

ADVENTURER EXPLORER TRAILBLAZER REBEL PIONEER CREATOR DEFENDER ADVENTURER EXPLORER TRAILBLAZER
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Generic Biosafety Refresher Information



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Introduction

This training was offered from April 19th, 2016 - June 30th 2017 to update the Generic Biosafety Training provided to permitted Biological Workers prior to April 2016.

As of July 2017, those with no/out-of-date training will need to complete the current version of Generic Biosafety Training which includes this material.

This presentation is as an informational resource ONLY, no training credit will be provided for this presentation.



Overview and Background

On December 1st 2015

- The Human Pathogens and Toxins Act ([HPTA](#)) and Regulation ([HPTR](#)) came into force.
- The [Canadian Biosafety Standards](#) (CBS) 2nd ed. is the guiding document for compliance.
- The Human Pathogen Import Regulation and the Canadian Biosafety Standard and Guidelines 1st ed. were repealed.



How is the new system different?

- We are all in the same boat as far as Public Health Agency of Canada (PHAC) is concerned
- Previously, principle investigators (PIs) were regulated individually
- The University of Manitoba holds a license which covers all facilities which use human and terrestrial animal pathogens and toxins



<http://www.kenmorestamp.com/canada-blunose>



Licensing Framework

Authority

- To undertake controlled activities (work with pathogens and toxins) the facility must hold a license issued by the Public Health Agency of Canada.
- License holder is Dr. Gary Glavin – Associate Vice President of Research.

Service Providers

Umanitoba.ca/biosafety
biosafetyprogram@umanitoba.ca

Steven C. Cole - Biosafety Officer

- Support the license holder
- First point of contact for PHAC
- Develop and support the institutional biosafety program
- Ensure the program framework meets regulatory compliance
- Provide services to lab clients
- Intake of BPAC's, Biohazardous Agent Transfer notifications and other administrative documents
- Animal Care Occupational Health
- Inspection services

Vanessa L. Pinto - Biosafety Specialist

- Partnered with the Biosafety Officer
- Serves as alternate when BSO is not available
- Support and administer the Biosafety Permit Program
- Biosafety Training
- Inspection and client services

Darrin J. Jolicoeur - Administrative Assistant

- UMLearn Access
- BPAC submissions and Pre-reviews
- BSAC admin support

Leona Page – EHS Coordinator



Biosafety Permits vs. Biosafety Project Approval Certificates

Biosafety permit

- Register PI's workers and their facilities
- Documents a PI's overarching risk assessment
- Verifies routine documentation
 - eg. Personnel training, BSC Certifications, bio-inventory etc.
- Reviewed by the BSO/Biosafety Specialist

Biosafety Project Approval Certificates

- Documents a PI's project specific risk assessment
- Establishes any project specific safety measures required beyond SOP at the U of M
- Provides a more detailed review of work compared to the permit
- Reviewed by the Biological Safety Advisory Committee
- Provides a mechanism to identify, review and control potential bio-weapons research



University of Manitoba: Tiered Permit System

4-tiered system of containment levels (CL) depending on the risk group (RG) of biological agents in use.

| CL1/Clinical | CL2 (Unregulated) | CL2-R (Regulated) | CL3 |
|---|--|---|---|
| <ul style="list-style-type: none">• Work with RG1 biological agents• Providing clinical services• Collecting clinical samples from patients or participants | <ul style="list-style-type: none">• Work with samples which are not known to be pathogenic• May be contaminated with pathogens• Blood, body fluid, tissues, cell cultures etc. | <ul style="list-style-type: none">• <u>Controlled activities</u>• Human and Terrestrial animal pathogens and toxins• Risk group and containment level 2 | <ul style="list-style-type: none">• <u>Controlled activities</u>• Narrow range of Risk group 3 containment level 2 pathogens |



What is controlled by PHAC?

- Human and terrestrial animal pathogens
- Toxins
- Security Sensitive Biological Agents

What is excluded by PHAC?

- Pathogens in their natural environment
 - Eg. Blood/tissue samples, soil samples
 - It becomes controlled activity when you manipulate the pathogen directly

What is controlled by Canadian Food Inspection Agency (CFIA) ?

- Foreign animal diseases
- Aquatic animal pathogens
- Bee pathogens
- Animal blood, body fluids, tissues and by-products



Transfer of Biological Agents:

HPTR requires shipping and receiving of all regulated materials must be reported to the BSO

REMINDER: RG1 biological agents and Pathogens/toxins found in their natural environment (i.e. blood/tissue samples, soil samples etc.) are exempt from licensure and this transport documentation.

International transfers

Commercial suppliers:
An electronic copy of the shipping confirmations/receipts must be submitted to the BSO

Int'l Institutes:
Biological Agent Transfer Form filled out and submitted to the BSO

Domestic transfers

(eg. Between Canadian universities)

Biological Agent Transfer Form must be filled out and submitted to the BSO

Transfers within the University

No form or notification necessary!

If you are unsure of the PHAC regulatory status of your bioagent, [contact us!](#)

For ALL transfers, update of EHSA bio-inventory is required!



Reporting of lab acquired infections (LAIs)

HPTA requires that LAIs and suspected LAIs are reported

- This is now a Duty of Law.
- If a licence holder has reason to believe that an incident involving a human pathogen or toxin... has, or may have, caused disease in an individual, the licence holder shall, without delay, inform the Minister of the incident and provide the Minister with the following information that is under the licence holder's control:
 - **(a)** a description of the incident;
 - **(b)** the name of the human pathogen or toxin; and
 - **(c)** any other information relating to the incident that the Minister may require.
- The BSO is required to report incidents to PHAC (incident description only) within 30 days

Reporting at the U of M
can be found here:

[Biological Agent
Incident Response and
Reporting Procedure](#)



Lab inspections/audits (internal/external)

- The regulations require that an inspection program must be in place to verify that biosecurity and biosafety program imperatives are being met.

Inspections/audits
will include:

[PI lab self-inspection](#)

[EHS lab inspection](#)

PHAC
facility
inspection
(within 5
years)

Please conduct
a self-inspection
at least once a
year and keep
this as part of
your lab
documentation



Annual Review of Training

University of Manitoba

- Updated online training released April 2016
- U of M Online Biosafety training can be found here:
 - [Generic Biosafety Training](#)

Site-specific training

- Critical responsibility of the permit holder
- Requires a training plan and documentation of training
- [Template for site-specific training](#)



Security Sensitive Biological Agents (SSBA)

Subset of human pathogens and toxins that pose an increased biosecurity risk due to their potential for use as a biological weapon.

The use of these agents requires a **HPTA Security Clearance****.

Intended recipients of SSBA who **do not receive them within 24h** of expected arrival must make reasonable efforts to:

locate the SSBA

inform the BSO without delay

provide the BSO with any relevant information.

****** Some SSBA can be used without additional permissions, however if use exceeds designated 'trigger volume' a HPTA Security Clearance is required! Eg. Cholera toxin has a trigger quantity of 20mg



Biosecurity - Containment Zones

To facilitate and document compliance with PHAC regulations, the Biosafety and Biosecurity Program will follow up with departments that use regulated pathogens to establish containment zones.

- Applies for **CL2 Regulated** and **CL3** permitted spaces.
- Emphasis is on security
- Prevent the theft loss and intentional misuse of pathogens, toxins and technologies that could be used to propagate pathogens
- Definition of zone (rooms vs floors)
- Zone requirements (closed doors and locked when unattended)



[dreamstime.com](http://www.dreamstime.com/stock-photography-vault-door-image1348962)

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Biosecurity Plan Requirements for Regulated Spaces (CL2-R & CL3)

| Requirements | Compliance |
|---|---|
| i. Physical Security | Doors to be locked after hours/working alone Granting and revoking access procedures |
| ii. Personnel Suitability and Reliability | University SOPs for hiring graduate students, staff and faculty |
| iii. Agent Accountability | EHSA Database vs. on site inventory info |
| iv. Emergency Response | U of M's Emergency Response plan Site-specific response plan |
| v. Information Security | Update passwords for database |



In Summary

- Pathogen/toxin work requires a regulated permit (CL2-R and CL3) with appropriate biosecurity
 - Excludes pathogens found in their natural environment (CL-2)
- Transport of pathogens/toxins must be reported
- LAIs must be reported
- Bio-inventory, biosafety permits and on-site documentation to be maintained and updated as required

When in doubt..



<http://www.laclosette.com/wp-content/uploads/keep-calm-and-ask-us-1-5.png>



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