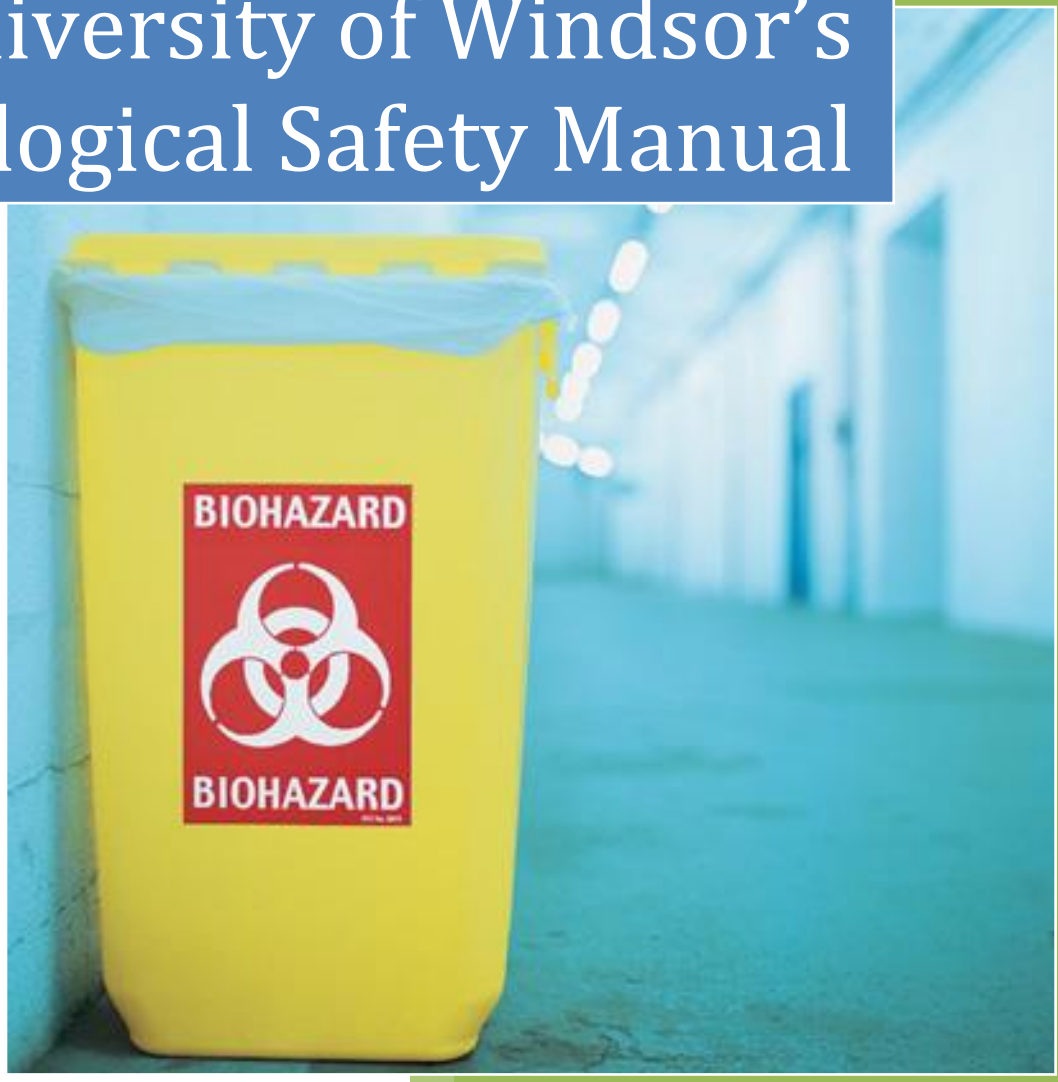
2023

University of Windsor's Biological Safety Manual



University of Windsor Biological Safety

Chemical Control Centre

Revised 2023

BIOLOGICAL SAFETY MANUAL

UNIVERSITY OF WINDSOR

Third Edition

2023

Approved: VP, Research & Innovation

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MANAGEMENT OF BIOLOGICAL SAFETY AT THE UNIVERSITY OF WINDSOR

1.1 University of Windsor's Biological Health & Safety Policy

"The University of Windsor is committed to providing a safe and healthy workplace and learning environment for its employees, students and visitors. The University is committed to preventing occupational illness and injury in the workplace, continually improving health and safety practices and performance. The University believes that all tasks can be accomplished in a safe manner and in compliance with relevant health and safety legislation, codes, standards and practices" (University of Windsor Health and Policy Statement).

The University is dedicated to managing the Biological Safety Program which is designed to control biosafety and biosecurity risks to protect the health and safety of workers, students and the public. The Biosafety Program includes Biosafety policies, workplace specific procedures, biological acquisition & inventory control measures and oversight of the program. The Biological safety program is managed by the Research Safety Committee and its chair and administered through Environmental Health & Safety.

The Biosafety Manual describes the requirements and procedures established by the University for personnel who work with potential biological pathogens, toxins, or infected animals. Throughout the manual biological material that contains human and/or animal pathogens will be referred to as "infectious material'. The manual is based upon the Government of Canada Canadian Biosafety Standards; the CFIA's Containment Standards for Facilities Handling Aquatic Animal Pathogens and reflects current best practices.

All work conducted by University members with infectious materials on University premises or under the control of the University is to be performed in accordance with the requirements of this manual.

Questions regarding application or interpretation of the Biological Safety Program or this manual should be directed to the Chemical Control Centre, at (519) 253-3000 ext. 3523 or by email at ccc@uwindsor.ca.

1.2 Regulation of Biological Agents at the University of Windsor

The Board of Governors of the University of Windsor has delegated to the President or his designate (Vice-President, Research & Innovation) the responsibility for the approval of University regulations and other actions to ensure regulatory compliance, safe working conditions, and a professional laboratory environment which is conducive to research & teaching activities, as it relates to the management of infectious materials on campus.

The Vice-President, Research (VPRI), has delegated the management of the program to the University of Windsor's Research Safety Committee (RSC), and its chair. The RSC is comprised of three sub committees, the Biological Safety Committee, the Radiation Safety Committee, and the Laboratory Safety Committee. The RSC is responsibility for the development and promulgation of safety standards for the conduct of research and teaching activities involving potentially hazardous materials by members of the University.

Campus Safety under the direction of the Director, Campus Safety & Emergency Planning, is responsible for ensuring the administration of the Biosafety program and to ensure that the associated activities are being performed in accordance with license activities, providing technical advice on safety procedures and equipment, laboratory compliance reviews, biological safety training, and providing guidance and information related to compliance with pertinent regulations.

For additional information, please visit the Biosafety website at: www.uwindsor.ca/biosafety or telephone, Chemical Control Centre, at (519) 253-3000 ext. 3523 or by email at ccc@uwindsor.ca.

1.3 Responsibilities

1.3.1 Research Safety Committee

The University of Windsor Research Safety Committee has the responsibility of, and authority for, establishing and enforcing the University's Research Safety Programs. The Committee formulates and reviews such programs as are necessary to ensure that the University is in compliance with guidelines and regulations outlined by the Canadian Nuclear Safety Commission (CNSC), Public Health Agency of Canada, Canadian Food Inspection Agency (CFIA), The Ministry of Environment, and all applicable Federal, Provincial and municipal legislation. The Committee reviews, approves and enforces the standards through the issuance of Certificates for all work with potentially hazardous biological, radioactive, and chemical materials.

1.3.2 Vice-President, Research & Innovation

The Vice-President, Research (VPRI) plays a key role in ensuring that the University of Windsor's Biological Safety Program is being implemented according to this manual; specifically, they are responsible to:

- Appoint a University employee as the Senior Biological Safety Officer who is knowledgeable by virtue of education, training, or experience in the handling of biological agents to be responsible on behalf of the institution for all aspects related to biological safety within the institution's laboratories or workplace.
- Ensure the University Biosafety Officer in informed of any research which utilizes biohazardous materials;
- Approve terms and conditions for research involving biohazardous materials conducted by other organizations involving the use of University facilities under a service agreement with the University; such research shall also be approved by the Research Safety Committee;

- Approve projects involving dual use research;
- Administer Material Transfer Agreements involving biohazardous materials. Copies of such agreements shall be forwarded to the Biosafety Officer;
- Establish and administer the appeal procedure;
- Receive and act upon recommendations of the Biological Safety Officer and/or Research Safety Committee and its Chair;
- Ensure that research funds are not released until the appropriate biosafety certificate has been submitted and approved by the Research Safety Committee or Chair of the Research Committee and Biosafety Vice Chair as appropriate;
- Suspend funding for research projects that contravene the Canadian Biosafety Standards & Guidelines, applicable federal, provincial or municipal laws or regulations, or are not in compliance with the biological safety certificate or this policy;
- Rescind the suspension of funding once the contravention is rectified to the satisfaction of the Research Safety Committee; and
- Advise the relevant granting Agency of any changes in eligible status of Grant Holders and Award Holders and/or of serious problems in the use of research funds as required by the Memorandum of Understanding between the University and the Tri-Council (NSERC, SSHRC and CIHR). The Biosafety Officer shall also be advised of such changes of status.

1.3.3 Academic Administrative Unit (AAU) Head

For departments that utilize potentially hazardous biological materials, the department head must be familiar with and follow all directions contained within this manual, or within any training program. In particular, AAU Heads are responsible to:

- Ensure that any activities involving the use of biohazardous materials in his/her department has received approval prior to the acquisition of the biohazardous materials and the commencement of the activities;
- Ensure that Principal Investigators in his/her department are fully aware of the University policies and guidelines regarding biohazardous materials;
- Co-sign all biosafety certificates application forms confirming the validity of the information;
- Advise the Biosafety Officer when a Principal Investigator is no longer employed by the University;
- Ensure that current inspection certificates for steam sterilizers in the department are posted, that sterilization cycles are verified using biological indicators on a regular basis, and that records of users, cycles, and verification are maintained; and
- Ensure the activities involving biohazardous materials in the department are in compliance with the certificates; and
- Report issues regarding non-compliance to the Chair of the University of Windsor's Research Safety Committee and the University Biological Safety Officer.

1.3.4 Director, Campus Safety & Emergency Planning (Senior Biological Safety Officer)

The Director, Campus Safety & Emergency Planning is the designated Senior Biological Safety Officer (BSO) for the University and is responsible and accountable for the administration of the Biosafety program to ensure that the associated activities are being performed in accordance with licence activities and the program. The Director, CSEP is responsible to,

- Serve on the Research Safety Committee;
- Co-sign approved biological safety certificates;
- Maintain and provide information, advice and general training on all elements of the biosafety program;
- Liaise with the Public Health Agency of Canada, the Canadian Food Inspection Agency, Animal Care Services, Occupational Health Services, Student Health Services, Security Services, Physical Resources personnel and applicable regulators on biohazard issues;
- Report to the Vice President of Research and Innovation on all matters pertaining to biosafety;
- Audit work areas for compliance with certificate requirements, legislation, codes, and guidelines and submit compliance reports to the Chair;
- Notify regulators as outline in the regulations;
- Assist in the development and maintenance of the Biosafety Manual and Standard Operating Procedures related to biosafety and biosecurity;
- Approve purchase orders and co-sign material transfer agreements for the acquisition and/or transfer of biohazardous materials;
- Investigate incidents involving biohazardous materials including exposures and lab-acquired infections and report the findings to the Chair; and applicable governing body;
- Order corrective actions for cases of non-compliance;
- Order, the suspension of any activity involving biohazardous materials when there is reason to suspect that the health and safety of University personnel, the public, and/or the environment is at risk or that regulatory conditions of the project have been breached;
- Liaise with local health and safety committees as applicable; and
- Serve on the Animal Care Committee and the Research Ethics Board (at their request).

1.3.5 Chemical Control Centre Coordinator (Biological Safety Officer)

The Chemical Control Centre (CCC) coordinator under the direction of the Director, CSEP performs the day-to-day activities of the Biosafety Officer. The CCC Coordinator provides advice and assistance in matters related to biological safety, performs laboratory inspections and assists in the administration of the biosafety program. The CCC Coordinator is responsible to;

- Serve on the Research Safety Committee as an alternate to the Senior Biosafety Officer;
- Maintain and provide information, advice and general training on all elements of the biosafety program;
- Report to the Director, CSEP on all matters pertaining to biosafety;
- Audit and verify work areas for compliance with certificate requirements, legislation, codes, and guidelines and submit compliance reports to the Chair and Director, CSEP.

- Assist in the development and maintenance of the Biosafety Manual and Standard Operating Procedures related to biosafety and biosecurity;
- Approve purchase orders for the acquisition of biological materials;
- Investigate incidents involving biohazardous materials including exposures and lab-acquired infections and report the findings to the Chair;
- Coordinate and maintain records of the annual certification of biocontainment cabinets;
- Recommend and assist in the implementation of corrective actions for cases of non-compliance; and
- In an emergency stop any unsafe activity involving biohazardous materials when there is reason to suspect that the health and safety of University personnel, the public, and/or the environment is at risk.

1.3.6 Principle Investigators

The primary responsibility for the safety of staff, students and the public lies with the Principal Investigator in charge of the research or teaching activities. Principal Investigators must be familiar with, follow, and ensure that all individuals working within their laboratories follow the procedures outlined in this manual. In particular, Principal Investigators are responsible to;

- Obtain biological safety certificates when required;
- Ensure that all conditions of the certificate and this manual are followed;
- Perform preliminary risk assessment of each pathogen they will be working with and identify if there is a dual use potential associated with their work;
- Ensure the appropriate containment cabinets are functioning properly by having them tested at the stipulated intervals;
- Ensure all workers have the appropriate vaccinations to work with pathogens within their laboratories.
- Ensure that all persons working under their control have had general biosafety training and appropriate specific training working with potentially hazardous biological materials, agents and toxins (Specific training is typically hands on and project/pathogen specific);
- Perform preliminary risk assessment of each pathogen for any dual use potential associated with their work;
- Provide appropriate personal protective equipment and standard operating procedures; and
- Report all incidents and accidents to the Biological Safety Officer and Campus Safety within 24 hours.

1.3.7 Individuals working with Biological Materials

Individuals who work with potentially hazardous biological materials must be familiar with and follow all directions given to them by their supervisor, contained within this manual, or within any training program. In particular, individuals working with potentially hazardous biological materials are responsible to:

- Follow all safety procedures;
- Take all required training prior to working with biological material;
- Report all concerns, incidents and accidents to Supervisor;
- Wear protective equipment; and
- Participate in medical surveillance programs when appropriate.

1.4 Licensing and Biological Safety Certificates

1.4.1 Requirement for University of Windsor Biological Safety Certificates

A University of Windsor Biological Safety Certificate is required for all (research and teaching) activities which involve the handling of potentially hazardous biological human and animal pathogens and toxins. A pathogen is a microorganism, nucleic acid or protein capable of causing disease in humans or terrestrial animals. This may include viruses, bacteria, fungi, parasites, recombinant DNA, prions and other micro-organisms / genetic systems, and human and animal tissues, cells, blood and body fluids), and which are:

(i) supervised or conducted by workers or members of the University, or
(ii) conducted on University premises, or in a building or location administered by or under the control of the University, or
(iii) supported by funds provided by or through the University, including start-up and operating funds.

All such activities are to be conducted and performed in accordance with the University of Windsor's Biological Safety Manual and any relevant guidelines or legislation.

All activities involving potentially hazardous biological agents and meeting any of the above criteria, and all sources of financial support for such activities whether or not directly supported by grants or contracts administered by the University, must be identified on the application for a University of Windsor Biological Safety Certificate. The release of grants and supporting funds by the University is dependent on a University Biological Safety Certificate.

For animal based activities, a copy of the approved Animal Care Utilization Protocol (AUPP) Certificate must be provided and attached to the application. Approval of the Biological Safety Certificate may be conditional on approved Animal Care Utilization Protocol Approval

For human based activities, a copy of the applicable Research Ethics Board Certificate must be provided and attached to the application. Approval of the Biological Safety Certificate may be conditional on approved Research Ethics Board Approval.

The submission of an application for a University of Windsor Biological Safety Certificate implies willingness to allow the University of Windsor's Biosafety Officer to visit the laboratory sites used by the

Biological Safety Certificate holder in order to determine compliance with the University of Windsor's Biological Safety Manual.

1.4.2 Types of Biological Safety Certificates

The University of Windsor issues Biological Safety Certificates based on the classification of pathogens capable of causing disease in humans or terrestrial animals. The factors used to determine which risk group an organism falls into is based upon a risk assessment which includes the particular characteristics of the pathogen, such as:

- pathogenicity
- route of infection
- mode of transmission
- survival in the environment
- infectious dose
- availability of effective preventive measures and treatment
- host range
- natural distribution
- impact of introduction and/or release into the environment or Canadian Public

These classifications presume ordinary circumstances in the research & teaching laboratories or growth in small volumes for diagnostic and experimental purposes. Four levels of risk have been defined as follows:

Risk Group 1 (RG1; low individual and community risk)

A microorganism, nucleic acid, or protein that is either a) not capable of causing human or animal disease; or b) capable of causing human or animal disease, but unlikely to do so. RG1 organisms capable of causing disease are considered pathogens that pose a low risk to the health of individuals or animals, and a low risk to public health and the animal population. RG1 pathogens can be opportunistic and may pose a threat to immunocompromised individuals. Neither of the RG1 subsets is regulated by the PHAC or the CFIA due to the low risk to public health and the animal population.[1]

Risk Group 2 (RG2; moderate individual risk, low community risk)

A pathogen or toxin that poses a moderate risk to the health of individuals or animals, and a low risk to public health and the animal population. These pathogens are able to cause serious disease in a human or animal but are unlikely to do so. Effective treatment and preventive measures are available and the risk of spread of diseases caused by these pathogens is low. Examples of RG2 human pathogens are included in Schedule 2 of the HPTA. [1]

[1] Canadian Biosafety Standard (CBS) – 3rd Edition, 2023

Risk Group 3 (RG3; high individual risk, low community risk)

A pathogen that poses a high risk to the health of individuals or animals, and a low risk to public health. These pathogens are likely to cause serious disease in a human or animal. Effective treatment and preventive measures are usually available and the risk of spread of disease caused by these pathogens is low for the public. The risk of spread to the animal population, however, can range from low to high depending on the pathogen. Examples of RG3 human pathogens are included in Schedule 3 of the HPTA. [1]

Risk Group 4 (RG4; high individual risk, high community risk)
A pathogen that poses a high risk to the health of individuals or animals and a high risk to public health. These pathogens are likely to cause serious disease in a human or animal which can often lead to death. Effective treatment and preventive measures are not usually available and the risk of spread of disease caused by these pathogens is high for the public. The risk of spread of disease to the animal population, however, ranges from low to high depending on the pathogen. Examples of RG4 human pathogens are included in Schedule 4 of the HPTA. [1]
Risk Group 4 pathogens are not permitted at the University of Windsor.

1.4.3 Application for a Biological Safety Certificate

Application forms for a University Biological Safety Certificate are provided with Explanatory Notes to assist the applicant and can be obtained by contacting the Chemical Control Centre, Team Leader, at (519)253-3000 ext. 3523. This application form is also available in electronic format via the Biological Safety homepage at: www.uwindsor.ca/biosafety. The form may then be printed, completed, signed by the applicant and submitted to the Team Leader at the Chemical Control Centre for review and approval.

The required information must be legibly printed or typed on the application form. In general, the Principal Investigator may use a single form to identify more than one project if these require similar containment conditions, instead of completing a separate application for a Biological Safety Certificate for each project. The project titles must be linked with the corresponding granting agency.

Identify and specify the hazardous biological agents to be used (e.g. human whole blood, Hepatitis B virus, chick embryo primary cell culture, CHO cells, E. coli O157). A risk assessment will be conducted to determine the risk group and containment level.

Following the review and approval process, a certificate will be issued based on containment level. Containment levels and risk group of the pathogen(s) are generally the same, however in some cases, not all biological material will fall into the same risk group and containment level. In these cases the photocopy of the validated Biological Safety Certificate will be returned to the applicant. The original will be retained on file at the Chemical Control Centre. Information will also be entered into eRSO (Research Information System) for review by the Office of Research Services. A valid Biological Safety Certificate must be on file before the University will release grant funds.

1.4.4 Biological Safety Certificate Renewal and Validation Periods

Containment Level 3; CL3 (1 year only):

A Biological Safety Certificate for activities requiring Containment Level 3 conditions is valid for one year from the date of approval by the University of Windsor's Research Safety Committee. The Principal Investigator / Course Instructor must submit a new application form, even if the activities involving biological agents have not been altered or modified since the previous submission.

Containment Level 2; CL2 (2 year only):

A Biological Safety Certificate for activities requiring Containment Level 2 conditions is valid for two years from the date of approval by the University of Windsor's Research Safety Committee. In the case of multi-year research or recurring teaching programs involving potentially hazardous biological agents, the Biological safety Certificate must be renewed annually. The renewal is valid for one year from the expiration date of the previous Certificate. The Principal Investigator / Course Instructor must submit a new application form, even if the activities involving biological agents have not been altered or modified since the previous submission.

Containment Level 1; CL1 (3 years):

A Biological Safety Certificate for activities requiring Containment Level 1 is valid for three years from the date of approval by the University of Windsor's Research Safety Committee or, in the case of a renewal, from the expiration date of the previous Certificate, after which it must be renewed. The Principal Investigator / Course Instructor must submit a new application form even if the activities involving biological agents have not been altered or modified since the previous submission.

1.4.5 Laboratory Decommissioning

At least 30 days prior to the expected date of vacating the laboratory or laboratory space, the Principal Investigator (PI) must notify, in writing, the Biosafety officer. The Principal Investigator must ensure that appropriate decontamination measures have been taken prior to the relocation or disposal of laboratory equipment used for the manipulation of biological agents.

After decontamination, the laboratory equipment may be recycled through the Facilities Services – Custodial Services. A "Safe-To-Work" tag should be completed and attached to the equipment, prior to it being removed from the laboratory. The tag may be obtained from the Chemical Control Centre at (519) 253-3000 ext. 3523.

Inspection and retesting is mandatory if a biological safety cabinet is relocated. Moves of a minor nature (i.e. within the same room) may be exempt from this requirement if the move is observed by the testing technologist and the cabinet has not been subjected to excessive stress or rough handling which could result in damage.

1.4.6 Enforcement of Biological Safety Policies

In the event that a biological safety certificate holder fails to observe the rules and regulations governing the safe use of biological agents, the BSO, shall advise such certificate holder of the violation(s) and shall report same to the Committee.

The Committee shall review reports of violations and when appropriate issue a written warning to the certificate holder and/or suspend or withdraw approval of the user(s) biological safety certificate.

If, in the judgment of the BSO, there is an emergency situation involving a biological hazard(s), they shall take immediate action to ensure the safety of personnel and the environment. A meeting of the Committee shall be called as soon as possible following such a situation to review the circumstances of the event.

Decisions of the Committee will be reported to the Vice-President, Research & Innovation (VPRI), through the Senior BSO, for action. Disagreement with any Committee decision may be appealed to the Vice President of Research and Innovation. Such appeals must be forwarded in writing to the VPRI within 14 days and a copy must be sent to the Committee and Senior Biosafety Officer.

1.4.7 Information and inquiries

Explanatory Notes offering more detail are provided with the University of Windsor's Biological Safety Certificate application form. Should you encounter difficulty or have any questions regarding the completion or submission of your application form, please contact the Chemical Control Centre website

1.5 Pathogen Safety Data Sheets

Pathogen Safety Data Sheets (PSDSs) (previously titled Material Safety Data Sheets for infectious substances) are technical documents that describe the hazardous properties of a human pathogen and recommendations for work involving these agents in a laboratory setting. These documents have been produced by the Public Health Agency of Canada (the Agency) http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php as educational and informational resources for laboratory personnel working with these infectious substances. Please note that work involving pathogens in Canada may require compliance with international, national, and provincial laws and guidelines. In addition, all SDS, including for infectious micro-organisms, can also be located on the University of Windsor's online SDS service

The PSDS's and SDS's are organized to contain health hazard information such as infectious dose, viability (including decontamination), medical information, laboratory hazard, recommended precautions, handling information and spill procedures. The intent of these documents is to provide a safety resource for laboratory personnel working with these infectious substances. Because these

workers are usually working in a scientific setting and are potentially exposed to much higher concentrations of these human pathogens than the general public, the terminology in these MSDS is technical and detailed, containing information that is relevant specifically to the laboratory setting. It is hoped along with good laboratory practices, these SDS will help provide a safer, healthier environment for everyone working with infectious substances.

Please note that although the information, opinions and recommendations contained in Material Safety Data Sheets are compiled from sources believed to be reliable, the University of Windsor along with the MSDS author accepts no responsibility for the accuracy, sufficiency, or reliability or for any loss or injury resulting from the use of the information. Newly discovered hazards are frequent and this information may not be completely up to date.

Access Material Safety Data Sheets (SDS) for all biological agents on campus at:
https://www.uwindsor.ca/chemical-control-centre/308/material-safety-data-sheet-msds

2 APPLICABLE LEGISLATION, GUIDELINES, AND STANDARDS

Activities involving the use of biological agents and laboratory animals, the production and disposal of waste, and the use of certain equipment, are governed by several Legislation, Policies, Guidelines and Standards. Adherence to the applicable legislation and the requirements of this Manual will ensure that work is performed safely and in compliance with the requirements of external agencies and regulatory bodies.

2.1 Internal Policy

The Health and Safety Policy Statement from the Office of the President reaffirms the University of Windsor's commitment to protect the health and safety of employees, students, and visitors. Commitment to the Health and Safety Policy Statement is also outlined in several Institutional Policies such as the Student Code of Conduct and Employee Handbook. These internal policies include expectations regarding behaviour, the completion of safety trainings, and the establishment, implementation and maintenance of safety programs designed to protect the health and safety of employees and meet applicable legislation.

The University of Windsor's Biosafety Program is specifically geared for researchers and students who acquire, handle, store, and dispose of RG2, 3, 4 biological agents and toxins. Certain RG1 biological agents and toxins may fall underneath the Biosafety Program after RSC review. This includes any biological agent that may affect human, animals, and the environment. Researchers and students who fall under the biosafety program must adhere to the biological safety manual and specific policies and procedures.

2.2 Government Legislation

The safe acquisition, use, handling, storage, distribution, and disposal of biological agents is governed by several Acts, Regulations and By-Laws, and enforced by various government agencies. The most relevant laws are summarized below:

Figure 1: **KEY GOVERNMENTAL ACTS, REGULATIONS, BYLAWS, STANDARDS AND GUIDELINES IN BIOSAFETY**

Legislative Act	***Regulation/Guidelines/Standards/Lists/ Bylaw***	***Enforcement Agency***
Occupational Health and Safety Act	-O.Reg.833: Control of Exposure to Biological and Chemical Agents -O.Reg.860: Workplace Hazardous Materials Information System	Ministry of Labour, Government of Ontario
Pathogen Control: Human		
Human Pathogens and Toxins Act	-Canadian Biosafety Standards, 3rd edition -Human Pathogens and Toxins Regulations	Public Health Agency of Canada, Government of Canada
Health Protection and Promotion Act	-O.Reg559/91 Specification of Reportable Diseases	Ontario Ministry of Health and Long Term Care, Government of Ontario
Pathogen Control: Plant/Animal		
Health of Animals Act Plant Protection Act	- Canadian Biosafety Standards, 3rd edition -Containment Standards for Facilities Handling Aquatic Animal Pathogens -Containment Standards for Facilities Handling Plant Pests-Health of Animals Regulations -Reportable Diseases Regulations -Plant Protection Regulations	Canadian Food Inspection Agency, Government of Canada
Animals for Research Act	-O.Reg. 22 General -O.Reg. 24 Research Facilities and Supply Facilities	Ontario Ministry of Agriculture, Food, and Rural Affairs, Government of Canada
Environmental Protection & Waste Control		
Canadian Environmental Protection Act	-Domestic Substance List (DSL) -New Substances Notification Regulations	Environment Canada, Government of Canada
Environmental Protection Act	-O.Reg.347: Waste Management -Guideline C-4: Biomedical Waste Management -Guideline C-17: Non-Incineration Technologies	Ministry of Environment, Government of Ontario
Sewer bylaw	B y-Law Number 11446	City of Windsor
Transportation		
Transportation of Dangerous Goods Act	Transportation of Dangerous Goods Regulation	Transport Canada

2.2.1 Occupational Health and Safety

The objective of the Occupational Health & Safety Act R.S.O. 1990 (OHSA) is to keep workers, unpaid students, learners and trainees, from getting hurt or sick on the job. The Act outlines the duties of employers and supervisors, as well as the rights and duties of workers in order to ensure safe work. The two main regulations pertaining to the biosafety program are:

1. O.Reg.833: Control of Exposure to Biological and Chemical Agents. Every employer shall take all measures reasonably necessary in the circumstances to protect workers from exposure to a hazardous biological or chemical agent because of the storage, handling, processing or use of such agent in the workplace.
2. O.Reg.860: Workplace Hazardous Materials Information System. The main objective of the provincial WHMIS legislation is to require employers to obtain health and safety information about hazardous materials in the workplace and to pass this information on to workers. The OHSA and associated regulations are enforced by the Ministry of Labour, Ontario.

2.2.2 Human Pathogen Licensing and Importation Requirements

The acquisition, use, handling, storage, and disposal of human pathogens and toxins classified as risk group 2 (RG2), risk group 3 (RG3), or risk group 4 (RG4) fall under the Human Pathogen and Toxins Act (HPTA) (2009) and are regulated by the Human Pathogens and Toxins Regulations (HPTR) (2015). The Act and associated regulations are enforced by The Public Health Agency of Canada.

Human pathogens classified by PHAC as Risk Group 1 (RG1) do not fall under the HPTA. Human pathogens that are also pathogenic to animals will be assigned whichever risk group is the highest.

Licensing

A valid Human Pathogen and Toxin License issued by the Public Health Agency of Canada (PHAC) is required for any company, person, or institution who falls under the HPTA. The University of Windsor possesses a license which individual Principal Investigators must use to acquire, use, store, and dispose of human pathogens. PHAC does not allow Principal Investigators to hold their own personal License. Principal Investigators must abide by the University Biosafety Program and have a valid biosafety certificate in order to be included under the Institutional License. The University Biosafety Program adheres to the Canadian Biosafety Standards, 3rd edition in order to meet the required regulations.

Importing

The validity of a license must be verified before importing or domestically acquiring human pathogens classified as risk group 2 (RG2), risk group 3 (RG3), or risk group 4 (RG4). The importation of human pathogens is regulated by the Human Pathogens and Toxins (HPTA), the Human Pathogens and Toxins Regulations (HPTR) and specific sections of the Health of Animals Regulations (HAR). Human pathogens, including pathogens which affect both humans and animals, under the control of AAFC, are listed in a database maintained by the Animal and Plant Health Directorate, AAFC. This is a dynamic listing which is

continuously amended to include emerging pathogens that may require restriction. Risk Group 1 (RG1) human pathogens are not regulated by PHAC and therefore a license is not required for their importation. Institutional permission and license verification is necessary in order to transfer and receive human pathogens across institutions within Canada from one scientist or laboratory.

The biosafety certificate application and biological agent transfer application can be found at the Chemical Control Centre website.

2.2.3 Animal and Plant Pathogens Licence and Importation Requirements

The Health of Animals Act (1990) and the Plant Protection Act (1990) gives the Canadian Food Inspection Agency (CFIA) the legislative authority to control the distribution and use of any pathogen which may cause infectious or contagious disease in animals and plants. This includes materials of animal or plant origin which contain potential pathogens. Any researcher/student who imports an animal or plant pathogen must adhere to:

1. Terrestrial & Amphibious Animals: Canadian Biosafety Standards, 3rd edition
2. Aquatic Animals: Containment Standards for Facilities Handling Aquatic Animal Pathogens, 1st edition
3. Plant Pests: Containment Standards for Facilities Handling Plant Pests, 1st edition

These regulations include the controls and safe practices for the acquisition, use, handling, storage, and disposal of animal pathogens.

The animal and plant pathogens which fall under the Acts are listed in the Animal Pathogen Database and the Plant Pest Database, both lists being maintained regularly by the CFIA. These lists are dynamic and continuously amended to account for emerging pathogens and outbreaks that may require restriction, especially animal pathogens not indigenous to Canada. For each animal pathogen, the CFIA must be consulted for its importation, use and distribution. Information on the status of veterinary pathogens may be obtained from:

Canadian Food Inspection Agency
59 Camelot Drive
Nepean, Ontario
K1A 0Y9
(613) 225-2342

Licensing and Importing

A CFIA import permit is required to import animal pathogens. The CFIA may request more information or choose to inspect the facilities in which the animal pathogen will be used. Once satisfied, the CFIA will issue the import permit and establish the conditions under which the animal pathogens will be maintained and the work will be carried out. Particular consideration will be given to the level of containment needed to prevent escape of an animal pathogen into the environment where it may constitute a risk to any indigenous animal species (e.g. the CFIA may restrict the release of

Recombinant organisms to only the lab). The CFIA application for an import permit must be provided to the University of Windsor's Chemical Control Centre to facilitate the acquisition process. The Chemical Control Centre will not provide signing authority without a valid biosafety certificate. The biosafety certificate application and biological agent transfer application can be found at the Chemical Control Centre website.

New microorganisms proposed for importation into or production within Canada are subjected to the Canadian Environmental Protection Act (CEPA) and the New Substances Notification Regulations. A new microorganism that is not found on the Domestic Substance List (DSL) requires notification under CEPA prior to importation. This includes both naturally occurring and genetically modified microorganisms.

2.2.4 Exportation of Pathogens from Canada

Canada presently imposes controls on certain toxicological and biological agents, as well as their related equipment, components, materials and technology under item 2007 of the Export Control List. Permits are required for the export from Canada of certain micro-organisms and associated equipment. For assistance or advice, contact:

Global Affairs Canada
Export Control Division
Lester B. Pearson Building
125 Sussex Drive
Ottawa, Ontario
K1A 0G2
(613) 996-2387

A copy of the application for a permit to export biological agents from Canada must be provided to the University of Windsor's Chemical Control Centre. The Chemical Control Centre will not provide signing authority without a valid biosafety certificate.

The biosafety certificate application and biological agent transfer application can be found at the Chemical Control Centre website.

2.2.5 Transportation of Biological Agents

The careful handling, transport and shipment of diagnostic specimens and infectious agents is absolutely essential if Canada is to maintain an effective health care system. Transportation methods must minimize risks to employees of the carrier, the public and the staff of the receiving laboratory. Hazards are compounded by improper packaging; a broken specimen container may lead to contamination of both laboratory and non-laboratory personnel, and an improperly labelled package may be opened inadvertently by secretarial, clerical or other untrained staff.

In Canada, effective July 1, 1985, Transport Canada has become responsible for regulations concerning the transportation of dangerous goods. Any person handling, offering for transport or transporting dangerous goods must comply with the Transportation of Dangerous Goods Act and Regulations, Registration SOR 85-77, as amended in 1994. Inquiries regarding these Regulations should be directed to:

Director General
Transport of Dangerous Goods Directorate, Transport Canada
Canada Building
344 Slater Street 14th Floor
Ottawa, Ontario
K1A 0N5
(613) 998-0517

The efficient and safe transfer of infectious substances requires good co-ordination between the sender, carrier, and receiver to ensure safe and prompt transport and arrival in proper condition. It is important that the sender make advance arrangements with the carrier and the receiver to ensure that specimens will be accepted and promptly processed. In addition, the sender must prepare the appropriate dispatch documents according to the Transportation of Dangerous Goods Act and Regulations. The sender should also forward all transportation data to the receiver. No infectious substances shall be dispatched before advance arrangements have been made between the sender, the carrier and the receiver, or before the receiver has confirmed with national authorities that the substance can be imported legally and that no delay will be incurred in the delivery of the consignment to its destination. Information can be obtained from:

Canadian Transport Emergency Centre (CANUTEC)
(613) 992-4624 (during business hours)
(613) 996-6666 (Emergencies: 24 hours per day)

Under the Transportation of Dangerous Goods Act and Regulations, biological agents such as microorganisms that is known or reasonably believed to cause disease in humans or animals are classed as "infectious substances". The infectious substance might be contained in blood, tissue, organs, body fluids, vaccines or cultures. A list of infectious substances can be found in Part 2 of the TDG Regulations under Appendix 3. This is not a complete list. Very specific packaging and documentation requirements must be met before such materials may be shipped from the University of Widnsor. A certified packaging system (Saf-T Pak, or equivalent) suitable for the legal transport of an "infectious substance" must be used. Risk Group 1 micro-organisms are not subject to these regulations.

Licensing

Although there is no official license required to ship biological agents, Transport of Dangerous Goods training is mandatory. Only individuals who are certified in the Transportation of Dangerous Goods are legally able to prepare packages and documentation for all dangerous goods, including biological agents.

Health and Safety offers Transportation of Dangerous Goods Training and more information can be gathered from their website or by phone: (519) 253-3000 ext. 2023. In lieu of training, The University of Windsor's Chemical Control Centre can assist in sending out any biological agent shipments. The Chemical Control Centre will not provide assistance if a biosafety certificate is required and not valid.

The biosafety certificate application and biological agent transfer application can be found at the Chemical Control Centre website.

2.2.6 Laboratory Animals

All aspects of the proposed use of vertebrate animals in research & teaching and their associated operational procedures for the care and maintenance of vertebrate animals must satisfy the Guidelines for the Care and Use of Experimental Animals of the Canadian Council on Animal Care and the local animal care authority as well as this manual if the animals are exposed to or infected with biological agents, in order to ensure not only protection for laboratory personnel and the environment, but to ensure that every care is taken to avoid causing the animals unnecessary pain or suffering and to provide the animals with the highest quality care.

Under the Ontario Animals for Research Act, and its Regulations, it is a requirement that all Principal Investigators who intend to conduct research, testing or teaching projects at the University of Windsor that involve the use of vertebrate animals, must obtain the approval of the University of Windsor Animal Care Committee before commencing the project. To obtain such approval, the Principal Investigator must submit the University of Windsor Animal Use Protocol Form which is available electronically at: http://www.uwindsor.ca/acc

The completed protocol form must be signed by the Principal Investigator and should then be submitted to the Animal Care Coordinator of the Animal Care Committee for review and approval.

Animal Care Coordinator
Office of Research Services
519.253.3000 ext. 3741
acc@uwindsor.ca

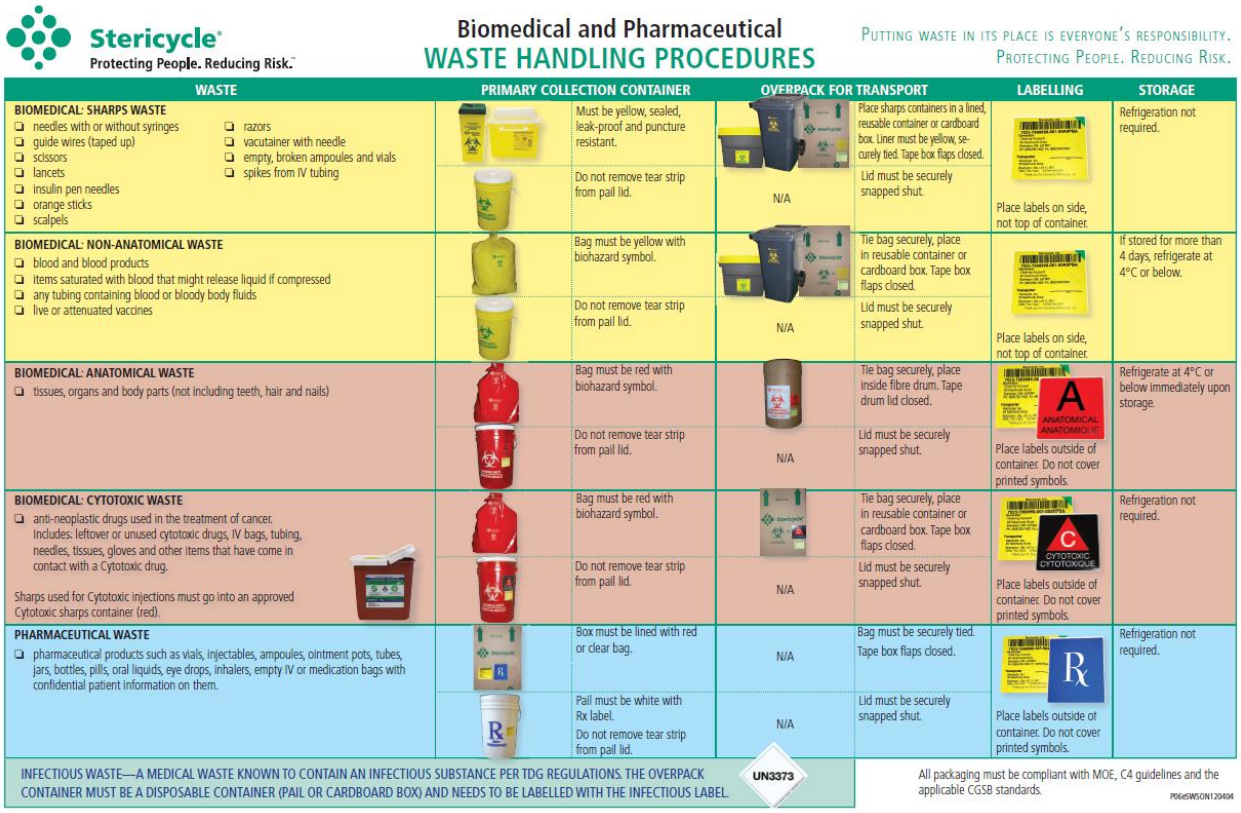
2.2.7 Waste Management

The handling, packaging, transport and disposal of waste in Onatario are governed by municipal, provincial and federal government legislation. The most pertinent legislation being the Environmental Protection Act (EPA) (1990), under which O.Reg. 347 on Hazardous Waste Management is enforced by the Ministry of the Environment. The Canadian Biosafety Standards, 3rd edition also offers insight into the proper decontamination and waste management of biological waste. This includes the use of autoclaves and treatment of liquid waste.

To comply with these regulations, the university has developed procedures focused on segregating research waste appropriately. Proper hazardous waste segregation is imperative to reduce risk and harm to humans, animals, and the environment. More information on the University's Hazardous Waste program and proper segregation can be found on the Chemical Control Centre's Website.

2.2.8 Other Legislation

While the Biosafety Program Manual does not intend to outline every single legislation when using biological agents at the University of Windsor, it is strongly recommended to review the Canadian Biosafety Standards for a general overview of the requirements. Any inquiries can also be made to the Chemical Control Centre.



Stericycle
Protecting People. Reducing Risk.

Biomedical and Pharmaceutical
WASTE HANDLING PROCEDURES

PUTTING WASTE IN ITS PLACE IS EVERYONE'S RESPONSIBILITY.
PROTECTING PEOPLE. REDUCING RISK.

WASTE	PRIMARY COLLECTION CONTAINER	OVERPACK FOR TRANSPORT	LABELLING	STORAGE
BIOMEDICAL: SHARPS WASTE ❑ needles with or without syringes ❑ guide wires (taped up) ❑ scissors ❑ lancets ❑ insulin pen needles ❑ orange sticks ❑ scalpels ❑ razors ❑ vacutainer with needle ❑ empty, broken ampoules and vials ❑ spikes from IV tubing	Must be yellow, sealed, leak-proof and puncture resistant. Do not remove tear strip from pail lid.	Place sharps containers in a lined, reusable container or cardboard box. Liner must be yellow, securely tied. Tape box flaps closed. Lid must be securely snapped shut. N/A	Place labels on side, not top of container.	Refrigeration not required.
BIOMEDICAL: NON-ANATOMICAL WASTE ❑ blood and blood products ❑ items saturated with blood that might release liquid if compressed ❑ any tubing containing blood or bloody body fluids ❑ live or attenuated vaccines	Bag must be yellow with biohazard symbol. Do not remove tear strip from pail lid.	Tie bag securely, place in reusable container or cardboard box. Tape box flaps closed. Lid must be securely snapped shut. N/A	Place labels on side, not top of container.	If stored for more than 4 days, refrigerate at 4°C or below.
BIOMEDICAL: ANATOMICAL WASTE ❑ tissues, organs and body parts (not including teeth, hair and nails)	Bag must be red with biohazard symbol. Do not remove tear strip from pail lid.	Tie bag securely, place inside fibre drum. Tape drum lid closed. Lid must be securely snapped shut. N/A	Place labels outside of container. Do not cover printed symbols.	Refrigerate at 4°C or below immediately upon storage.
BIOMEDICAL: CYTOTOXIC WASTE ❑ anti-neoplastic drugs used in the treatment of cancer. Includes: leftover or unused cytotoxic drugs, IV bags, tubing, needles, tissues, gloves and other items that have come in contact with a Cytotoxic drug. Sharps used for Cytotoxic injections must go into an approved Cytotoxic sharps container (red).	Bag must be red with biohazard symbol. Do not remove tear strip from pail lid.	Tie bag securely, place in reusable container or cardboard box. Tape box flaps closed. Lid must be securely snapped shut. N/A	Place labels outside of container. Do not cover printed symbols.	Refrigeration not required.
PHARMACEUTICAL WASTE ❑ pharmaceutical products such as vials, injectables, ampoules, ointment pots, tubes, jars, bottles, pills, oral liquids, eye drops, inhalers, empty IV or medication bags with confidential patient information on them.	Box must be lined with red or clear bag. Pail must be white with Rx label. Do not remove tear strip from pail lid.	Bag must be securely tied. Tape box flaps closed. N/A Lid must be securely snapped shut. N/A	Place labels outside of container. Do not cover printed symbols.	Refrigeration not required.

INFECTIOUS WASTE—A MEDICAL WASTE KNOWN TO CONTAIN AN INFECTIOUS SUBSTANCE PER TDG REGULATIONS. THE OVERPACK CONTAINER MUST BE A DISPOSABLE CONTAINER (PAIL OR CARDBOARD BOX) AND NEEDS TO BE LABELLED WITH THE INFECTIOUS LABEL. UN3373

All packaging must be compliant with MOE, C4 guidelines and the applicable CGSB standards.

P06eSWSON120404

2.3 Funding Agency Requirements

For research involving biological agents/materials, the implementation of the Biosafety Program ensures Principal Investigators (PIs) comply with external funding agency requirements, specifically the Tri-Council's Agreement on the Administration of Agency Grants and Awards by Research Institutions.

All research involving biological agents/materials is subject to the same standards outlined in this agreement regardless of the source of funding or whether it is funded or not.

3 CLASSIFICATION OF BIOLOGICAL AGENTS

The standards and practices described in this manual apply to all laboratory research and teaching activities conducted within the University of Windsor and its affiliated institutions where such activities involve the use of known biological agents or cultures, or when an agent has been recently isolated or is suspected to be present in the material handled.

Judgements of the inherent risks of a pathogen are made on the basis of a variety of factors, including:

- Pathogenicity and Virulence
- The Routes of Infection
- Mode of Transmission
- Survival in the Environment
- Infectious Dose
- Availability of Effective Preventive and Therapeutic Treatments
- Host Range
- Natural Distribution
- Impact of Introduction and/or Release into the Environment or the Canadian Public

This judgement should take into account the existence of effective therapies, immunization, the presence or absence of vectors, quantity of agent and whether the agent is indigenous to Canada, as well as possible effects on other species, including plants and animals. Due to their unknown characteristics, emerging pathogens and novel agents may require more stringent specialized practices and procedures for their safe handling

3.1 Risk Assessment and Risk Group Classification

It is the responsibility of the Principal Investigator to complete a risk assessment and properly classify each and every biological material/agent they will be working with into the appropriate risk group. There are 4 Risk Group Classifications outlined in Section 2.3 of the Canadian Biosafety Standards, 3rd Edition – Risk Group 1 being the least dangerous, Risk Group 4 being the most dangerous. Classification of the inherent risks of a pathogen are made on the basis of a variety of factors which take into account the overall safety of the work performed. These classifications presume ordinary circumstances in the laboratory, or growth in small volumes for experimental, diagnostic or

teaching purposes. The classifications of biological agents reflect the judgements made on their inherent risks.

3.1.1 Risk Group 1 (RG1)

Low individual and community risk

A microorganism, nucleic acid, or protein that is either a) not capable of causing human or animal disease; or b) capable of causing human or animal disease, but unlikely to do so. RG1 organisms capable of causing disease are considered pathogens that pose a low risk to the health of individuals or animals, and a low risk to public health and the animal population. RG1 pathogens can be opportunistic and may pose a threat to immunocompromised individuals. Neither of the RG1 subsets is regulated by the PHAC or the CFIA due to the low risk to public health and the animal population.

Although PHAC and the CFIA do not regulate RG1 organisms, it does not negate the need for RG1 material to be handled safely in a basic laboratory or animal work area. The Canadian Biosafety Handbook outlines safe practices when working with RG1 material. The University of Windsor requires an internal biosafety certificate when working with RG1 material.

3.1.2 Risk Group 2 (RG2)

Moderate individual risk, low community risk

A pathogen or toxin that poses a moderate risk to the health of individuals or animals, and a low risk to public health and the animal population. These pathogens are able to cause serious disease in a human or animal but are unlikely to do so. Effective treatment and preventive measures are available and the risk of spread of diseases caused by these pathogens is low. Examples of RG2 human pathogens are included in Schedule 2 of the HPTA.

3.1.3 Risk Group 3 (RG3)

High individual risk, low community risk

A pathogen that poses a high risk to the health of individuals or animals, and a low risk to public health. These pathogens are likely to cause serious disease in a human or animal. Effective treatment and preventive measures are usually available and the risk of spread of disease caused by these pathogens is low for the public. The risk of spread to the animal population, however, can range from low to high depending on the pathogen. Examples of RG3 human pathogens are included in Schedule 3 of the HPTA.

3.1.4 Risk Group 4 (RG4)

High individual risk, high community risk

A pathogen that poses a high risk to the health of individuals or animals and a high risk to public health. These pathogens are likely to cause serious disease in a human or animal which can often lead to death. Effective treatment and preventive measures are not usually available and the risk of spread of disease caused by these pathogens is high for the public. The risk of spread of disease to the animal population, however, ranges from low to high depending on the pathogen. Examples of RG4 human pathogens are included in Schedule 4 of the HPTA.

4 CONTAINMENT OF BIOLOGICAL AGENTS

Containment level refers to the minimum physical containment and operational practices required for a containment zone (normally the laboratory area) where infectious material or toxins can be safely handled. These parameters protect personnel, the immediate work environment, the community, and the external environment from exposure to potentially hazardous biological material. Determining the appropriate containment level will be based on the biological agent risk groups being used.

Figure 2: What is a Containment Zone? Chapter 3, Canadian Biosafety Handbook, 2nd Edition

> *A containment zone itself is a physical area that meets the requirements for a specified containment level. This can be a single room (e.g., a laboratory) or a series of co-located rooms (e.g., several non-adjoining but lockable CL2 laboratory work areas), or it can be comprised of several adjoining rooms of the same containment level (e.g., containment level 3 [CL3] suite comprised of dedicated laboratory work area and support areas, such as anterooms, change rooms, storage rooms, preparation areas, wash up rooms, centralized autoclave room). A containment zone may include one or more work areas of different types (i.e., laboratory work area, large scale production area, animal work areas), as long as they are of the same containment level.*

4.1 Human and Terrestrial Animal Pathogen Containment Levels

The Canadian Biosafety Handbook describes the three containment levels regulated by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA), ranging from the lowest level permitted to work with pathogens, toxins, and other regulated infectious material (containment level 2 [CL2]) to the highest level of containment (containment level 4 [CL4]). These containment levels are used when working with Human and Terrestrial Animal Biological Agents.

In addition to the three containment levels regulated by Health Canada, the University of Windsor has four levels of containment (1 - 4). These levels of containment are to be regarded as adequate for most laboratory uses of the listed agents. It remains the responsibility of the principal investigator or laboratory supervisor and the University of Windsor to require a higher level of containment for specific manipulations, if these appreciably increase the possibility of infection.

Classification of organisms according to risk group is not meant to establish the actual handling of biological hazards in the laboratory setting. For example, the risk group system does not take into account the procedures that are to be employed during the manipulation of a particular organism. Therefore, all researchers who are working with biological agents need to develop local risk assessment and provide instructions which are to be followed by all individuals within their laboratory, such as personal protective equipment requirements, spill response, and methods to reduce exposure.

Containment levels are selected to provide the end-user with a description of the minimum containment required for handling the pathogen safely in a laboratory setting. The containment system includes the engineering, operational, technical and physical requirements for manipulating a particular

pathogen. These containment levels are applicable to facilities such as diagnostic, research, clinical, teaching and production facilities that are working at a laboratory scale.

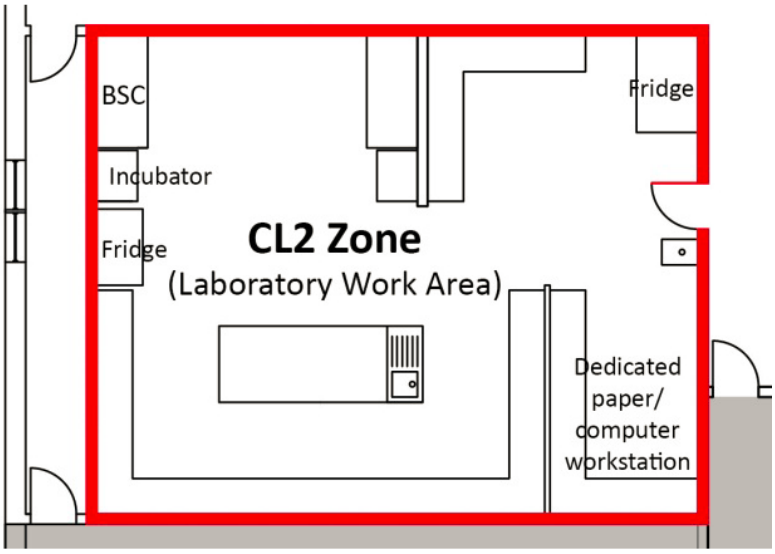
4.1.1 Containment Level 1 (CL1)

Work with RG1 biological material can be safely performed in a basic laboratory work area, large scale production area, or animal work area, often described as CL1. CL1 incorporates features that provide the foundation for biosafety upon which the requirements for all higher level containment zones are built. Biosafety is primarily achieved through the use of good microbiological laboratory practices in addition to basic physical containment design elements, such as handwashing sinks, that serve to protect personnel and the environment from the biological material being handled.

Although PHAC and the CFIA do not regulate RG1 biological material, it does not negate the need for RG1 material to be handled safely in a basic laboratory or animal work area. The Canadian Biosafety Handbook outlines safe practices when working with RG1 material. The University of Windsor still expects that the Laboratory Safety Manual protocols and those outlined in section 5.1 of this manual to be followed.

4.1.2 Containment Level 2 (CL2)

Containment level 2 (CL2) builds upon the basic laboratory foundation established for CL1. Biosafety and biosecurity at CL2 are achieved through operational practices and a core subset of physical containment requirements that are proportional to the risks associated with the pathogens and toxins handled therein. Operational practices for CL2 include administrative controls (e.g., biosafety program management, training) and procedures (e.g., work practices, personal protective equipment [PPE] use, and decontamination) that mitigate the risks associated with the activities conducted within the zone. Physical containment features include facility design (e.g., location of laboratory, surface finishes, access control) and provision of biosafety equipment, such as primary containment devices (e.g., biological safety cabinets [BSCs]) for certain activities. More information on these laboratories can be found in the Canadian Biosafety Handbook, 2nd Edition.



A representative diagram of two CL2 zones is provided in above Figure 3-1 (shown above). The solid red lines around the CL2 zones illustrate the containment zone perimeter (discussed in Chapter 3.3.1, Canadian Biosafety Handbook, 2nd Edition). This diagram depicts some basic physical features for CL2 zones, such as doors to separate public areas from the containment zones, primary containment devices (e.g., BSCs) located away from high traffic areas/doors, and sinks provided to facilitate handwashing upon exit from the containment zone.

4.1.3 Containment Level 3 (CL3) and 4 (CL4)

The University of Windsor has not commissioned any Containment Level 3 and Level 4 zones. More information on these laboratories can be found in the Canadian Biosafety Handbook, 2nd Edition. Biological agents requiring CL3 or CL4 containment are prohibited at the University of Windsor

4.1.4 Containment Level for Blood and Body Fluids

The need for precautionary measures extends also to situations in which human blood and other body fluids or feces must be handled. The precautions required may be more stringent when the specimens are used for culturing purposes, their handling should be consistent with Containment Level 2. Reduction of the containment level may be acceptable if potential hazards associated with the material are expected to be diminished because of dilution, use of chemical or other treatments or additional protective measures and practices are in place.

4.1.5 Special Considerations

Chapter 4.3 of the Canadian Biosafety Handbook (CBH), 2nd Edition, provides an overview of particular biological agents that require special considerations in addition to Bacteria, Viruses, and Fungi. Additional information on some of these biological agents is provided in this section. It is recommended that the CBH be reviewed if any of the following biological agents in the box below are being handled. Emerging pathogens and novel agents may also warrant particular attention due to the uncertain nature of handling such an agent.

Bacteria	Fungi	Viruses
Toxins	Prions	Security Sensitive Biological Agents
Non-Indigenous Animal Pathogens	Parasites	Large Scale Work of Biological
Animal Work	Cell Lines	Recombinant DNA
Infectious RNA	Autologous Cells, Tissues, & Specimens	
Genetically Modified Organisms (Viral Vectors, Synthetic Organisms)		
Primary Specimens (cell culture, tissue)		

4.1.5.1 Animal Cells, Blood and Body Fluids, and Fixed Tissues

The biological hazards of animal cells, tissues, blood and body fluids arise from the possibility that they might contain or transmit infectious agents. It is prudent to consider all cell lines to be potentially infectious. Cells known or suspected to contain such agents, or primary cultures from animals and humans known or reasonably suspected to be infected, should be assigned to the risk group for the suspected agent.

Non-recombinant cell lines

For every new cell line that is manipulated in a laboratory, a detailed risk assessment must be done in order to determine the appropriate level of precautions to be taken. A detailed risk assessment should include, but is not limited, to the following:

- source of cell line: the closer phylogenetically to humans, the greater the potential risk (highest to lowest risk: human autologous, human heterologous, primate, other mammalian, avian, invertebrate);
- source tissue: provides an indication of possible contaminants and latent (oncogenic) viruses;
- type of cell line highest to lowest risk: primary cell cultures, continuous cell cultures, intensivelycharacterized cell cultures;
- quantity of cells per culture;
- source population of the specimen from which the cell line was derived.
- recombinant cell lines (in addition to the above criteria)
- properties of the host cell line (in the case of hybridomas, the properties of each of the
- contributing cells must be considered);
- vector used for transformation (may increase containment level requirements);
- transfer of viral sequences (may increase containment level requirements);
- transfer of virulence factors (may increase containment level requirements);
- activation of endogenous viruses (may increase containment level requirements);
- recombinant gene product (may increase containment level requirements);
- helper virus presence (may increase containment level requirements).

Once all the relevant information regarding the cell line has been obtained, including any hazards associated with the media to be used during manipulation of the cell culture, it can be assessed to ascertain the hazards posed by manipulating the particular cell line. The cell line is to be handled at the containment level appropriate to the level of risk determined by the assessment.

4.1.5.2 Fixed Tissues and Tissue Sections

Tissues and tissue sections from human and animal sources are routinely fixed by treatment with chemical agents to preserve structures for later examination and study. Generally, these chemical treatments inhibit all biological activity. Most, but not all, intracellular and intercellular biological agents

are inactivated during this treatment. A notable exception is the group of unconventional agents known as 'prions'.

In general, fixed tissues and tissue specimens should be handled under at least Containment Level 1 conditions. A higher level of containment may be required depending on the source of the material, the nature of the agent and whether or not it is inactivated.

Where a biological agent that usually requires a higher level of containment is present in the tissue, the laboratory director / principal investigator should provide documentation to the University of Windsor's Research Safety Committee to support a request for a lower level of containment.

4.1.5.3 Security Sensitive Biological Agents (SSBA's)

Security Sensitive Biological Agents (SSBAs), are a subset of human pathogens and toxins that have been determined to pose an increased biosecurity risk due to their **dual-use potential** as a biological weapon. As such, greater administrative and physical containment requirements must be met before working with these biological agents. Security clearance through the Canadian Security and Intelligence Service and the Royal Canadian Mounted Police is also required before work is allowed to begin. At the Unviersity of Windsor, any research utilizing SSBAs must be reviewed and approved by the Research Safety Committee.

More information on SSBAs can be found in Section 2.3.5 of the Canadian Biosafety Standards and Section 10 of the Human Pathogens and Toxins Regulations which provides more details on the requirements. SSBAs includes all Risk Group 3 and Risk Group 4 human pathogens that are in the List of Human and Animal Pathogens for Export Control, published by the Australia Group, as amended from time to time, with the exception of Duvenhage virus, Rabies virus and all other members of the Lyssavirus genus, Vesicular stomatitis virus, and Lymphocytic choriomeningitis virus; as well as all toxins listed in Schedule 1 of the Human Pathogens and Toxins Act that are listed on the List of Human and Animal Pathogens for Export Control when in a quantity greater than that specified in Section 10(2) of the Human Pathogens and Toxins Regulations. A complete list of SSBAs can be found on the PHAC website.

4.1.5.4 Primary Cell Cultures and Animal tissues

The following containment requirements apply to primary cell cultures and tissues from human, non-human primate and non-primate animal sources when handled in the laboratory or used for animal passage. Cells and tissues known or suspected to be contaminated or infected with any of the agents included must be handled at the containment level appropriate to those agents.

Human and non-human primate material: Containment Level 2

Non-primate animal material: Containment Level 1

4.1.5.5 Bacteria, Fungi, Viruses & Parasites

Cell lines contaminated with bacteria and fungi are readily identified when grown in antibiotic-free media because they quickly overgrow the cells. Unlike bacteria and fungi, viruses are not readily identified and so can pose a significant hazard to those manipulating primary cell lines. Because of the

varying risks associated with cell line material, the World Health Organization proposed a classification of cell lines based on each line's likelihood of carrying viruses pathogenic to humans.

Low likelihood: cell lines derived from avian and invertebrate tissues.

Medium likelihood: mammalian non-hematogenous cells, such as fibroblasts and epithelial cells.

High likelihood: blood and bone marrow cells derived from human or non-human primates; human pituitary cells, caprine and ovine cells, especially those of neural origin; and hybridoma cells when at least one fusion partner is of human or non-human primate origin.

Cell lines with known or potential viral contaminants are to be handled at the containment level appropriate for the contaminating agent of the highest risk. One of the primary hazards of manipulating cell cultures is the expression of latent viruses. Endogenous viral sequences have been found in a variety of cell lines derived from mammalian species, including humans. Cell lines can be grown in an altered manner by applying various treatments (e.g., change in pH, serum level, temperature, medium supplements, cultivation).

These treatments may cause altered expression of oncogenes, expression of latent viruses, interactions between recombinant genomic segments or altered expression of cell surface proteins. Manipulations that may alter the "normal" behaviour of cell lines to a more hazardous state are to be conducted at a containment level appropriate to the new hazardous state.

Parasites

Freshly prepared primary cell lines may be at risk of parasite contamination if the cell line was obtained from a specimen known or suspected to be infected with a human parasite. Parasites have many lifecycle stages, and not all stages are infective. This must be taken into consideration when determining the appropriate level of containment. Cell lines in which the life-cycle stage of the infecting parasite is not known are to be manipulated at the containment level appropriate for the contaminating agent of the highest risk.

4.1.5.6 Cell Lines

The biological hazards associated with the use of mammalian or other cells in culture, and an appropriate Risk Group, will be influenced by the following criteria. Micro-organisms that are demonstrated to be nonpathogenic, containing no adventitious agents and having a long history of safe industrial use are not considered here.

1. Primary cultures of mammalian or other cells may harbor infectious agents or integrated DNA originally present in the animal or human from which the cultures were derived. Whenever possible, the donor should be tested for suspect pathogens prior to the preparation of the culture, and the culture should be considered to be contaminated until proven to be free of the suspect agents. Such primary cultures should be handled in a manner appropriate to the Risk

Group of the suspected contaminant, and precautions should be taken to protect laboratory personnel.

2. Cell lines known to contain infectious agents or integrated DNA should be handled in a manner appropriate to the Risk Group for the agent.

3. Cell lines that are deemed to be free of infectious agents rarely pose a biological hazard. If there is unintentional parenteral inoculation, normal immune response should provide protection, prevent progressive growth, and cause rejection of accidentally transplanted cells.

4.1.5.7 Genetically Modified Organisms

Genetically Modified Organisms are created by altering the genetic material of a biological species. A GMO can be as simple as rDNA cloned into a viral host to transgenic or knock-out animals. For activities involving genetically modified organisms,

- The host organism should be non-pathogenic, with no adventitious agents, a history of safe use, and limited ability to survive in the environment.
- Vectors with known inserts should be well characterized and free of sequences that result in adverse effects to humans, animals, plants, or the environment.
- The genomic insert should be limited in size to the smallest sequence required and should not increase the stability of the gene product in the environment.

4.1.5.8 Recombinant DNA and Genetic Manipulation

Genetic methods such as selection, cross breeding, conjugation and transformation have been used for many years to alter animals, plants and microorganisms. These methods have recently been supplemented with newer and much more efficient ones, of which the best known are the techniques of recombinant DNA.

Guidance in assessing potential risks in recombinant DNA research can only be very general; each case requires individual assessment. It is unrealistic to define all of the genetically engineered organisms which might be created or used in the laboratory. The vast majority of this research involves only the remotest possibility of creating a hazard because the source of the DNA being transferred, the vector and the host are all innocuous or have low risk characteristics. However, some genetic manipulation does raise a significant possibility of risk. The containment level of the recipient and donor organism, the replication competency of the recombinant organism and the properties of the donor protein should be considered when determining containment level.

1. If none of the components of the genetic manipulation (DNA, vector, host) presents any known hazard and none can be reasonably foreseen in their combination, then no restrictions beyond the requirements of Containment Level 1 are necessary.

2. If one of the components used in the procedure is hazardous, then, in general, determination of the containment level required will begin at the level appropriate to the known hazard. The level of containment may be increased or decreased depending on the particular gene

transferred, the expression of the gene in the recombinant organism, the envisaged interactions between the transferred gene and the host-vector system, and other relevant factors.

3. In any activity involving genes coding for hazardous products, host-vector systems with limited ability to survive outside of the laboratory (affording biological containment) should be used. Their use may reduce the level of physical containment required.

4. The containment level may be reduced if it is known that the DNA or vector is mutant and defective in their disease-causing or replication characteristics.

5. In the case of animal virus vectors, including retroviruses, one must consider the nature of the helper cells and the likelihood that replication-competent viruses may be produced.

Each case needs to have a risk assessment, as it is not realistic to try to define in advance all the possible genetically engineered organisms that might be created or used in the laboratory. Assistance with the risk assessment can be provided by the Public Health Agency of Canada's.

4.1.5.9 Special Cases

Particular attention is given to the following scenarios due to the inherent risks, and they require more stringent specialized practices and procedures for their safe handling.

1. Small Animal Work
2. Large Animal Work
3. Large Scale Production
4. Prion Work
5. Select Security Biological Agents Work

The Canadian Biosafety Standards, 3rd Edition, identifies and outlines all additional requirements in the matrices. The Canadian Biosafety Handbook, 2nd edition also provides additional information on the safe handling of special cases.

Transgenic animals should be handled according to the Guidelines of the Canadian Council for Animal Care and the University of Windsor's Animal Care Committee guidelines. An important consideration is the ability of the animal to transmit genes by breeding with another animal of the same or a related species. Transgenic animals must be adequately contained to prevent the unintentional spread of genetic modifications. It is recommended that transgenic animals be produced using methodology which restricts the potential for transmission of genes to another host.

Emerging pathogens and novel agents may also warrant particular attention due to the uncertain nature of handling such an agent.

Prions

The protein-only infectious particle, or prion, is accepted as the causative agent of transmissible spongiform encephalopathies, such as bovine spongiform encephalopathy (BSE). Cell cultures derived from bovine sources known or suspected to be BSE positive, and in vitro primary diagnostic tests of cell cultures derived from bovine sources known or suspected to be BSE positive are to be handled using TSE specific guidelines. Information and the TSE guidelines can be found by contacting:

Canadian Food Inspection Agency (CFIA),
http://www.inspection.gc.ca/english/sci/bio/bioe.shtml

4.2 Plant Pests and Pathogens

The CFIA does not assign plant pests and pathogens a particular risk group, however, Section 2.2 of the Containment Standards for Facilities Handling Plant Pests, 1st edition provides a framework to perform a risk assessment of plant pests and pathogens to determine the appropriate laboratory safety controls and protocols.

4.2.1 Transgenic Plants

There is considerable potential for commercial production of biological products in transgenic plants and animals. The potential release of transgenic organisms into the environment and transmission of novel genes to other plants and animals must be considered when designing both the production system and facilities to contain the transgenic organisms. In each case, the risk level should be determined in consultation with the appropriate Government agency.

Transgenic plants may transmit novel characteristics to other plants, thereby modifying the gene pool of existing species. Since this transmission is mediated by pollen, transgenic plants should be made sterile or contained in a growth chamber or greenhouse designed to prevent pollen release via air or insects. If plants are allowed to mature, care must be taken to contain seeds in the growth chamber or greenhouse.

If viable micro-organisms are used as vehicles for transfection, the containment level for the plants or animals inoculated with these viable recombinant micro-organisms must be at least as high as that required for work with that specific micro-organism. Transgenic plants and animals produced by microinjection, by use of replication defective vectors, or other sequences that are not normally horizontally transmitted, generally may be handled at Containment Level 1.

The following recommendations should be considered prior to the initiation of transgenic experiments.

- Complete copies of the replication competent genome should not be used.
- The constructs should not contain genes capable of causing neoplastic transformation in animals.
- The probability of recombination with extraneous micro-organisms should be minimal or nonexistent.

4.3 Plant Pest Containment Levels

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

4.3.1 Plant Pest Containment Basic

Basic containment is the lowest containment level for plant pests and it provides simple, but adequate, barriers to pest escape. Facilities may consist of field plots, basic laboratories or simple glass, plastic or screen houses which may have dirt or gravel floors and unscreened vents. Containment of plant pests is achieved through sanitation, spatial isolation from susceptible hosts, physical security, signage, destruction of waste and destruction of all viable pests at the end of the experiment or the testing period. Basic containment is applicable for work with low to very low risk plant pests for scientific, research, educational, processing, and industrial or exhibition purposes.

4.3.2 Plant Pest Containment Level 1 (PPC-1)

PPC-1 containment is the next highest containment level for plant pests. Facilities include permanent structures such as laboratories, greenhouses and screen houses. Windows that can be opened must be fitted with appropriate screens, and greenhouses must be fully screened and caulked to both contain and exclude arthropods. An autoclave must be available to treat waste and waste water must be treated to kill pests where appropriate.

4.3.3 Plant Pest Containment Level 2 (PPC-2)

PPC-2 facilities include permanent structures such as laboratories and greenhouses but not screen houses. Containment is achieved through facility design, operational procedures and the use of specialized equipment. All PPC-1 physical and operational requirements also apply to this containment level.

4.3.4 Plant Pest Containment Level 3 (PPC-3)

PPC-3 is the highest containment level for plant pests. All PPC-1 and PPC-2 physical and operational requirements apply to this containment level. Containment is achieved through the use of specialized facilities, stringent operational procedures and the use of specialized equipment. Designing, constructing and maintaining a PPC-3 greenhouse facility is complex and expensive. The use of growth chambers or growth rooms within a PPC-3 facility can be a cost-effective alternative to constructing a PPC-3 greenhouse.

4.4 Aquatic Containment Levels

The CFIA states that facilities handling aquatic animal pathogens must be constructed and operated to ensure the appropriate containment level for the anticipated work. Consideration is given to the pathogen itself, as well as to the procedures used to manipulate infectious materials and animals, and the volume of the biological material that will be handled.

In order to provide a framework to ensure the appropriate aquatic animal pathogen containment in Canada, a containment classification system has been developed that is similar to the systems used for

human, plant, and terrestrial animal pathogens. The classification system for aquatic animal pathogens consists of three levels: AQC1, AQC2 and AQC3, with associated in vitro and in vivo requirements for AQC2 and AQC3. At this time, there are no pathogens requiring AQC4; however, the decision to designate a pathogen as requiring level AQC4 will be made by the CFIA on a case-by-case basis.

4.4.1 Aquatic Containment Level 1 (AQC1)

Although the physical requirements for AQC1 facilities are not formally described in this document, AQC1 corresponds to the physical and operating conditions which characterize any well-run laboratory or aquatic animal holding facility working with pathogens that may be present in the aquatic environment but that are not considered a risk to aquatic animals or to the aquatic environment. An AQC1 facility follows basic biosafety and biosecurity protocols related to personnel, animals (if present) and laboratory practices (use of laboratory coats, hand washing stations, standard biohazard waste sites and disposal, good microbiological techniques, appropriate decontamination procedures, sanitary carcass disposal, standard operating procedures (SOPs), etc.).

4.4.2 Aquatic Containment Level 2 (AQC2)

In AQC2 in vitro facilities, containment is achieved through facility design, operational procedures and the use of specialized equipment. An autoclave or other proven technology must be available to treat solid waste and waste water. Containment is achieved primarily through operational practices including training in biosafety and containment precautions, limiting access to authorized personnel, use of protective clothing, effective sanitation and housekeeping, and the use of good microbiological laboratory practices. All AQC1 physical and operational requirements also apply to this containment level.

For AQC2 in vivo work, certain enhancements are required in order to address the unique risks associated with the transmission of aquatic animal pathogens in water, such as the connection of drains and associated piping to an effluent treatment system.

4.4.3 Aquatic Containment Level 3 (AQC3)

AQC3 in vitro containment is achieved through highly specialized facilities, stringent operational procedures and the use of specialized equipment. This type of containment is achieved primarily through physical requirements including inward directional airflow and controlled access systems.

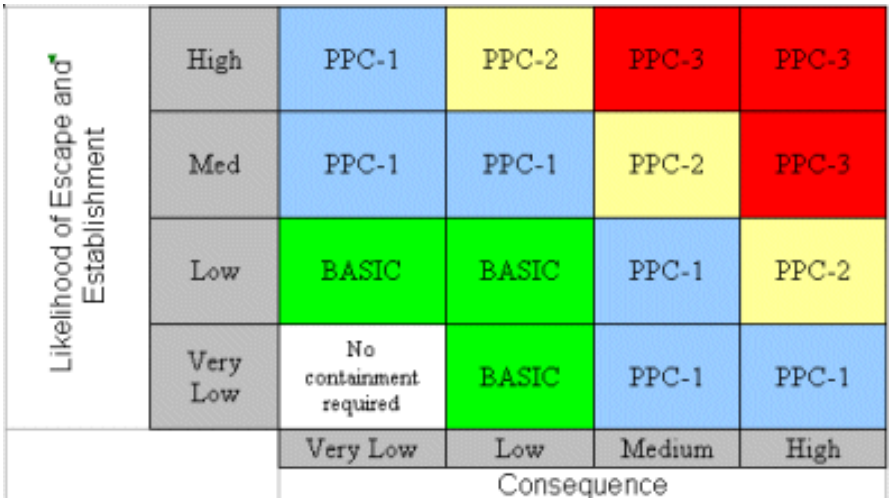
For AQC3 in vivo work, certain enhancements are required in order to address the unique risks associated with the transmission of aquatic animal pathogens in water and containment is achieved through additional physical requirements and operational practices. Washing or showering upon exit may be required based on a local risk assessment. There may be additional heating, ventilation and air conditioning (HVAC) requirements for large scale or in vivo facilities handling pathogens transmissible via the airborne route.

4.4.4 Aquatic Containment Level for Large Scale Work

Enhancement of the containment standards may be required for large scale in vitro work with aquatic animal pathogens. The applicable physical and operational containment requirements depend on the specific pathogen, the volume of pathogen involved, the frequency of activities, and the processes used. Therefore, the containment requirements for handling a large volume of aquatic pathogens will be determined on a case-by-case basis. For specific requirements related to the containment and safe handling of a large volume of microorganisms for research purposes, the OBCS should be contacted. For regulatory requirements pertaining to the manufacturing and testing of vaccines or diagnostic tests for aquatic animals, the VBS should be contacted.

Specific requirements and additional information can be found in the Containment Standards for Facilities Handling Aquatic Animal Pathogens – 1st Edition.

Any work involving animals should be handled according to the Guidelines of the Canadian Council for Animal Care and the University of Windsor's Animal Care Committee guidelines



The Containment Standards for Facilities Handling Plant Pests – 1st Edition, published by the CFIA, outlines the specific requirements for each containment levels for Plant Pests.

5 BIOLOGICAL SAFETY PRACTICES AND PROCEDURES

5.1 General Laboratory Safety Practices

The following requirements are basic for any laboratory using hazardous biological or toxic agents, specific requirements are outlined in the current version of the Canadian Biosafety Standard:

1. All laboratory personnel and others whose work requires them to enter the laboratory must understand the chemical and biological hazards with which they will come in contact during their normal work in the laboratory, and be trained in appropriate safety precautions and procedures. A standard operating procedure (SOP) must be prepared or adopted for use with biological agents. It is the responsibility of the principal investigator and/or laboratory supervisor to ensure that it identifies known and potential biological hazards and specifies the practices and procedures to eliminate or minimize such risks. The SOP must contain an emergency response plan. Personnel must be required to know, understand, and follow standard practices and procedures. Training in laboratory safety shall be provided by the laboratory supervisor / principal investigator and they shall ensure competence in safe technique is demonstrated before the worker is allowed to work with the hazardous agents or toxic material.

2. The laboratory must be kept neat, orderly and clean, and storage of materials not pertinent to the work must be minimized.

3. Protective laboratory clothing (uniforms, coats, gowns) must be available, and worn properly fastened by all personnel including visitors, trainees, and others entering or working in the laboratory. Protective laboratory clothing must not be worn in non-laboratory areas.

4. Suitable footwear with closed toes and heels and preferably with non-slip soles must be worn in all laboratory areas.

5. Gloves must be worn for all procedures that might involve direct skin contact with toxins, blood, infectious materials or infected animals. Rings or hand jewelry which interferes with glove use must be removed before gloving. The wearing of jewelry in the laboratory should be discouraged. Gloves must be removed carefully and decontaminated with other laboratory wastes before disposal. Reusable gloves (e.g. insulated, chemical resistant, etc.) may be used where necessary and must be appropriately decontaminated after use.

6. Face and eye protection (e.g., glasses, goggles, face shields, or other protective devices) must be worn when necessary to protect the face and eyes from splashes, impacting objects, harmful substances, UV light, or other rays.

7. Eating, drinking, smoking, storing food or utensils, applying cosmetics, and inserting or removing contact lenses are not permitted in any laboratory work area. Contact lenses are not protective devices, and must be used only in conjunction with appropriate protective eyewear in eye hazard areas.

8. Oral pipetting is prohibited in any laboratory.

9. Long hair must be tied back or restrained.

10. Hands must be washed after gloves are removed, before leaving the laboratory, and after handling materials known or suspected to be contaminated, even when gloves have been worn.

11. Work surfaces must be cleaned and decontaminated with the appropriate disinfectant at the end of the day and after any spill of potentially hazardous material. Loose or cracked work surfaces must be repaired or replaced.

12. All technical procedures must be performed in a manner that minimizes the creation of aerosols.

13. All contaminated or infectious liquid or solid materials must be decontaminated before disposal or reuse. Contaminated materials that are to be autoclaved or incinerated at a site away from the laboratory must be double-bagged or placed into containers, the outsides of which are disinfected.

14. Access to containment level 1 and 2 laboratories must be limited to authorized personnel as determined by the director / principal investigator (e.g. only persons who have been advised of the potential hazards and meet any specific entry requirements such as immunization should be allowed to enter the laboratory area). Persons under the age of 16 years shall not be permitted in the laboratory or support areas. Pregnant women and immunocompromised people who work in or enter the laboratory must be advised of the associated risks.

15. Hazard warning signs, indicating the containment level or the risk group of the agent used, must be posted outside each laboratory. Where the infectious agent used in the laboratory requires special provisions for entry, the relevant information must be included in the door sign. The agent(s) must be identified in the information provided for signing along with the names of the laboratory supervisor and other responsible person(s), and any special conditions for staff entry.

16. The use of needles and syringes and other sharp objects must be strictly limited. Hypodermic needles and syringes must be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Extreme caution must be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles must not be bent or sheared. Disposable needles and syringes must not be replaced in their sheath or guard. They must be placed into a puncture-resistant yellow container and autoclaved, if contaminated, before disposal, or incinerated. Sharps containers are available at both the Biological Sciences Stockroom and Chemical Control Centre.

17. All spills, accidents (needlesticks, punctures, cuts, etc.) and overt or potential exposures must be reported in writing to the laboratory supervisor or acting alternate as soon as circumstances permit. This person must file this report with Health & Safety within 24 hours. Appropriate medical evaluation, surveillance, and treatment must be sought and provided as required. Actions taken to prevent future occurrences should be documented.

18. Baseline serum or other specimens shall be collected from laboratory and other at-risk personnel and stored when deemed necessary. Additional serum specimens may be collected periodically, depending on the agent handled or the function of the facility. Baseline and

periodic serum or other specimens shall be collected and maintained by the University's Occupational Health Service or an equivalent health service. Confidentiality will be maintained according to the legal obligations of the Regulated Health Disciplines Act, or its subsequent revision. Tests will not be performed without the informed consent of the donor.

19. Laboratory workers should be protected by appropriate immunization where possible. Levels of antibody considered to be effective should be documented. Appropriate immunization or evidence of exposure should be maintained in a confidential manner. Particular attention must be given to individuals who are or may become immunocompromised, as vaccine administration may be different than for immunologically competent adults.

For more information on various types of safety equipment use in preventing infection from biological agents, please refer to Appendix A – Safety Equipment

5.1.1 Laboratory Requirements –Containment Level 1

University of Windsor's Research Safety Committee & the Public Health Agency of Canada has defined well-characterized agents that are not known to consistently cause disease in healthy adult humans and/or pose a minimal potential hazard to laboratory personnel and the environment. These agents require Biological Safety Level 1 containment.

A Biological Safety Certificate is required for all CL1 work

In addition to the general laboratory safety practices, the following operational procedures must be followed at the University of Windsor for all certified laboratories that handle infectious substances that require a Level 1 Containment Level (CL1), including:

1. Each laboratory must obtain and post in a conspicuous location a valid copy of their University of Windsor Biological Safety Certificate which lists all substances that the laboratory is approved to utilize as part of their research and/or teaching program.

2. A copy of the University of Windsor's Biological Safety Manual must be made available for all individuals working within the laboratory. A copy of this manual can be downloaded from the University of Windsor's Biological Safety Program website www.uwindsor.ca/biosafety or requested from the Chemical Control Centre ccc@uwindsor.ca.

3. Personnel must receive training on the potential hazards associated with the work involved and the necessary precautions to prevent exposure to infectious agents and release of contained material; personnel must show evidence that they understood the training provided; training must be documented and signed by both the employee and supervisor; retraining programs should also be implemented.

Physical Requirements

- A room separated from public areas by a door is required. There are no particular restrictions on locating the facility near public or heavily travelled corridors; however, doors should remain closed.
- Coatings on walls, ceilings, furniture, and floors should be cleanable. Windows that can be opened should not be near working areas or containment equipment and should be equipped with fly screens.
- There are no special air handling requirements beyond those concerned with proper functioning of the biological safety cabinets, if used, and those required by building codes.
- Handwashing facilities must be provided, preferably near the point of exit to public areas.
- Separate locations should be provided for hanging street clothing and laboratory coats at the entrance/exit.
- Eye wash stations should be available.

5.1.2 Laboratory Requirements – Containment Level 2

University of Windsor's Research Safety Committee and the Public Health Agency of Canada has defined well-characterized agents that have a moderate potential hazard to personnel and the environment. Pathogen Safety Data Sheets can be found using the link below.
http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php

It differs from CL1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

A Biological Safety Certificate is required for all CL2 work

In addition to the requirements outlined in Section 5.1 and those listed in the current version of the Canadian Biosafety Standards, the following operational procedures must be followed at the University of Windsor for all certified laboratories that handle infectious substances that require a Level 2 Containment Level (CL2).

1. Each laboratory must obtain and post in a conspicuous location a valid copy of their University of Windsor Biological Safety Certificate which lists all substances that the laboratory is approved to utilize as part of their research and/or teaching program.

2. A copy of the University of Windsor's Biological Safety Manual must be made available for all individuals working within the laboratory. A copy of this manual can be downloaded from the

University of Windsor's Biological Safety Program website www.uwindsor.ca/biosafety or requested from the Chemical Control Centre ccc@uwindsor.ca.

3. Personnel must receive training on the potential hazards associated with the work involved and the necessary precautions to prevent exposure to infectious agents and release of contained material; personnel must show evidence that they understood the training provided; training must be documented and signed by both the employee and supervisor; retraining programs should also be implemented.

4. Good microbiological laboratory practices intended to avoid the release of infectious agents are to be developed and employed.

5. Appropriate signage indicating the nature of the hazard being used (e.g., biohazard sign, containment level) must be posted outside each laboratory; if infectious agents used in the laboratory require special provisions for entry, the relevant information must be included on the placard; the contact information of the laboratory supervisor or other responsible person(s) must also be listed.

6. Entry must be restricted to laboratory staff, animal handlers, maintenance staff and others on official business. All people working in the containment area must be trained in and follow the operational protocols for the project in process. Trainees must be accompanied by a trained staff member. Visitors, maintenance staff, janitorial staff and others, as deemed appropriate, must also be provided with training and/or supervision commensurate with their anticipated activities in the containment area.

7. Emergency procedures for spill clean-up, BSC failure, fire, animal escape and other emergencies must be written, easily accessible and followed. A record must be made of other people entering the facility during an emergency.

For more information on each of these areas, please see Section 4 – Emergency Procedures within this manual.

Operational Requirements:

- Class I or II biological safety cabinets (see Appendix B – Biological Safety Cabinets) are required for all manipulations of agents which may create an aerosol. The biological safety cabinet must have been tested and certified within the previous 12 months according to accepted standards (see Section 3.8).

- Good microbiological laboratory practices intended to avoid the release of biological agents are to be employed. Centrifugation must be conducted with closed containers or aerosol proof safety heads or cups. These should be opened only in the biological safety cabinet.

- Organisms which have been experimentally infected must remain in the laboratory or appropriate animal containment facility.

- Vacuum lines used for work involving the agent must be protected from contamination by HEPA filters or equivalent equipment.

- Laboratory coats are to be worn only in the laboratory area. Either front-button coats or wrap around gowns are acceptable. These coats shall not be worn outside the containment laboratory. Gloves must be worn when handling infected organisms or when hands may be exposed to biological agents.

- Contaminated glassware must not leave the facility. Decontamination must be carried out using procedures demonstrated to be effective. If there is no autoclave or incinerator in the laboratory, contaminated materials must be disinfected chemically or be double bagged and transported to the autoclave or incinerator in durable, leakproof containers which are closed and wiped on the outside with disinfectant before leaving the laboratory.

- Periodic intensive cleaning must be done at regular intervals. Cleaning and maintenance staff should receive appropriate immunization and medical surveillance as required.

5.2 Working with Human Pathogens

Some micro-organisms (viruses, bacteria, fungi, etc.) are species specific, selectively infecting and causing disease in a limited number of, or only one, host species. Unrelated and distantly related species may not be similarly affected by the same infectious micro-organism due to differences in physiology, metabolism, biochemistry, etc. In general, the risk to a worker, working with a virus that only infects and causes disease in rodents is lower than the risk to a worker, working with tissues and cells from humans or other primates. If the human material contains a viable pathogen, it will likely be a human pathogen, with the potential to infect and cause disease in another human.

Although a single mode of transmission may predominate, disease causing micro-organisms can be spread or transmitted from one host to the next, directly or indirectly, by a number of methods, including aerosol generation and inhalation, ingestion of contaminated food and water, skin and mucous membrane contact with contaminated surfaces, contact contamination of an open wound or lesion, and autoinoculation via a cut, laceration or puncture with a contaminated instrument.

5.2.1 Human Bloodborne Pathogens

Human blood is recognized as a potential source of pathogenic micro-organisms that may present a risk to workers who are exposed during the performance of their duties. Although the hepatitis B virus (HBV)

and the human immunodeficiency virus (HIV) are often cited as examples, a "bloodborne pathogen" is any pathogenic micro-organism that is present in human blood or other potentially infectious materials and that can infect and cause disease in persons who are exposed to blood containing this pathogen.

"Other potentially infectious materials" means material which has the potential to transmit bloodborne pathogens. This includes infected human tissues and the following body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, saliva in dental procedures, and any other body fluid that is visibly contaminated with blood.

The biosafety requirements identified for research & teaching laboratories may not always be applicable to all workplace settings where workers handle or are exposed to human blood, body fluids or other materials potentially containing biological agents.

5.2.2 Universal Blood and Body Fluid Precautions

The Center for Disease Control (CDC) recommends that blood and certain other body fluids from all humans be considered potentially infectious and that precautions be taken to minimize the risk of exposure. This approach, called "Universal Precautions", is a method of infection control, intended to prevent parenteral, mucous membrane, and non-intact skin exposure of workers to bloodborne pathogens. All human blood, certain human body fluids, and other materials are considered potentially infectious for hepatitis B virus (HBV), human immunodeficiency virus (HIV), and other bloodborne pathogens. Precautions must be consistently used.

Body fluids to which universal precautions apply include blood, body fluids containing visible blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid.

Universal precautions generally do not apply to feces, breast milk, nasal secretions, sputum and saliva, sweat, tears, urine, and vomitus unless they contain visible blood. Although these materials are not implicated in the transmission of bloodborne pathogens, it is prudent to minimize non-intact skin and mucous membrane contact with these materials.

Hepatitis B immunization is recommended as an adjunct to universal precautions for workers who have occupational exposure to human blood or other potentially infectious materials. This immunization is provided to employees at risk is performed by the employee's personal physician and is covered by the University of Windsor's extended health plan. Individuals who do not have extended health coverage will be reimbursed by the University of Windsor to facilitate immunization.

General Precautions

- All workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with human blood or other body fluids is anticipated.

- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited.

- Gloves should be worn when touching blood and body fluids, mucous membranes, or non-intact skin, for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture and other vascular access procedures. If a glove is torn or damaged during use, it should be removed and a new glove used as promptly as safety permits. Disposable gloves should not be washed or disinfected for reuse. Washing with surfactants may enhance penetration of liquids through undetected holes in the glove. Disinfecting agents may cause deterioration of the glove material.

- Masks and protective eyewear or face shields should be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of mucous membranes of the mouth, nose, and eyes.

- Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or other body fluids. Protective clothing should be removed before leaving the area.

- Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids. Hands should be washed immediately after gloves are removed since no barrier is 100% effective. Alternatively, the University of Windsor's Biological Safety Program provides Hand Sanitizer stations in all BSL-1 and BSL-2 facilities to be used in the decontamination of hands and other skin surfaces.

- Workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures, when cleaning used instruments, during disposal of used needles, and when handling sharp instruments after procedures. Needles and syringes should be used only in those situations when there is no alternative. To prevent needlestick injuries, needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal. The puncture-resistant container should be located as close to the use area as practical. Contaminated reusable pointed and sharp objects such as large bore needles and scalpels should be placed in a puncture resistant container for transport to the reprocessing area.

- Mouthpieces, resuscitation bags, or other ventilation devices should be available for use in areas in which the need for resuscitation is predictable.

- Workers who have exudative lesions, weeping dermatitis, cuts, open wounds or other breaks in the skin should either refrain from all direct contact with blood and other body fluids until the condition resolves, or utilize protective barriers to reduce the risk of exposure.

- Pregnant workers should be especially familiar with and strictly adhere to precautions to minimize the risk of perinatal transmission of bloodborne pathogens.

Additional Precautions for Clinical Laboratories

- All blood and body fluid specimens should be in a well-constructed container with a secure lid to prevent leaking during transport.

- Gloves should be worn by all persons processing blood and body fluid specimens. Gloves should be removed and replaced and hands should be washed upon completion of specimen processing since no barrier is 100% effective.

- Masks and protective eyewear or a face shield should be worn if mucous membrane contact with blood or body fluids is anticipated.

- A biological safety cabinet is not necessary for routine procedures such as histologic and pathologic studies or microbiological culturing. However, biological safety cabinets should be used whenever procedures involve activities that have a high potential for generating aerosol droplets (blending, sonicating, vigorous mixing, etc.)

- Mouth pipetting is prohibited. Mechanical pipetting devices should be used for manipulating all liquids in the laboratory.

- Laboratory work surfaces should be decontaminated with an appropriate chemical germicide after a spill of blood or other body fluids and when work activities are completed.

- Hands should be washed after completing laboratory activities and protective clothing should be removed before leaving the laboratory area.

- Equipment and instruments should be decontaminated and cleaned before being repaired in the laboratory or transported to the manufacturer or repair shop.

- Contaminated materials should be decontaminated before processing for reuse. Disposable contaminated wastes must be collected in the appropriate containers.

Additional Precautions for Autopsies or Morticians' Services

These additional precautions are applicable for work completed at the Schulich School of Medicine – Windsor program.

- All persons performing or assisting in postmortem procedures should wear gloves, masks, protective eyewear, gowns, and waterproof aprons.

- Instruments and surfaces contaminated during postmortem procedures should be decontaminated with an appropriate chemical germicide. Gloves should be worn during the cleaning and decontaminating procedure.

5.3 Working with Laboratory Animals

Animals can harbor infectious organisms which are acquired naturally. Some infectious agents can give rise to a chronic carrier state, or an agent might be shed intermittently. If the possibility that such an agent may be excreted, secreted, exhaled or shed by an animal during the course of an experiment cannot be excluded, then all those animals should be kept at the containment level appropriate to the risk.

Animals may also be intentionally inoculated with viruses or other organisms in any of the four Risk Groups or with viable materials (e.g., transformed cells) suspected of containing these agents. Under these circumstances, the animals should be kept at the containment level appropriate to the risk of the agent, recognizing that in some cases, in vivo work may increase that risk.

Naturally occurring or experimentally induced infections in laboratory animals may be transmitted to other laboratory animals, invertebrates and laboratory workers. Laboratory animals and insects may scratch or bite or may be the source of an aerosol. Besides the risk from an infection that the animal or insect may be harboring, there is also a risk that some of the material being injected may adhere to the fur or exoskeleton and remain as a potential hazard.

In all situations, it is the responsibility of the principal investigator, laboratory supervisor and the University of Windsor's Research Safety Committee, in consultation with Government agencies and the animal care authorities, to determine the risk levels inherent in the proposed activity.

The requirements for the maintenance of animals may differ in scale and degree, but the basic principles for microbiological safety will be similar to those outlined in Section 5.1 - General Laboratory Safety Practices and should include the following precautions.

1. Infected animals and insects should be segregated from uninfected animals wherever possible, and it is preferable to separate any handling area from the holding area.

2. Animals or insects in use in an experiment must be maintained at a level of containment that is at least equivalent to the containment level for the biological agent with which it has been infected or treated.

3. Provision must be made to ensure that inoculated animals or insects cannot escape.

4. Dead animals or insects and the refuse from the animal room and cages (e.g. bedding, feces and food) must be placed in a leak-proof container and autoclaved or incinerated.

5. All cages must be properly labelled, and procedures in the holding area must minimize the dispersal of dander and dust from the animals and cage refuse.

6. Protective clothing, including scratch/bite resistant gloves, eye protection, appropriate chemical restraint and proper handling equipment are recommended for the handling of non-human primates.

7. Disposable latex gloves should be worn by animal care providers while feeding and watering animals or cleaning cages.

8. Non-disposable gloves, boots, floors, walls and cage racks should be disinfected frequently.

In addition to the preceding, the following must also be satisfied:

9. All aspects of the proposed use of animals in research & teaching must meet the current veterinary standards and regulations for the care and maintenance of experimental animals as described by the Canadian Council on Animal Care, relevant provincial legislation, and local animal care authorities.

10. The appropriate species must be selected for the animal experiments.

11. The investigator and / or person(s) responsible for the animal experiment must ensure that all those having contact with the animals and waste materials are familiar with and aware of any special precautions and procedures that may be required. Where possible, personnel should be protected by immunization with appropriate vaccines.

12. All incidents, including animal bites and scratches or cuts from cages or other equipment must be documented and the employee should report to the Occupational Health Service for medical assessment and follow-up.

13. Small laboratory rodents or other small animals that escape from their cages should be killed when captured, their carcasses incinerated, and the area should be thoroughly decontaminated. In the event that animals escape through the containment perimeter, the relevant authorities must be notified promptly and appropriate action initiated.

Unexpected illness or deaths among animals must be reported to the principal investigator and the veterinarian, who will be responsible for final disposition. Animals should not be touched until instructions are given by the person-in-charge.

5.4 Laboratory Equipment

5.4.1 Autoclaves / Steam sterilizers

Autoclaves / steam sterilizers which have steam in the piping at a pressure of 15 psi (pounds per square inch) or higher are covered by Chapter B9 of the Boilers and Pressure Vessels Act of Ontario.

This equipment should have a valid certificate of operation issued by a Boiler Inspector holding a valid Certificate of Competency. Generally, in Ontario this service is provided by the Insurer which provides Boiler and Machinery Insurance coverage. The University of Windsor has such insurance coverage through CURIE, an insurance broker.

Every autoclave must be inspected at the time of installation and should have a valid certificate from TSSA (Technical Safety and Standards Authority) of Ontario.

After the initial installation, this equipment is to be inspected annually. The scope of inspection will include a visual inspection, a review of the conditions of operation and the protective devices such as the pressure relief valves, temperature controls (if any), steam quality control, and the measures being taken by the user for its safe and efficient operation as required by the Boilers and Pressure Vessels Act of Ontario.

Upon satisfactory completion of the inspection, a certificate of inspection will be issued which will authorize operation of the equipment. The user should not operate any sterilizer which has steam heating coils with a pressure of 15 psi or higher without a valid certificate of operation. The persons responsible for the operation should be fully familiar with the requirements of the Boilers and Pressure Vessels Act of Ontario.

The University's insurer maintains a list indicating the locations of autoclaves. Annual inspections are performed automatically, according to this list. If you have received a new autoclave or are using one that has not been inspected during the previous 12 months, please notify the Chemical Control Centre, the University of Windsor's Department of Finance (Attn: Manager - Risk Management & Insurance) and provide the information necessary to have this equipment added to the equipment list so that the required inspections are scheduled and performed in future.

Validation and Verification testing is conducted and recorded by the Chemical Control Centre in accordance with the HPTA.

5.4.2 Biological Safety Cabinets

The purpose of an air exhaust system is to remove contaminated air from a work area, to convey it through a decontaminating system if necessary, and to discharge it to the outside. Its design should provide adequate air exchanges, a negative pressure differential between the room and the air source to ensure that contaminated air departs only through the exhaust system, and air flow patterns through the room so that all parts of the room are swept by the air flow. The influence of opening and closing

doors on these air flow patterns is of particular importance. Decontamination of air is best achieved with a high efficiency particulate air (HEPA) filter. HEPA filters are ineffective unless properly installed. Testing of these filters in situ with an aerosol at the time of installation and at regular intervals is essential to ensure the integrity of the barrier. Normally, HEPA filters will require replacement only when they offer excessive resistance to air flow due to loading or when irreparable leaks are detected.

Biological safety cabinets, when properly used in research and teaching activities involving the manipulation of hazardous biological agents, are effective in containing and controlling particulates and aerosols and complement good laboratory practices and procedures.

Biological safety cabinets used in laboratory activities requiring Containment Level 2 or 3 conditions at the University of Windsor must be inspected, tested and approved for use annually, unless otherwise noted, by trained service personnel to ensure that the cabinet is functioning as intended by the manufacturer.

Inspection and testing is mandatory if a biological safety cabinet is relocated. Moves of a minor nature (i.e. within the same room) may be exempt from this requirement if the move is observed by the testing technologist and the cabinet has not been subjected to excessive stress or rough handling which could result in damage.

The routine decontamination and testing of used Class II biological safety cabinets shall include the following required procedures and tests which shall be conducted in accordance with, and in the manner described below.

The testing of biological safety cabinets at the University is conducted by an external contractor. Fees for this service are charged to the Principal Investigator, researcher or department.
The University of Windsor's Chemical Control Centre coordinates the annual testing of all biological safety cabinets on campus.

Decontamination

Cabinet decontamination with paraformaldehyde vapour shall be conducted prior to the testing of biological safety cabinets which have been used for activities involving biological agents assigned to the Risk Groups identified by Health Canada. The biological safety cabinet shall be sealed and decontaminated using the paraformaldehyde vapour technique which is described in NSF Standard 49, and cited in CSA Z316.3-95, or an equivalent procedure acceptable to the University of Windsor. The paraformaldehyde holding / contact time shall be a minimum of 2 hours, after which the paraformaldehyde vapour shall be neutralized or vented to the exterior of the building.

Containment System Integrity

Containment system integrity (pressure) testing shall be performed on all biological safety cabinets having air plenums which convey potentially contaminated air at positive pressure and where any portion of these plenums also forms part of the containment shell of the cabinet. The cabinet interior

shall be pressurized with air to a differential pressure of 2"w.g. A liquid leak detector shall be applied along all welds, gaskets, penetrations, and seals on the exterior surfaces of the cabinet air plenums. Leakage will be indicated by the presence of bubbles or by the feel or sound of escaping air. Detected leakage shall be corrected using acceptable methods and materials and the repaired area shall be retested to confirm the success of the corrective action. Note: The performance of this test is required at the time of initial cabinet installation, following cabinet relocation, and at least once in every three year period.

Air Velocities and Volumes

Air velocities shall be measured at multiple points on a grid, across the face of the HEPA filters. The location and spacing of the co-ordinates shall be according to the manufacturer's recommendations and / or applicable standards. Additional air velocity measurements may be required by the manufacturer of the cabinet. The blower speed and air dampers shall be adjusted as required so that the final measured and calculated values are within the acceptable ranges indicated by the manufacturer of the biological safety cabinet.

HEPA Filter Integrity

HEPA filter leak testing shall be performed using sufficient dioctylphthalate (DOP) aerosol (or equivalent) to challenge the air filtration system. The aerosol concentration upstream of the HEPA filters shall be sampled and used as the 100% reference for photometer adjustment prior to testing. All air diffusers and protective grilles downstream of HEPA filters shall be removed to allow direct access to the entire filter surface and perimeter (bond area, gasket, filter frame, and mounting frame) which shall be scanned in overlapping strokes at a traverse rate of not more than 2" per second. Aerosol penetration exceeding 0.01% of the upstream concentration shall be sealed or corrected using generally accepted methods and the repaired area shall be retested to confirm the success of the corrective action.

Airflow Smoke Patterns

These tests shall be performed using a source of visible smoke to demonstrate the acceptability of airflows associated with the biological safety cabinet.

Other Procedures and Tests

Other procedures and tests (electrical safety, fluorescent and UV lighting intensity, vibration, noise level, etc.) may be recommended or performed, depending on the cabinet design and the circumstances of its installation and usage, but their performance is not required on a routine basis.

5.4.3 Fume hoods

A Fume hood is an enclosed working chamber fitted with an exhaust ventilation system. It is one component of an exposure control system that is designed to contain, dilute and disperse gases, mists, vapors and particulate matter to the external environment. It is also an integral part of the building air handling system. The fume hood is the primary engineering control device in most laboratories for protecting workers and students from exposure to hazardous chemicals. It is therefore imperative that

it function properly at all times during its operation. All activities involving the purchasing, use, maintenance, and disposal of fume hoods must comply with the fume hood manual and all applicable legislation. The Fume Hood Manual is available from the Chemical Control website at www.uwindsor.ca/ccc.

6 EMERGENCY PROCEDURES

6.1 Biological Spill Response

Spills, accidents or exposures to infectious materials and losses of containment must be reported immediately to the laboratory supervisor; written records of such incidents must be maintained, and the results of incident investigations should be used for continuing education.

Emergency plans and procedures to be readily available and to include appropriate equipment and training for emergency response to spills or accidental release of organisms (i.e., personal protective equipment, disinfectants); training to be documented.

Laboratory bench tops and surfaces are to be decontaminated after any spill of potentially infectious materials and at the end of the working day.

If there is a spill during use, surface decontaminate all objects in the cabinet; disinfect the working area of the cabinet while it is still in operation (do not turn the cabinet off).

Decontamination of the laboratory space, its furniture and its equipment requires a combination of liquid and gaseous disinfectants. Surfaces can be decontaminated using a solution of sodium hypochlorite (NaOCl); a solution containing 1 g/l available chlorine may be suitable for general environmental sanitation, but stronger solutions (5 g/l) are recommended when dealing with high-risk situations. For environmental decontamination, formulated solutions containing 3% hydrogen peroxide (H_2O_2) make suitable substitutes for bleach solutions.

Whenever possible, suitable gloves should be worn when handling biohazardous materials. However, this does not replace the need for regular and proper hand-washing by laboratory personnel. Hands must be washed after handling biohazardous materials and animals, and using the washroom, and before leaving the laboratory, and eating.

In most situations, thorough washing of hands with ordinary soap and water is sufficient to decontaminate them, but the use of germicidal soaps is recommended in high-risk situations. Hands should be thoroughly lathered with soap, using friction, for at least 10 minutes, rinsed in clean water and dried using a clean paper or cloth towel (if available, warm-air hand-dryers are also recommended).

The Biological Spill Procedures outline in the University of Windsor hazardous materials spill response manual shall be followed.

6.1.1 Biological Spill Reporting

MINOR BIOLOGICAL SPILLS: Spills and accidents that result in exposures to organisms shall be immediately reported to your supervisor with an **incident report** forwarded to Health & Safety and the University of Windsor's Biological Safety Officer (ext. 3523). Written records to be maintained. Medical attention and surveillance will be provided as appropriate.

MAJOR BIOLOGICAL SPILLS: All major biological spills shall be immediately reported to your supervisor, Emergency procedures for spill clean-up, BSC failure, fire, animal escape and other emergencies must be written, easily accessible and followed. A record must be made of other people entering the facility during an emergency. **Health & Safety and the University's Biological Safety Officer must be immediately notified**. An incident report must be completed and sent to health & safety within 24 hours and written records shall be maintained. Medical attention and surveillance will be provided as appropriate.

Biological Spill Kit

The kit should be maintained in a white 6-gallon leak-proof bucket and contain the following:

- Concentrated household bleach – check expiration date
- Spray bottle for making 10% bleach solution
- Forceps or tongs for handling sharps
- Paper towels or other suitable absorbent
- Biohazard bags of various sizes
- Disposable gloves
- Disposable foot covers
- Face protection – at a minimum safety glasses and mask
- Spill sign to post on door

Biohazardous Spill Kits are available at the Chemical Control Centre.

6.2 Emergency Medical Procedures

In life-threatening situations requiring immediate medical attention, telephone the University of Windsor's Campus Community Police (Ext 911) and they will contact the appropriate authorities and co-ordinate the response.

6.2.1 Medical Surveillance & Immunioprophylaxis

Laboratory personnel should be protected against laboratory-acquired infections by appropriate immunization with relevant, licensed vaccines unless documented to have pre-existing immunity. Hepatitis B immunization is strongly recommended for all persons who handle or are exposed to human blood, body fluids, organs or tissues. Immunoprophylaxis and information pertaining to the availability and the advisability of immunizing agents are available through the following:

Windsor Essex Health Unit – Immunization Unit,
1005 Ouellette Avenue,
Windsor, Ontario N9A 4J8
(519) 258-2416 ext. 1222.

Immunizing agents are available to protect laboratory workers against:

Anthrax	Lyme disease	Rabies
Botulism	Measles	Rubella
Cholera	Meningococcus	Tetanus
Diphtheria	Mumps	Tuberculosis (BCG)
Hemophilus influenzae type b	Pertussis	Typhoid
Hepatitis A	Plague	Vaccinia
Hepatitis B	Pneumococcus	Varicella
Influenza A	Polio	Yellow fever
Japanese encephalitis		

6.2.2 Animal Bites and Scratches

The following emergency response procedures shall be followed when a worker has been exposed to zoonotic agents via animal bite or scratch, via mucous membrane contact, or via non-intact skin contact.

Laboratory Worker, Student, and Visitors

The exposed site must be washed immediately.

A. Wash with soap and water after allowing the wound to bleed freely.

B. If mucous (eyes, nose, mouth) membrane or non-intact (cuts, rash, eczema or dermatitis) skin contact, flush with water at the nearest faucet or eye wash station.

The individual must immediately inform the supervisor / principal investigator of the exposure incident.

The individual must seek prompt medical attention at the nearest hospital emergency department or emergency clinic, a medical practitioner of their choosing. The individual must provide information for a University of Windsor Accident/Incident (obtained from her / his supervisor / principal investigator), describing the incident in detail, including the route of exposure and the emergency actions taken, and a description of the individual's duties as they relate to the exposure incident.

6.2.3 Exposure to Human Blood and Body Fluids

The following emergency response procedures shall be followed when a worker has been exposed to blood or body fluids via a needlestick, cut or puncture wound, via mucous membrane contact, or via non-intact skin contact.

Laboratory Worker, Student, Visitors

The exposed site must be washed immediately.

A. Wash with soap and water after allowing the wound to bleed freely.

B. If mucous (eyes, nose, mouth) membrane or non-intact (cuts, rash, eczema or dermatitis) skin contact, flush with water at the nearest faucet or eye wash station.

The laboratory worker, student, or visitor must immediately inform the supervisor / principal investigator of the exposure incident.

6.2.4 Exposure to Infectious and Communicable Disease Agents

The following emergency response procedures shall be followed when a worker has been exposed to infectious or communicable disease agents via inhalation, a needlestick, cut or puncture wound, via ingestion or mucous membrane contact, or via non-intact skin contact.

Laboratory Worker, Student, Visitors

The exposed site must be washed immediately.

A. Wash with soap and water after allowing the wound to bleed freely.

B. If mucous (eyes, nose, mouth) membrane or non-intact (cuts, rash, eczema or dermatitis) skin contact, flush with water at the nearest faucet or eye wash station.

The laboratory worker, student, or visitor must immediately inform the supervisor / principal investigator of the exposure incident.

6.2.5 Important Medical Emergency Numbers & Contacts

Emergency Number (Fire, Police, Ambulance)	911
Hospitals:	
Hotel-Dieu Grace Hospital	(519) 973-4444
Windsor Regional Hospital (Metropolitan Campus)	(519) 254-1661
Windsor Regional Hospital (Western Campus)	(519) 257-5100
Poison Control Centre	(800) 268-9017

UNIVERSITY CAMPUS EMERGENCY NUMBERS

Campus Community Police (Emergency 24Hrs)	ext. 911, ext. 4444
Campus Community Police (Non-Emergency)	ext. 1234
Chemical Control Centre	ext. 3523
Chemical Control Centre (Emergency)	ext. 2055
Student Health Services Room 242 CAW Student Centre	519-973-7002

6.3 Medical Incident Reporting Requirements

6.3.1 Individual

The laboratory worker, student, or visitor must seek prompt medical attention at the nearest hospital emergency department or emergency clinic, a medical practitioner of their choosing. The laboratory worker, student, or visitor must provide information for a University of Windsor Accident/Incident (obtained from her / his supervisor / principal investigator), describing the incident in detail, including the route of exposure and the emergency actions taken, and a description of the individual's duties as they relate to the exposure incident.

6.3.2 Supervisor/Principle Investigators

1. The supervisor must refer the affected individual(s) to the nearest hospital emergency department or medical practitioner of their choosing.

2. Supervisors and/or Principle Investigators must complete and sign the University of Windsor's Accident / Incident report (www.uwindsor.ca/safety) under "Report an Accident".

3. The supervisor must ensure that the exposure incidents are reported within 24-hours to Health and Safety (519.971.3671 – fax).

6.3.3 Environmental Health & Safety

Environmental Health & Safety office shall confer with the affected individual(s) and / or attending physician(s) / caregiver(s) to determine whether the exposure is of a nature that may transmit the biological agent HBV, HIV or any other bloodborne pathogens.

Counselling regarding potential HBV, HIV or other bloodborne pathogen exposure and infection, chemo /immunoprophylaxis and follow-up testing shall be offered to any individual if their exposure is determined to be of a nature that may transmit HBV, HIV or other bloodborne pathogens. A hepatitis B vaccine or other appropriate post-exposure prophylaxis shall be offered if the individual has not been immunized previously or does not demonstrate adequate antibodies.

If the individual refuses appropriate post-exposure prophylaxis and / or testing, this shall be documented in the medical record and countersigned by the employee, or a refusal document should be signed retained. These reports shall be presented as prescribed to managers, supervisors, employees, and the appropriate Safety Committee(s).

7 SECURITY

7.1 Dual Use

Biological agents may have a dual-use potential. They can be used in research & teaching for the advancement of science and the diagnosis of disease, but can also be misused, stolen or intentionally released. The director/principal investigator working with biological agents will conduct a dual use potential assessment as part of the biological safety certificate application process. This evaluation will be reviewed by the Research Safety Committee and Vice President of Research and Innovation as necessary. The handling of infectious disease agents requires a security plan to ensure that biological agents are used as intended and stored securely.

7.2 Physical Protection

The physical protection risk assessment should include all levels of a security review: perimeter security, facility security, laboratory security and agent specific security, and outline procedures for securing the area, e.g., card access, key pads, locks etc.

All laboratories should adopt security practices to minimize opportunities for unauthorized entry into laboratories, animal and storage areas, as well as the unauthorized removal of infectious materials from their facility. The aim is to have a dedicated and controlled access into the laboratory limited to authorized personnel, laboratory staff, and maintenance staff. Within the laboratory, access to biological agents should be controlled as well. The containment perimeter (i.e., doors, windows) should provide the required level of security and should be kept closed.

7.3 Personnel Reliability & Suitability

For all laboratories requiring Containment Level 3 or other controlled & sensitive materials, background checks and security clearances may be required before employees are granted access to these facilities. It may be appropriate to use photo identification badges for employees and temporary badges for escorted visitors to identify individuals with clearance to enter restricted areas.

Procedures must be developed for approving and granting visitors access to controlled areas. In this capacity the access to agents and storage facilities is limited to legitimate use/individuals only. Biosafety training should include address security issues and must be provided to all personnel who are given access. Personnel must demonstrate that they have understood the biosecurity training provided.

7.4 Pathogen Accountability

The University of Windsor is required to use a system to properly label, track of internal possession, inactivation and disposal of cultures after use, and transfers within and outside the facility. These controls also assist in the tracking of pathogen storage locations and in clarifying under whose responsibility the pathogens lie.

The institution requires all biological safety certificate holders to update their inventories within the University of Windsor's Hazardous Materials Information system, including any new additions as a result of diagnosis, verification of proficiency testing, or receipt from other locations as well as to remove agents after transfers or appropriate inactivation and disposal mechanisms have been used. Disposal of agents after use should include all sub-cultures of that agent as well.

Laboratories are required to keep records of all pathogen inventories, who has access to agents, who has access to areas where agents are stored or used, as well as transfer documents. A record of culture collections and other agents not currently used for research should be included in inventory lists as well. A notification process for identifying, reporting, and remediation of security problems, i.e., inventory discrepancy, equipment failure, breach of security, release of agents, etc., should be in place.

7.5 Storage

Agents stored and maintained for on-going research, teaching, or as part of a culture collection should have adequate physical protection. Agents should be stored securely, in consideration of the containment level of the agent itself and should have restricted access. An inventory of stored agents should also be maintained so that pathogen storage locations are tracked, and also so that it is clear who is responsible for the pathogens. Documentation procedures should include proper labelling, tracking of internal possession, inactivation and disposal of cultures after use and transfers within and outside the facility. Other records on who has access to the agents, who has access to where the agents are stored or used and transfer documents, should also be kept.

7.6 Reporting

Biosafety and biosecurity incidents are to be reported to the Senior Biological Safety Officer immediately. The immediate reporting allows for procedures to be promptly initiated to contain any possible release of regulated materials, repair or perform corrective actions to containment systems, secure assets with dual-use potential, and when applicable, notify the appropriate regulatory agencies.

Notification must be provided to PHAC without delay when:

- A human pathogen or toxin that a person is not authorized to possess is inadvertently produced or comes into possession.

- An incident involving a human pathogen or toxin has, or may have, caused disease in an individual.
- There is reason to believe that a human pathogen or toxin has been lost or stolen.
- All other criteria listed in the HPTR

Appendixes

Appendix A – Safety Equipment

An essential element in maintaining personal safety and environmental protection is the correct selection, use and maintenance of safety equipment in the laboratory. Safety equipment must be maintained and regularly serviced. There must also be a regular program of testing and inspection, and accurate records must be kept. The following is a list of safety devices appropriate to the containment laboratory:

Type	**Application**
Animal cages or boxes	partial to total containment of aerosols; provide protection from cross-contamination and personnel and environmental protection
Autoclaves	high temperature steam sterilization
Blenders and mixers	aerosol-free blenders provide containment of aerosols
Biological Safety Cabinet	*See Appendix D – Biological Safety Cabinets*
Centrifuge equipment	safety cups with sealed heads provide containment of aerosols
Face / eye wash station	device for flushing face and eyes with water in event of splash or spray of biological or chemical agents
Face and eye protection	safety glasses, goggles and full-face shields provide protection from flying objects and splashes
Fume hoods	provide personnel and environmental protection; for removal or control of gases and vapors.
Gloves	provide hand protection of varying degrees; check technical specifications to determine degree of protection
HEPA filters	high efficiency particulate air filters available in various sizes, including cartridges; disposable; provide 99.97% removal of 0.3 µM particulates
Incinerators – micro	electric or gas with side-arm to contain splatters when flaming inoculation and transfer loops
Laboratory clothing	head covers, shoe covers, coats, gowns or ventilated suits appropriate to hazard
Leak-proof containers	variety of containers, preferably of stainless steel and autoclavable, with tight-fitting lids, and which may be used for transporting waste materials to an autoclave
Pipetting devices	variety of devices which eliminate need to pipette by mouth
Respiratory protection	partial or full-face protection; provided with variety of filters

Sharps waste containers	autoclavable, puncture-resistant containers which are used for collection and disposal of used hypodermic syringes and needles, blades and other sharp waste

Appendix B – Biological Safety Cabinets

A biological safety cabinet is a ventilated cabinet which uses a variety of combinations of HEPA filtration, laminar air flow and containment to provide personnel, product or environmental protection or protection of all components against particulates or aerosols from biohazardous agents. It is distinguished from a chemical fume hood by the presence of HEPA filtration and the laminar nature of the airflow.

There are three kinds of biological safety cabinets, designated as Class I, II, and III have been developed to meet various research, teaching, and clinical applications.

Class I: Open fronted cabinets with laminar airflow directed away from the user through a HEPA filter. The cabinet may be ducted to exhaust system or may exhaust into the room. Class I cabinets provide personnel and environmental protection, but no product protection. It is similar to the air movement within a chemical fume hood, but has a HEPA filter in the exhaust system to protect the environment.

Suitable for some work procedures at Containment 1 and 2.

Class II types A, B1, B2, and B3: A Class II biological safety cabinet provides personnel, environmental, and product protection. They utilize a re-circulated HEPA filtered vertical laminar airflow within a partially contained cabinet with a glass sash leaving 8-10 inch work opening. The component of the airflow that is exhausted through HEPA filters may be ducted to the outside or re-circulated to the room. Class II cabinets provide a high degree of protection to the worker, the work and the environment.

Suitable for work at Containment Level 1, 2 and 3.

Class III: These cabinets were designed for working with microbiological agents assigned to Biosafety level 4 and provide maximum protection to both the environment and the worker. These enclosed cabinets contain a HEPA filtered supplied air, non-recirculated HEPA filtered laminar flow air over the work surface and hard ducted to outside. The work surface is accessed only through glove ports or sealed air locks. These cabinets provide a totally contained area to protect the worker, the work and the environment.

Suitable for work at Containment Level 1, 2, 3, and 4.

Biological Risk Assessed	Protection Provided			BSC Class
	Personnel	Product	Environmental	
BSL 1-3	YES	NO	YES	I
BSL 1-3	YES	YES	YES	II (A, B1, B2, B3)
BSL 4	YES	YES	YES	III B1, B2

HIGH EFFICIENCY PARTICULATE AIR FILTERS (HEPA):

HEPA filters are using the exhaust and/or supply systems of biological safety cabinets. A typical HEPA filter is a single sheet of borosilicate fibers which has been treated with a wet-strength water-repellant binder. The filter medium is pleated to increase the overall surface area inside the filter frame, and the pleats are often divided by corrugated aluminum separators

HORIZONTAL/VERTICAL LAMINAR FLOW "CLEAN BENCH":

These units discharge HEPA-filtered air across a work surface towards the user. These devices only provide product protection and can be used for certain clean activities, include the dust-free assembly of sterile equipment. These units are not biological safety cabinets and should not bused used when handling cell culture materials or drug formulations as individuals can be exposed to materials which can cause hypersensitivity.

Use of Biological Safety Cabinets:

To help facilitate the registration and certification of any biological safety cabinet, it is requested that you notify the University of Windsor's Biological Safety Cabinet Coordinator (Chemical Control Centre, ext. 3523 Option 4) if a biological safety cabinet is to be ordered, installed, moved or relocated from another institution. The proposed location for the cabinet must be known.

Cabinets acquired from another institution or from another laboratory on campus, must be decontaminated before being moved to University of Windsor laboratories. Documentation will be required.

New cabinets or cabinets which have been moved must be recertified after they are installed in the new location. All Class II biological safety cabinets must be recertified annually by an approved testing service

A University of Windsor Biological Safety Certificate must have been completed for all of the agents that will be used in the cabinet. Facilities must be consulted for installation requirements.

Use of Natural gas and propane is not permitted inside Class II cabinets and is not recommended inside Class I cabinets.

For more information on Biological Safety Cabinets please see the University of Windsor's guidelines on the "Safe operation of Biological Safety Cabinets" (www.uwindsor.ca/biosafety)

Appendix C – References

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