, cut, contact with non-intact skin):

- Immediately wash exposed area with soap and water without scrubbing;
- Rinse with water;
- Allow the injury to bleed freely, then cover lightly;
- Do not promote bleeding by cutting, scratching, squeezing or puncturing the skin; this may damage the tissue and increase the risk of exposure to pathogen(s);
- Do not use bleach or alcohol to disinfect the exposed area/wound.

➢ **Mucous membrane exposure (splash to eyes, mouth, nose):**

- Immediately rinse thoroughly with water.

2. **Report for medical evaluation at the Emergency Department of the closest hospital within 2 hours**. Bring a sample of the source material for testing.

3. Report the exposure to your supervisor and the Biosafety Officer as soon as possible.

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Appendix X: BBP Exposure Memo (SEM 20.26)

THOMPSON RIVERS UNIVERSITY
Safety & Emergency Management

Office of Safety and Emergency Management (OSEM)

Exposure to human blood, body fluids, tissues, or contaminated equipment.

To: Name
From: Name of Occupational Health Program Coordinator (OSEM)
Date: (Today's date)
Subject: Information following exposure to human blood, body fluids, tissues, or contaminated equipment
Cc: Supervisor's Name, Department

You have experienced an occupational exposure to possible blood-borne pathogens such as hepatitis B or C or HIV. Although such exposures rarely result in the transmission of infection, every effort will be made to prevent such infection. In the unlikely event of the infection, every effort will be made to diagnose and treat the conditions to eliminate or minimize any adverse medical consequences. Brief descriptions of the main viral agents transmissible by such occupational exposures can be found below.

You will be asked to provide a baseline (immediate) and follow-up blood samples to permit serologic testing. These tests will help to determine whether or not you have become infected. Depending upon your vaccination status and other potential seriousness of the exposure, you may receive Post-Exposure Prophylaxis (PEP) with vaccinations, injections of immune globulin and/or pills to take by mouth.

As a general rule, there are few, if any, side effects associated with injection of vaccines or immune globulin. In contrast, almost all people who take pills to prevent transmission of HIV following such exposures develop mild-to-moderate side effects. Should you experience any side-effects, feel free to consult with Health Services. Rest assured, that this service remains completely confidential despite the occupational nature of the injury.

Should a virus become established in your body, there is a chance that it could be transmitted to intimate contacts (e.g. spouse, sexual partner, a developing fetus, or children). Such transmission can occur via blood, semen, breast milk, organ or tissue donations, and the sharing of needles or even toothbrushes and razors. As a result, for exposures considered to be medium or higher risk, employees are encouraged to avoid any activity that could potentially spread the infection to another person for a period of 3 months following PEP (i.e. until serologic testing can be completed and an infection ruled out). For example, women should not breast feed or attempt to become pregnant and both men and women should practice safer sex (e.g. using condoms). This advice should be reviewed during a medical consultation so that it can be specifically tailored to your situations.

Should you have any further questions or concerns, you may contact Health Services (250) 828-5126.

Employees can also call the Employee Assistance Program (Ceridian) at (877) 207-8833.

Students can also contact Counselling Services via Student Services between 8pm and 4pm, Monday through Friday at

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Appendix XI: Blood borne Pathogen Post Exposure Information (SEM 20.27)

THOMPSON RIVERS UNIVERSITY
Safety & Emergency Management

Post-Exposure Information Sheet

Following an exposure to human blood, blood products, tissues, or contaminated equipment

The purpose of this document is to provide information to assist you in making decisions with your doctor on the best management of your exposure incident. Please review the information below and direct your questions to your physician so you are comfortable with your treatment.

HEPATITUS B VIRUS (HBV): HBV is transmitted via blood exposure. Many individuals have received the three vaccine series for protection against it. Vaccine Responders are well protected by this vaccine; non-responders and those not vaccinated remain susceptible. Following an exposure, your immunity will be checked with a blood test. You will be notified within time to receive the vaccine if it is necessary.

HEPATITIS C VIRUS (HCV): HCV may be transmitted by needle stick or other blood exposure. There is currently no vaccine available to immunize against this disease. According to the CDC, the risk of acquiring infection following an exposure to HCV-containing blood after a needle stick or cut exposure is 1.8%. However, infection through this route has been observed to be as high as 10% in some situations. This range may be reflective of the depth of injury and the variety of possible known and unknown routes of infection available to this virus via blood exposure. Your physician will attempt to determine if the source of your exposure is infected with Hepatitis-C. If the source is found to be infected with HCV, you will be advised to have special testing done between 3 to 10 weeks post exposure, at the discretion of your physician, to determine if you became infected. If the virus is detected in your blood, you will be referred to a physician who specializes in treating Hepatitis C virus infection, often a Hepatologist or Infectious Disease Physician.

HUMAN IMMUNODEFICIENCY VIRUS (HIV): The risk of acquiring HIV infection following an exposure to HIV-infected blood of body fluids is low; about 0.3% for a needle stick and about 0.1% for a splash of blood onto intact skin. Various factors may increase or decrease the chance of acquiring HIV after an exposure. Among these factors are whether the source fluid actually contained HIV, the amount of HIV in the fluid, the amount of fluid involved, and the manner in which the exposure occurred.

Even without treatment after exposure, (Post Exposure Prophylaxis, or PEP), the risk of acquiring HIV is small. Whether taking HIV-PEP will prevent you from acquiring HIV or not is unknown. However, studies seem to indicate that taking PEP reduces the risk of infection substantially. The Center for Disease Control (CDC) suggests that HIV-PEP has little to no effect in preventing infection if started more than 72 hours after exposure. Therefore, it is imperative that PEP initiation be initiated soon as possible following a suspected exposure event.

HIV-PEP medications are taken for 4 weeks and often have significant side effects. You should communicate any adverse side effects to your treating physician promptly; also notify him/her immediately if you stop taking your medications.

A few special precautions are recommended (until your 6-month HIV, Hepatitis B, Hepatitis C blood results are negative, or unless otherwise advised by your treating physician):

- You should not donate blood, organs, or semen;
- You should not breastfeed your child;
- You should use barrier protection when engaging in sexual intercourse, i.e., use of latex condoms.

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