UNIVERSITY OF MANITOBA

Biosafety Manual (2018)

Protecting staff, students, visitors, the public and the environment from hazardous exposure to pathogens.

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1. Intention and Scope

The intention of this Biosafety Manual is to describe the University of Manitoba Biosafety Program for users in the context of the Government of Canada's guiding documents on biosafety. This manual will outline how the University program is designed to meet the imperatives identified in the Canadian Biosafety Standard and Handbook but not restate the information provided in those documents.

The scope of this manual includes the user's operation and administration of labs for all permit levels up to and including Risk Group and Containment Level 2.It expressly does not include labs using biological agents which are Risk Group 3 or 4 (refer to Figures 1 and 2 for risk group and containment level classification at the University of Manitoba, respectively.)This manual also excludes the operation of animal holding facilities and plant pathogen use labs. For additional information regarding agents that belong to excluded groups, contact the University of Manitoba Biological Safety Officer(s).

This Manual will make reference to supporting documents written by the Biosafety Program as well as documents supplied, implemented and controlled by other administrative units of the University and other regulatory bodies. These documents may change without prior notice and may exist outside the control of the Biosafety Program.

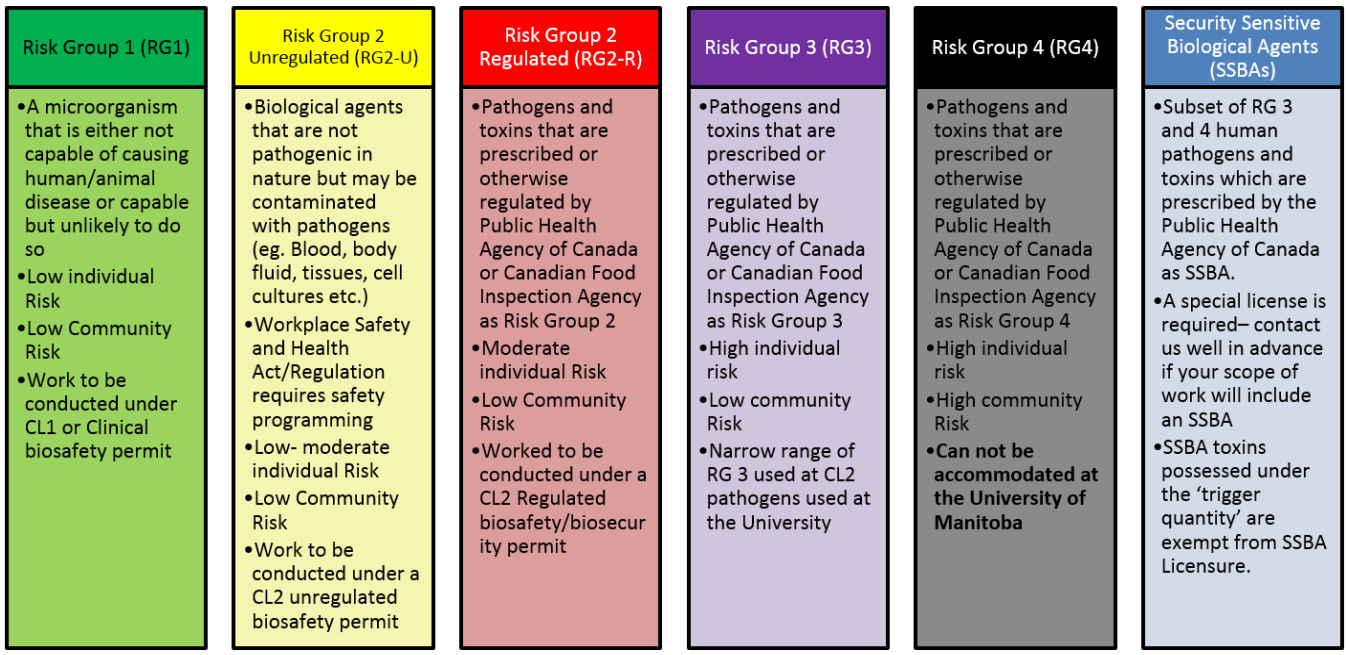

Figure 1: Risk Groups of Biological Agents University of Manitoba

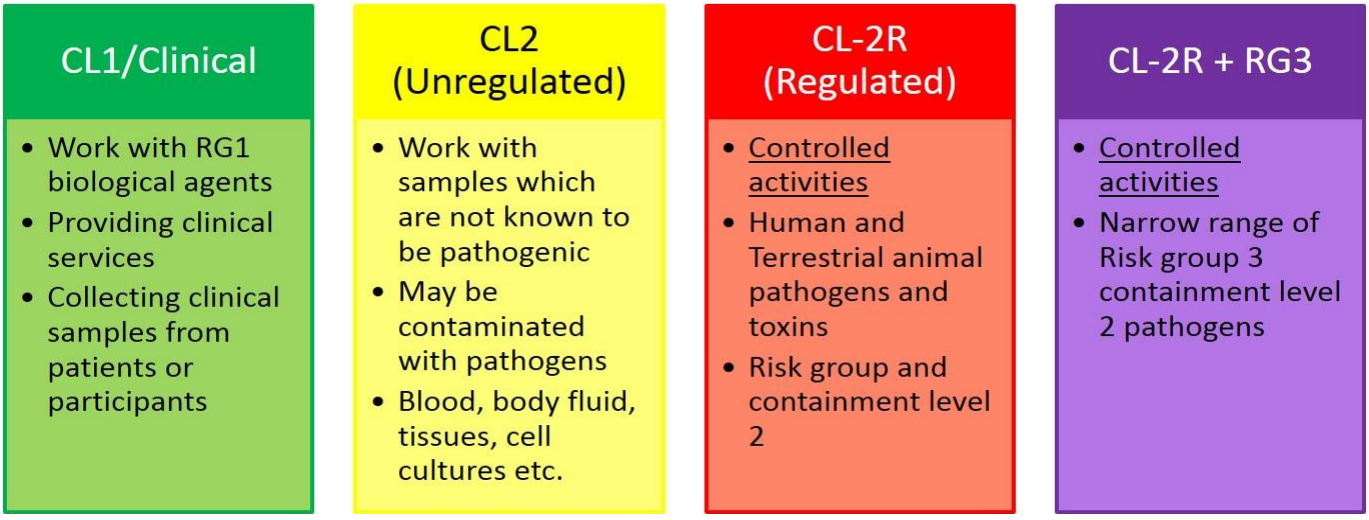

Figure 2: University of Manitoba's Biosafety Program Permit tiers.

2. Governance and Biosafety Program Administration

The Biosafety Program is governed by the University of Manitoba Biosafety Policy and Biosafety Procedure. These are Governing Documents of the University of Manitoba approved by the Board of Governors, Senate and the University Administration. The official versions of these documents are found on the University Governance web site and are updated continuously as changes are approved by the relevant institutional stakeholders. For more information on the University Biosafety Program see the Biosafety Policy (**Appendix 1**), Procedure (**Appendix 2**) and refer to section 4.1 of this manual.

2.1 Human Pathogens and Toxins Act License Holder

The University must appoint a Human Pathogens and Toxins Act License Holder to comply with the Human Pathogens and Toxins Act. The Associate Vice President (Research) acts as the License Holder on behalf of the institution. It is the license holder's responsibility to ensure that the University achieves and maintains compliance with the Human Pathogens and Toxins Act through implementation of the Biosafety Policy and Procedure. Contact the Office of the Vice President (Research and International) for more information regarding the current Associate Vice President (Research) / Human Pathogens and Toxins Act License Holder.

2.2 Biological Safety Officer

The University is responsible for appointing an Institutional Biological Safety Officer(s) to comply with the Human Pathogens and Toxins Act. The Biological Safety Officer(s) is part of Environmental Health and Safety and works on behalf of the License Holder to develop and implement the University Biosafety Program. Contact Environmental Health and Safety for more information regarding the current Biological Safety Officer(s).

2.3 Biosafety Committee

The University is responsible for establishing a Biosafety Committee to oversee the development and implementation of the institutional Biosafety Program. The committee is empowered to advise the License Holder on matters pertaining to Biosafety policy, procedure and any other measures relevant to the administration of the Biosafety Program at the University. Specific duties and details of the committee are outlined in the Biosafety Committee Terms of Reference document (see **Appendix 3**). Contact Environmental Health and Safety for more information regarding the Biosafety Committee.

3. Physical Containment Requirements

Physical containment requirements are established to ensure that labs are built to be compatible with the type of work being conducted.

3.1 Structure and Location

Labs are built or renovated according to the University of Manitoba Chemical Safety Procedure. The Summary of Needs User Guide (see **Appendix 4**) and the Summary of Needs Labs (see **Appendix 5**) are used to document and guide lab design.

It is the responsibility of lab supervisors to ensure that the required essential biosafety equipment which is independent of the building infrastructure is in place and used according to manufacturer's recommendations. The requirements for essential biosafety equipment such as biological safety cabinets or high efficiency particulate air filtered enclosures are determined as part of the Biosafety Program Permit risk assessment.

3.2 Containment Barrier

A lab's containment barrier is what physically prevents unauthorized personnel from being able to enter facilities that use infectious or potentially infectious materials. The barrier is intended to prevent hazardous exposures and illegal use of pathogens. For more information regarding containment barriers refer to the University of Manitoba Biosecurity Manual.

3.3 Access

Information regarding controls for access to bioagent labs is found in the University of Manitoba Biosecurity Manual.

Biohazard warning signage is provided using the University Workplace Hazard Information Placard (WHIP). These placards identify hazardous materials in labs and must be kept up to date to ensure the information provided is current and correct. The WHIP Application Form (**Appendix 6**) is to be completed and submitted to Environmental Health and Safety for production and posting.

Labs must provide space for the storage of personal protective equipment at the entrance to the lab (inside). This includes items such as lab coats, gloves and safety glasses. Personal protective equipment required for entry and work in the lab is determined according to the Biosafety Program Permit risk assessment.

3.4 Surface Finishes and Casework

The University has elected to build all new labs or renovate existing laboratories to be compliant with the requirements for a Containment Level 2 laboratory as described in the current Canadian Biosafety Standard. The intention is to develop laboratories that

are versatile and meet the changing needs of users over the service life of the facility. If needed, versatile labs can be readily updated with a minimum of expense and logistical difficulty. These standards are to be used for all levels of containment.

The various standards create default basic laboratory requirements for laboratories that are not discussed in the Summary of Needs document. Here are some examples of measures that will automatically be incorporated into any laboratory design:

- provisions to post any required signage
- access to emergency showers
- seamless flooring
- 3.0 square meters of free floor space per occupant
- 1 cubic foot per minute of exhaust per square foot of floor space
- chemical resistant countertops
- telephone or alternate emergency communication
- space for storage of personal items outside a laboratory
- food preparation/storage areas are excluded from a laboratory
- study desks are excluded from laboratories
- offices associated with a laboratory must have separate access to hallways, ie. sole access cannot be through the laboratory
- emergency lighting
- requirements for more than one exit
- provisions for separate hand-washing and lab ware sinks

For more information refer to the Summary of Needs User Guide (**Appendix 4**) and the Summary of Needs Labs (**Appendix 5**).

3.5 Air Handling

For labs operating at Containment Levels 1-2R inward directional air flow is not required. Labs are built with air supply designed to meet the American Society of Heating, Refrigerating and Air-Conditioning Engineers Standard 62.1-2010 Ventilation for Acceptable Indoor Air Quality. Air supply at this level is intended to make facilities comfortable for work but cannot be relied upon to control exposures to hazardous or noxious substances. For additional information refer to the University of Manitoba Chemical Safety Manual.

3.6 Facility Services

Handwashing sinks must be placed as close to the exit to the lab as is feasible. The sink must be stocked with hand soap and paper towels to dry hands after washing. It is best practice to have the handwashing sink dedicated to handwashing but in older labs this may be difficult to accommodate. In new builds and renovations a handwashing sink is to be incorporated.

Emergency eyewash and showers need to be installed in labs according to containment zone activities. If large volumes of agents which are infectious, corrosive or otherwise dangerous by splashes to the skin and eyes are used in the lab eyewashes and safety showers may need to be installed directly in the laboratory. If volumes and hazards are reduced it may be appropriate to rely on the eyewashes and safety showers found in the corridors outside the labs. The need for these items of safety equipment are assessed as part of the summary of needs document. Refer to the Summary of Needs User Guide (**Appendix 4**) and the Summary of Needs Labs (**Appendix 5**).

3.7 Essential Biosafety Equipment

Biological safety cabinets are primary containment devices and must be used to control the spread of infectious or potentially infectious aerosols that come from work with unfixed biological agents. Aerosol generating procedures with unfixed biological agents which need to be conducted in a biological safety cabinet include but are not limited to:

- Sonication
- Homogenization

When Risk Group 2 Regulated work (refer to Figure 1 for Risk Group information at the University) is conducted the following procedures must be conducted in a biological safety cabinet (or equivalent containment system or enclosure):

- Tissue dissection
- Cell sorting
- Pipetting
- Opening centrifuge tubes
- Streaking petri dishes
- Changing media
- Vortex mixing

Process equipment must be designed to prevent the release of infectious agents when working with Risk Group 2 Regulated and Unregulated agents. This includes the use of vacuum systems to aspirate Risk Group 2 Regulated and Unregulated agents. Refer to **Appendix 6** Vacuum System Set Up which provides construction guidelines and part numbers to guide users as to how to assemble vacuum systems with aerosol protection.

Autoclaves are the main method to decontaminate biological agent waste before final disposal. Autoclaves must be validated according to the University guiding document for autoclave validation (see **Appendix 7**). As part of the validation process representative loads must be used to verify that the parameters used are effective and that contaminated biological agent waste is not being disposed unsafely. This is

especially important to prevent hazardous exposures to individuals who handle lab wastes outside the lab such as caretaking staff. Recording devices such as autoclave printer systems must be maintained and operate correctly at all times. This is a vital component in verifying that the correct autoclave parameters are met during waste decontamination loads and that untreated waste is not leaving the lab facility.

Two way communication systems are to be provided in the lab facility to ensure that workers can contact emergency assistance should the need arise. This can take the form of a landline phone or two-way radios. Cellular phones are also acceptable however; their use in the lab is strongly discouraged except in situations where it becomes necessary to call for emergency assistance. Cell phone/device use is to be limited to paper work stations only. Casual use of a cell phone in a lab setting can lead to contamination of the device and possible lab acquired infections both in and outside the lab. It is possible that people who don't work in the lab could experience a hazardous exposure to a pathogen when contaminants are transported out of the lab.

4. Operational Practice Requirements

This chapter describes the operational practices in place at the University designed to comply with those required by the Canadian Biosafety Standard. Operational practices are intended to mitigate risks associated with handling or storing pathogens, toxins, or other regulated infectious material, including infected animals through the use of administrative procedures.

4.1 Biosafety Program Management

4.1.1 Administrative Controls

The University of Manitoba Biosafety Policy, Procedure, Biosafety and Biosecurity Manuals define and describe the implementation of the Plan for Administrative Oversight for Pathogens and Toxins in a Research Setting.

The University appoints a Biosafety Officer(s) to fulfil the duties identified in the Standard. Duties specified in the standard relevant to the University include:

- Verifying accuracy and completeness of applications pertinent to government regulations
- Communicating with Public Health Agency of Canada and Canadian Food Inspection Agency on behalf of the University License Holder
- Promoting and monitoring compliance with applicable legislation and guiding documents at the University
- Notifying Public Health of inadvertent possession of pathogens not authorized under the University License

- Conducting biosafety and biosecurity inspections of facilities authorized under the University License and reporting the findings
- Advising the License Holder of non-compliance issues
- Developing the Biosafety and Biosecurity Program
- Investigating incidents involving biohazardous or potentially biohazardous agents

4.1.2 Biosafety Permits, Risk Assessment and Planning

Before any work with biological agents of any Risk Group is conducted a Biosafety Program Permit must be reviewed by the Biosafety Committee and approved by the chair. When work with biological agents is concluded all facilities must be decontaminated, all samples must be transferred to another permitted user or destroyed. When decommissioning is complete a Biosafety Permit Declaration of Decommissioning (see **Appendix 8**) must be submitted to the Biosafety Officer(s) to terminate the permit. If a permit holder fails to decommission appropriately the responsibility falls to their department head.

Overarching biosafety risk assessments are conducted on a user-by-user basis through the Biosafety Program Permit system. During the Program Permit application process an applicant will document their lab activities, the agents they use, training and measures that are taken to reduce risks and protect the safety of workers.

Environmental Health and Safety administers the Biosafety Program Permit system on behalf of the committee. The program provides access and consultation services to users to assist them in submitting their applications. Refer to the Biosafety Program web site for additional information.

Biosafety Program Permits are submitted for review by the Biosafety Committee. Permit classifications are assigned during the application and review process. . Biosafety Program Permits are categorized as summarized in Figure 2. Labs must be certified (Facility Certification) to a level which can accommodate the risk level identified in the Biosafety Permit application.

4.1.3 Biosafety Manuals

This document fulfils the requirement for an Institutional Biosafety Manual on behalf of the University. It describes how lab managers should proceed in the University Biosafety and Biosecurity Program to achieve compliance under our License and Program requirements.

Bioagent use laboratory facility managers must maintain Biosafety and Biosecurity Program Permit information which is relevant and specific to their facilities. This documentation must focus on the actual biological agents and procedures used in the facility as well as safe work and security procedures used to prevent hazardous

exposures and illegal use of biological agents. This documentation fulfils the requirement for individual facilities to have a Site Specific Biosafety Manual as described in the Canadian Biosafety Standard.

4.1.4 Bioagent Lab/Facility Certification

Bioagent Lab/Facility Certifications categorize facilities into the following Containment Levels:

- Clinical spaces (for work consistent with clinical services provided by a health care practitioner)
- Containment Level 1 (for non-pathogenic work)
- Containment Level 2 (for work with agents not known to be pathogenic but which may contain pathogens as contaminants)
- Containment Level 2 Regulated (for work with regulated pathogens)

The Biosafety Officer(s) documents a lab's Containment Level based on documentation submitted by the applicant and a physical inspection of the proposed facility. Refer to the Biosafety Program web site for additional information on facility certification. To arrange for a facility certification submit a PI Lab Registration Request form (see **Appendix 9**) and a Biosafety Officer(s) will arrange a time to meet with you to complete the facility certification application and inspection.

4.1.5 Biosecurity

The University Biosecurity Plan is laid out in the Biosecurity Manual as released by the Biosafety Officer(s). Refer to that document for additional information.

4.1.6 Respiratory Protection

The University Respiratory Protection Program is administered by Environmental Health and Safety. Respirators are personal protective equipment used to prevent the inhalation of hazardous particulates in the context of biosafety. A medical questionnaire must be completed (see **Appendix 10**). After the questionnaire is complete representatives of Environmental Health and Safety will conduct a fit test to ensure the respirator fits correctly and will not leak while in use. Contact the Environmental Health and Safety General Office for more details.

4.1.7 Standard Operating Procedures

Standard operating procedures which are developed for use institution-wide are attached as appendices to this manual. Others are developed which may not apply to all labs but help standardize procedures used by a specialized core of users. These procedures are updated and added as needed. Refer to the appendices noted as SOP Appendix #. Researchers may use agents or techniques which are unique to their programs and are not adequately covered by existing institutional standard operating

procedures. In those cases researchers are responsible for writing and implementing their own standard operating procedures which specifically state the risks and safety procedures which must be followed to reduce risks and prevent injuries.

4.1.8 Inspections

Biosafety inspections at the University are implemented in two parts. Part one is lab self-inspections for which a self-inspection checklist has been provided (see **Appendix 11**). This checklist is to be used by labs as a guide to inspecting their own facilities and documenting the inspection in a format which can be provided to inspectors upon request. The maximum self-inspection interval is one year. On an annual basis this checklist must be completed and held as part of the lab's facility documentation.

Part two is compliance inspections conducted by Biosafety Program or Environmental Health and Safety representatives. Facilities under review are normally scheduled for inspection ahead of time and facility supervisors or their knowledgeable designate are asked to be present to accompany the inspectors. Inspection findings will be presented verbally to the facility supervisor or designate at the time of inspection. After the inspection is completed the facility supervisor will be able to access the written report through their Environmental Health and Safety Assistant database account. Responses to the inspection are filed through the database web interface. Records of inspections conducted by the Biosafety Program or Environmental Health and Safety will be maintained in the Environmental Health and Safety Assistant database for a period as prescribed by Public Health Agency of Canada Regulation. These historical records are also available to lab supervisors through their database accounts.

Be advised that any bioagent facility may be subject to federal compliance inspections at any time regardless of their scope of work.

4.2 Medical Surveillance Program

A medical surveillance program requires that lab acquired infections or hazardous exposures to a pathogen or toxin are reported to an internal authority. This is fulfilled by the accident reporting procedures mandated at the University. All workplace injuries must be reported using the Notice of Injury Form (see **Appendix 12**) and the Incident Investigation Form (see **Appendix 13**). These investigation procedures are not in any way intended to punish workers or supervisors. The intent of the procedure is to document the occurrence and prevent reoccurrence in the future. This is not a punitive process.

In the event of a lab acquired infection or hazardous exposure to a pathogen the facility supervisors or workers must report the incident to the Biosafety Officer(s) for investigation by the Biosafety Committee. The report must be made as soon as possible ***after*** the immediate medical needs of the worker have been met. The

Biosafety Officer(s) will assist the reporting supervisor in the investigation process and the preparation of the Incident Investigation Form for review by the Biosafety Committee. It is the duty of the Biosafety Officer(s) to report the incident to the Public Health Agency of Canada if it is found that a lab acquired infection or exposure to a pathogen has occurred. Reporting does not identify specific individuals or facilities.

The necessity for an emergency medical contact card will be assessed at the time of application for a Biosafety Program Permit. Emergency medical contact cards are needed to summarize important information regarding higher risk pathogens or toxins used in a project.

4.3 Training Program

A training needs assessment has been conducted as part of the Biosafety Program development process and consists of the following elements:

4.3.1 Generic Biosafety Training

This training orients workers on the concepts of biological safety and security. It employs a combination of the training modules provided by the Public Health Agency of Canada and a section specific to Biosafety topics at the University. This generic training must be completed before workers begin work with biological agents of any class at the University. This training is assessed annually and refresher training is provided when the training has been deemed obsolete due to changes in the institutional program or the regulatory environment implemented by relevant government agencies.

4.3.2 Site Specific Biosafety Training

Generic Biosafety Training fulfils the basic requirements for safety training in biological agent labs but does not include sufficient detail to satisfy all requirements. Site Specific Biosafety Training must be provided to workers which includes the details of the agents and techniques in use. The Laboratory Safety Checklist for New Lab Personnel includes (see **Appendix 14**) a Site Specific Biosafety Training template which can be used to guide facility supervisors in establishing their Site Specific Training. Workers must be assessed for competency by qualified lab staff or supervisor until they are deemed competent to conduct lab activities independently. Records of training and the assessment of competency must be documented in writing.

4.3.3 Biosafety and Biosecurity Awareness Information

This document (see **Appendix 15**) is provided to support staff who provide services in lab spaces but don't work directly with biological agents. This would include trades workers and administrative staff who have access into bioagent lab facilities. The document is intended to orient those workers on how to interpret the door signs posted at the entrance to the labs and give basic information about biohazards.

4.3.4 Animal User Training Course and Wet Labs

Workers who work with animals are trained to handle animals in the online Animal User Training Course and given practical training in Wet Lab sessions. This does not replace any of the training identified above. The Laboratory Animal Allergy and Zoonoses training and Animal Biosafety Level 2 training are implemented and provided by the Office of Research Ethics & Compliance (Animal Care). Contact that office for additional information.

4.4 Personal Protective Equipment

Minimum personal protective equipment required for safe entry into the bioagent lab must be housed at the entrance to the lab facility so workers can don the equipment before they enter the lab and become contaminated. Personal protective equipment required for use in a Containment Zone must be dedicated to that zone. Personal protective equipment must not be worn in public spaces and should be removed near the exit of the lab zone in such a way that contamination of skin and hair are kept as low as possible. Even when gloves are worn, hands are to be washed before leaving the lab to prevent contamination of public spaces.

4.4.1 Minimum Personal Protective Equipment for Trades and other Support Staff

In order to enter a bioagent lab at any Containment Level the minimum basic personal protective equipment includes full shoes (closed toe and heel) and pants or a garment which effectively covers the legs. This basic level of protection is intended to prevent splashes from directly contacting the skin in the event that a hazardous agent is dropped or spilled on the floor. This level of protection is adequate for trades or administrative workers entering the lab to conduct a specific short-term task. This includes trades workers even when they are working for extended periods in the lab since areas which are being serviced by those workers must be decommissioned according to the University Decommissioning Process. That process must render the immediate area in which trades workers work safe and free from hazardous products. It is however always prudent to offer these workers the use of a clean lab coat when they enter the facility as an added measure of protection.

4.4.2 Minimum Personal Protective Equipment for Lab Workers

Lab workers are expected to wear a lab coat which is donned at the entrance to the lab facility in addition to the minimum personal protective equipment identified above. This additional level of protection is intended to protect against spills and splashes to the upper body in the context of their work which is made more likely by the length of time these workers spend working in the lab environment. Lab coats should be selected, used and cleaned according to the University Lab Coat Selection, Use and Care for Work with Biological Agents (see **Appendix 16**)

4.4.3 Additional Personal Protective Equipment for Lab Workers

The necessity for additional personal protective equipment for lab workers is established as part of the Biosafety Program Permit assessment. Additional equipment can include but is not limited to:

I. Face protection in the form of safety eyewear or a face shield to be used when there is a risk of exposure to splashes or flying objects. Instances where this should be considered is when liquids are being poured, aspirated, pipetted or injected.

II. Disposable gloves made of a moisture resistant material are to be worn whenever handling biological agents to prevent contamination of the hands. Most commonly used are vinyl or nitrile disposable gloves. Latex should be avoided as it may cause hypersensitivity reactions (skin rashes) in some workers. These reactions break down the skin barrier and reduce resistance to infection by pathogens.

III. Respiratory protection is not normally used in the lab setting to prevent the inhalation of hazardous aerosols. In the majority of circumstances, a biological safety cabinet should be used to control exposure to aerosols from the use of biological agents. There are instances where the equipment needed for procedures may be incompatible with the use of a biological safety cabinet. In those cases a fit tested respirator (see section 4.1.3 above) can be used. The minimum level of protection which can be used is an N95 respirator. This respirator looks like a dust mask but it is designed to meet a quantitative standard of protection (eliminate 95% of aerosols from inhalation by the wearer). If N95 is not printed on the respirator it does not meet this standard and will not adequately protect the worker. N100 respirator cartridges are also available for half face respirators (rubber gas masks). These are designed to remove 100% of particulates from air inhaled through the cartridges. These types of respirator cartridges can also be used in powered air purifying respirators but are encountered very rarely in the academic research setting.

4.5 Entry and Exit of Personnel, Animals and Material

The entrance to all lab facilities authorized for the use and storage of biological agents on University property shall be signed using the Workplace Hazard Information Placard. This system requires that users request a sign (see **Appendix 17**) and the Environmental Health and Safety administer the system and post the sign once complete. The signage shall identify the room, entry requirements, hazardous materials which may be present in the lab, indicate the Containment Level and emergency contacts.

Personal clothing is to be stored separately from the personal protective equipment used in lab spaces. This is intended to help prevent the contamination of personal clothing such as coats, sweaters or bags by lab coats which have been used for work with biological agents or other hazardous products. For example; do not store your used lab coat in a locker with your coat and backpack. In a previous incident, the investigation found that storing used lab coats in close proximity to personal clothing lead to a serious (reportable) lab acquired infection. For the same reason, personal belongings are to be kept in an area separate from those used for work with biological agents. Best practice is to store these materials in a locker or office.

4.6 Work Practices

The work practices identified in the Canadian Biosafety Standard are prescriptive and should be followed accordingly. These practices will not be restated here but can be reviewed in **Appendix 18** of this manual.

4.7 Animal Work Considerations

Animal work considerations are not included as part of this manual. Refer to the Animal Care Occupational Health Program or contact the Office of Research Ethics and Compliance (Animal Care) for details regarding safety in animal research.

4.8 Decontamination and Waste Management

The goal of decontamination and waste management is to ensure that no infectious agents leave the lab environment in such a way that they can pose any threat to individuals outside the lab environment. All waste should be disposed of as to not pose a danger to the public or the environment. This is one of the most crucial aspects of biosafety and the intent of decontamination and waste management must be carried out effectively at all times by all users.

4.8.1 Biological Waste Disposal Standard

All biological agent waste must be disposed according to the University Biological Waste Disposal Standard (see **Appendix 19**). Waste handling procedures at the University are standardized to ensure that waste disposal systems in the labs are consistent and meet the procedures established for waste handling workers on campus. Waste handling workers include Caretaking Services and Environmental Health and Safety. Deviation from the established procedures increases the risk of injury to workers in the waste disposal stream and can result in refusal of services.

Careful consideration to the methods used for decontamination of waste must be given to ensure that the method used is effective and appropriate. Guiding information for chemical disinfectants is provided in manufacturer's instructions or product inserts that identifies the types of biological agents which can be killed by the product. The manufacturer's information will also indicate the concentration and contact time that

needs to be used for maximum effect. This information must be incorporated into the decontamination and disinfection procedures used in the lab. In some cases such as when disinfectants are being used in a manner not described by the manufacturer the effectiveness of the process used must be validated to ensure that waste is disinfected fully before disposal.

The necessity for using bleach as a disinfectant should be reviewed because the type of plumbing pipe used for waste water at the University is susceptible to degradation by bleach. Autoclaving is the preferred method for decontamination of liquid waste since it prevents degradation of the pipes and gives better control and documentation of the waste decontamination process.

4.8.2 Autoclave Validation

Autoclaves are to be used and validated according to the Autoclave Validation for Biological Waste guiding document (see **Appendix 7**).

4.8.3 Room Decommissioning

Prior to releasing a lab to a new user or for major renovation, the lab must be decontaminated to render it safe for contractors to enter or for new users to take control. The intention is that nothing should be left behind to endanger contractors or subsequent users. The U of M Decommissioning Form for Laboratories or Rooms guides users through the process (see **Appendix 20**).

4.8.4 Area Decommissioning

If an area in an active lab requires maintenance or repair but does not warrant full room decommissioning a Laboratory Hazard Clearance Declaration (see **Appendix 21**) should be completed. The intention of an area decommissioning is to clear hazards around the immediate area which will be serviced to protect trades workers from hazardous exposures in the lab.

4.8.4 Equipment Decommissioning

Equipment must be decontaminated prior to service or disposal. The U of M Decommissioning Form for Laboratory Equipment (see **Appendix 22**) guides users through this process. The intention is that hazardous waste is not being released into the environment and service workers are not being exposed to hazardous agents originating in the lab.

4.9 Emergency Response

Emergency procedures are established to help limit the effects of hazardous incidents in the lab. Workers must be trained and refreshed on emergency response plans so they are prepared to implement them when an incident occurs.

4.9.1 Institutional Emergency Response Plan

The University's Emergency Response Plan has been developed by Risk Management (see **Appendix 23**). An Emergency Quick Reference Guide has also been developed by Risk Management (see **Appendix 24**). These emergency response plans are general for the University and intended to deal with the most likely emergencies experienced by the institution as a whole. Specific to Biosafety, a Biological Spill Response document has been prepared to guide users on the safe containment and decontamination of spills of biological agents (see **Appendix 25**). Individual labs may be required to establish their own emergency response plans as part of their Biosafety Program Permits if the nature of their work is unique and cannot be effectively handled according to the University's Emergency Response Plans. Caretaking services workers are under no circumstances instructed to clean up spills of biological agents in lab facilities. Cleaning up spills is the responsibility of the lab staff assigned to the lab facility in which the spill occurs.

4.9.2 Biohazardous Incident Response Plan

Incidents involving biological hazards are investigated and reported according to the medical surveillance plan information provided above. All qualifying incidents of verified or suspected lab acquired infections will be reported to the Public Health Agency as per the Human Pathogens and Toxins Act/Regulation requirements. Incidents may also be reported to agencies such as the Regional Health Authority, Provincial Health or Manitoba Workplace Safety and Health when required.

4.10 Records and Documentation

Records must be kept as proof that a bioagent lab is independently complying with internal policies and procedures as well as external regulatory imperatives. Documentation enables facilities to provide proof of compliance to regulatory inspectors upon request. These records are to be kept electronically, paper copies are strongly discouraged.

4.10.1 Training Records

Two types of training are required at the University. Generic Biosafety Training is the first training required and is provided by the Biosafety Program. Upon completion, the training will be entered into the Environmental Health and Safety Assistant Database by program staff. Those records are available to users through the Environmental Health and Safety Assistant database. All workers must complete Generic Biosafety Training as provided by the program.

Site-specific biosafety training must be documented in writing by the bioagent facility supervisor or designated individual. See the Training Program section above for additional details.

4.10.2 Inventory Records

Inventory information for biological agents used in facilities must be recorded in the Environmental Health and Safety Assistant database as part of the permit application process. Doing so facilitates the program based risk assessment process and enables the Biosafety Officer(s) to access inventory information which may be required by external regulators on an institution wide basis. Inventory information must be kept up to date including the receipt of new agents and the final disposal of agents no longer required. If a new agent is described as part of a biosafety permit application it must be listed in the inventory even if it has not been received yet. It can be noted as pending receipt in the inventory entry and serves as part of a facility's declaration of intent to use that particular agent.

4.10.3 Inspection Records

Records of inspections conducted by on-site staff, Biosafety Program representatives or external regulators must be kept on file. Self-inspections conducted by on-site staff must be kept as part of the lab compliance documentation and in such a format as can be provided upon request by either institutional or federal regulatory inspectors. The self-inspection checklist (Appendix #) should be used to document these self-inspections.

4.10.4 Facility and equipment Maintenance Records

Certification records for biological safety cabinets must be maintained as part of the facility user's compliance documentation and be available for review by compliance inspectors. These certificates are provided by the biological safety cabinet certifier at the time of service and EHS will be responsible for updating the recertification dates in the EHSA database.

Records pertaining to the maintenance of bioagent labs must be kept as part of the facility compliance documentation. It is sufficient to keep the confirmation number provided by Physical Plant at the time a work order is placed, copies of the work orders and any pertinent documentation that is available from Physical Plant at the time of inspection.

4.10.5 Biohazardous Agent Transfer Notification Records

The transfer of pathogens regulated by Public Health or Canadian Food Inspection Agency must be recorded using the Biohazardous Agent Transfer Notification (see **Appendix 26**) or an equivalent document used at another licensed facility. This notification must be kept as part of the bioagent lab documentation for a period of not less than 2 years as per the Canadian Biosafety Standard.

4.10.6 Incident Investigation Records

Any records or documents pertinent to the investigation of an incident related to hazardous exposures involving biological agents must be kept as part of the facility documentation. Those records must be maintained for no less than 10 years. These documents may include notice of injury reports, incident investigation forms or any document used to support these processes. Refer to the Medical Surveillance section above.

4.10.7 Summary of Documents and Retention Time

Table 1: Summary of Documents and Retention Time

Record	**Documents**	**Document Retention Period**
Training	• Generic Biosafety Training is available through UMLearn • Site specific training template can be found The Laboratory Safety Checklist for New Lab Personnel includes (see **Appendix 17**)	5 Years
Inventory	EHSA Database PSDS to be uploaded/kept electronically	5 Years
Inspection	• EHS-conducted inspections available through EHSA database • Self-inspections (Appendix #)	5 Years
Facility and equipment maintenance	BSC certification reports Equipment maintenance documentation Physical Plant	5 Years
Bioagent Transfer Form	Biohazardous Agent Transfer Notification (see **Appendix 26**)	5 Years
Incident Investigation	Notice of Injury Form (see **Appendix 15**) and the Incident Investigation Form (see **Appendix 16**)	10 years

5. Performance and Verification Testing Requirements

Performance verification demonstrates that procedures used in facilities are effective for their intended purpose.

5.1 Verification of Facility Performance

Facility performance is verified by conducting regular visual inspection of the lab areas. That inspection must verify that the facility is in good repair, waste is handled and packaged appropriately and that safety and containment systems are in good working condition. Refer to the section on inspections above.

5.2 Verification of Autoclave Performance

Autoclave performance must be validated and documented according to the University guiding document on autoclave validation (see **Appendix 7**).

5.3 Verification of Biological Safety Cabinet Performance

Biological Safety Cabinets at the University are tested and certified by an external contractor according to NSF/ANSI 49. Cabinets must be certified before use, when received or moved, and must be decontaminated before service or being moved (see **Appendix 27**).

Other Web Resources and References

Lab Safety/Standard Operating Procedures

- Sharps Safety
- Post-Exposure Protocols for Fort Garry and Bannatyne Campuses
- Biological Agent Incident Response & Reporting Procedure
- Working Alone or in Isolation
- Bioagent Transport Procedure for Inside and Outside (ie Public Space) Containment Zones

Risk Assessments

- Working with Cell Cultures
- Working with Human Blood Tissues and Body Fluids
- Microorganism Risk Assessment Worksheet
- Working with Lentiviral Vectors
- rDNA Risk Assessment Worksheet
- Dual Use Potential Risk Assessment Standard – 2018

Public Health Agency of Canada

- Human Pathogens and Toxins Act (HPTA)
- Human Pathogens and Toxins Regulation (HPTR)
- Canadian Biosafety Standards 2nd Edition (CBS)
    - CBS App for Android and iOS
- Canadian Biosafety Guideline: Containment Level 1: Physical Design and Operational Practices
- Canadian Biosafety Guideline: Developing a Comprehensive Biosecurity Plan
- Canadian Biosafety Guideline: Veterinary Practices: Physical Design and Operational Practices for Diagnostic Activities
- Canadian Biosafety Handbook 2nd Edition
- Pathogen Safety Data Sheets (PSDS)
- List of Security Sensitive Biological Agents and Toxins (with trigger quantities)
- HPTA Schedule 1 (regulated toxins)
- HPTA Schedule 2 (Risk Group 2 Human Pathogens)
- HPTA Schedule 3 (Risk Group 3 Human Pathogens)
- HPTA Schedule 4 (Risk Group 4 Human Pathogens) **Prohibited at the U of M**
- HPTA Schedule 5 (Prohibited Human Pathogens and Toxins)

Canadian Food Inspection Agency (CFIA)

- Animal Pathogen Safety Data Sheets
- Importing Animal Pathogens
- Aquatic Animal Pathogens
- Plant Pest Standards and Information

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