

Implementation of the requirements of the Human Pathogens and Toxins Act

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Objectives

- Understand the requirements of the Human Pathogens and Toxins Act (HPTA)
- Assess the impact on the PHL safety management system
- Compare the requirements of the Human Pathogens Importation Regulations (HPIR) with the requirements of the HPTA
- Register the multi-site public health laboratories
 - Twelve laboratories throughout Ontario

Public health laboratories



Understand the HPTA requirements

- Attendance at several consultations on Bill C54
 - Saskatchewan
 - Toronto
 - Teleconferences

Major requirements of the Act

- Applicable to all facilities with RG 2, 3 or 4 pathogens
 - Use, import, transfer, storage, destruction
- Prohibitions – possession of specific pathogens
 - Smallpox
- Reporting of incidents resulting in Laboratory Acquired Infection (LAI)
- Compliance with Laboratory Biosafety Guidelines (LBG)
- Security screening
- Penalties for violation
- Replace the HPIR

PHL safety management system



PHL Safety elements / HPTA alignment

- Safety policies with assigned roles and responsibilities
- Designated safety officer and safety committee
- Documented laboratory safety manual
- Biosafety and biosecurity program aligned with LBG
- Risk assessment and hazard identification
- Various levels of hazard controls in place

PHL Safety elements/ HPTA alignment

- Biohazardous waste management
 - All waste decontaminated prior to release from laboratories
- CL2 and CL3 physical and operational requirements in place
- Systematic accident/incident reporting and investigation
- Specific staff training
- Medical surveillance
 - No record of laboratory acquired Infections
- Emergency response and business continuity planning

PHL compliance with HPIR

- Approximately 168 import permits maintained
- Centrally coordinated and maintained at Toronto PHL
- PHAC and CFIA facility compliance for all PHL
- All import permits listed as part of document controlled system
- Inventory of pathogens maintained at each PHL

PHL document control system

Custom Filter - Documents List - Q-Pulse

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Register: Active Documents By Type

Document Type

Document Number Document Title Revision Active Date

Document Type: SAFETY PROGRAM\IMPORT PERMITS

Document Number	Document Title	Revision	Active Date
F-IP-C-001	Public Health Laboratory - Toronto, Import Permits CFIA	002	15/03/2010
F-IP-C-002	Public Health Laboratory - Toronto, Import Permits PHAC	002	15/03/2010
F-IP-H-001	Public Health Laboratory - Hamilton, Import Permits	001	21/12/2009
F-IP-K-001	Public Health Laboratory - Kingston, Import Permits	001	21/12/2009
F-IP-L-001	Public Health Laboratory - London, Import Permits	001	21/12/2009
F-IP-M-001	Public Health Laboratory - Timmins, Import Permits	001	21/12/2009
F-IP-P-001	Public Health Laboratory - Peterborough, Import Permits	001	21/12/2009
F-IP-R-001	Public Health Laboratory - Orillia, Import Permits	001	21/12/2009
F-IP-S-001	Public Health Laboratory - Sault Ste. Marie, Import Permits	001	21/12/2009
F-IP-T-001	Public Health Laboratory - Thunder Bay, Import Permits	001	21/12/2009
F-IP-U-001	Public Health Laboratory - Sudbury, Import Permits	001	21/12/2009
F-IP-W-001	Public Health Laboratory - Windsor, Import Permits	001	21/12/2009

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- REGIONAL LABORATORIES
- SAFETY PROGRAM
 - CONTAINMENT LEVEL THREE LABORATORIES
 - ERAP
 - IMPORT PERMITS
 - Hamilton
 - Kingston
 - London
 - Orillia
 - Ottawa
 - Peterborough
 - Sault Ste. Marie
 - Sudbury
 - Thunder Bay
 - Timmins
 - Toronto
 - Windsor
 - SAFETY MANUAL
 - VISUAL IDENTITY

Inventory of pathogens and toxins

Microsoft Access

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Type a question for help

tbIOPHL Pathogens/Toxins Inventory : Table

Field Name	Data Type	Description
No	Text	
Laboratory	Text	
Section	Text	
Pathogens/Toxins	Memo	
Room Number	Text	
Freezer (-20° C)	Yes/No	
Freezer (-70° C)	Yes/No	
Incubator	Yes/No	
Refrigerator	Yes/No	
Comments	Memo	

Field Properties

General Lookup

Field Size: 255

Format:

Input Mask:

Caption: No.

Default Value:

Validation Rule:

Validation Text:

Required: No

Allow Zero Length: Yes

Indexed: No

Unicode Compression: No

IME Mode: No Control

IME Sentence Mode: None

Smart Tags:

A field name can be up to 64 characters long, including spaces. Press F1 for help on field names.

Design view. F6 = Switch panes. F1 = Help.

NUM

Requirements for registration

- Identify all laboratories within the PHL
- Identification of pathogens and toxins at all laboratories
 - Risk groups 2, 3, 4
- Confirmation of presence / absence of Wild Polio virus and Variola virus
- Identification of responsible officer
- Identification of safety trained and experienced contacts
 - as per 70 (1) (c) of the Act

What were the challenges?

- Leadership and responsibility for registration (multiple sites)
- Confirm presence/absence of Polio virus and Variola virus
- Confirm presence/absence of select toxins
- Inventory system for pathogens and toxins
- Impact on research at the PHL
 - real or perceived?
- Security screening requirements
- Biosecurity requirements

Overcoming the challenges

- PHL registered as one entity
 - Centralized registration process – laboratories safety office
 - Medical director as responsible individual
 - Safety trained personnel designated as institutional contact (biosafety)
- Survey PHL for possession of Wild Polio virus and Variola virus
- All labs required to update pathogens list to include toxins

Overcoming the challenges

- Access database used for inventory of pathogens and toxins
 - To be routinely updated
- Research activities at the PHL
 - Importation of pathogens remained unchanged
 - Existing biosafety program allowed for continued progress of research activities in compliance with HPTA

Next steps

- Enhancement of safety program to be in full compliance with LBG
- Designation of biological safety officer
 - As specified by proposed regulations
- Enhancement of biosecurity at all PHL
- Include pathogens and toxins inventory as a controlled document

Conclusion

- Registration of the PHL
 - Seamless based on existing safety management system
 - Safety program aligned with the PHAC LBG
 - Compliance with HPIR provided the framework for simplified process
- Anticipate simplified transition with the implementation of the proposed regulations
 - Regulations based on PHAC LBG

Questions?