

Human Pathogens and Toxins Act Implementation at UHN

2016 TORONTO RESEARCH MANAGEMENT SYMPOSIUM, TORONTO

*Ian McDermott
Senior Director, Research Facilities
Planning and Safety
University Health Network*

*John Shannon
Safety Manager, Biosafety Officer,
Laser Safety Officer
University Health Network*

Employee possibly exposed to Ebola virus at Winnipeg lab

Worker at animal health laboratory is in isolation, and risk to public is considered low, officials say

CBC News | Posted: Nov 08, 2016 12:15 PM ET | Last Updated: Nov 08, 2016 5:38 PM ET



The Canadian Science Centre for Human and Animal Health in Winnipeg is the first facility in the world to have high containment laboratories for human and animal health in one building. (Trevor Brine/CBC)

An employee at the national animal health lab in Winnipeg was potentially exposed to the Ebola virus yesterday, federal officials say.

The employee of the National Centre for Foreign Animal Disease (NCFAD) was evaluated by an infectious disease specialist and has put himself in isolation for 21 days — the maximum time from Ebola infection to the onset of symptoms, according to the World Health Organization.

Winnipeg researcher charged with smuggling Ebola material into U.S.

CBC News | Posted: May 13, 2009 6:54 AM ET | Last Updated: May 13, 2009 6:35 PM ET

A former researcher at the National Microbiology Lab in Winnipeg is facing charges in the United States after allegedly trying to smuggle genetic material from the Ebola virus across the Manitoba-North Dakota border.

U.S. authorities allege Konan Michel Yao had 22 vials of the substance in the trunk of his car when he tried to cross the border on May 5. He is charged with smuggling merchandise, which carries a maximum penalty of 20 years in prison and a fine of \$250,000 US.

Human Pathogens and Toxins Act Implementation at UHN (University Health Network)

What we will cover today:

- Who is UHN?
- What is the HPTA/HPTR/CBS?
- Why have legislation?
- Need for HPTA/HPTR/CBS?
- HPTA/HPTR/CBS timeline.
- Specifics of HPTA/HPTR/CBS.
- UHN implementation

University Health Network



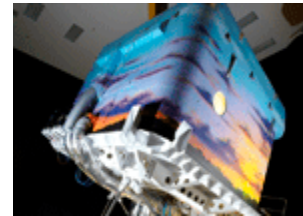
**Princess Margaret
Cancer Centre**



**Toronto General
Hospital**



**Toronto Western
Hospital**



**Toronto Rehabilitation
Institute**



Michener Institute

One of Canada's largest teaching hospitals.

UHN at a Glance

Nearly 18,000 staff, medical staff and students

Nearly 1,200 beds

9 Separate Sites

\$1.9B Annual Budget

Laboratory Medicine Program

Research @ UHN



**Princess Margaret
Cancer Research
Institute**



**TGRI
Toronto General
Research Institute**



**KRI
Krembil Research
Institute**



**TRI
Toronto Rehabilitation
Institute**



The largest research hospital in Canada

Research by the numbers at **UHN**

991,894

Sq Ft

3,402

Publications

4,654

Staff

\$356,167,153

Funding

Space

2015 Data

Laboratory Medicine Program (LMP)

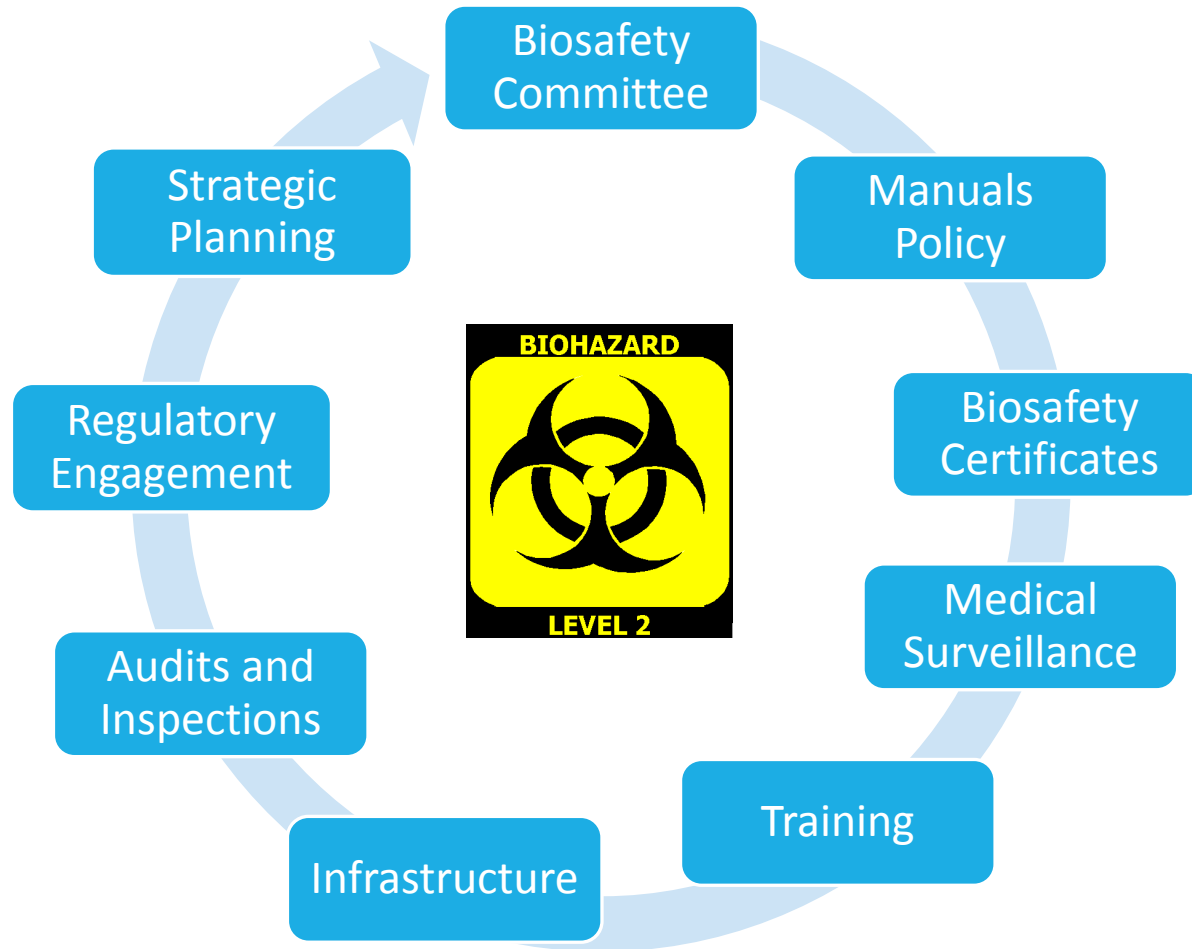
Largest academic laboratory medicine program in Canada

- Over 500 staff including over 65 medical and scientific staff

Complex and routine laboratory medicine services to all UHN programs

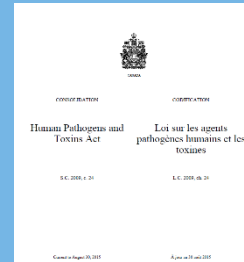
- Over 20,000 specimens/day
- Over 22 million tests /yr

UHN Research Biosafety Program



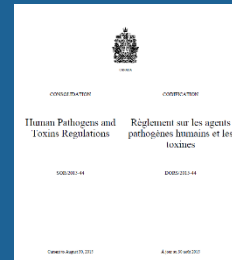
Oversight by Public Health Agency of Canada

Human Pathogens and
Toxins Act



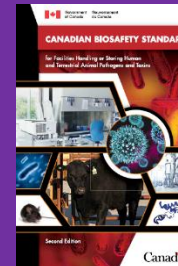
June 23,
2009

Human Pathogens and
Toxins Regulation



December 1
2015

Canadian Biosafety
Standard (CBS) 2nd Ed.



December 1
2015

Why have Laws, regulation & standards for the use of biohazardous materials?

- Health, Safety and Security of People
- Health, Safety and Security of workers
- Health and safety of animals
- Sustain and protect the environment

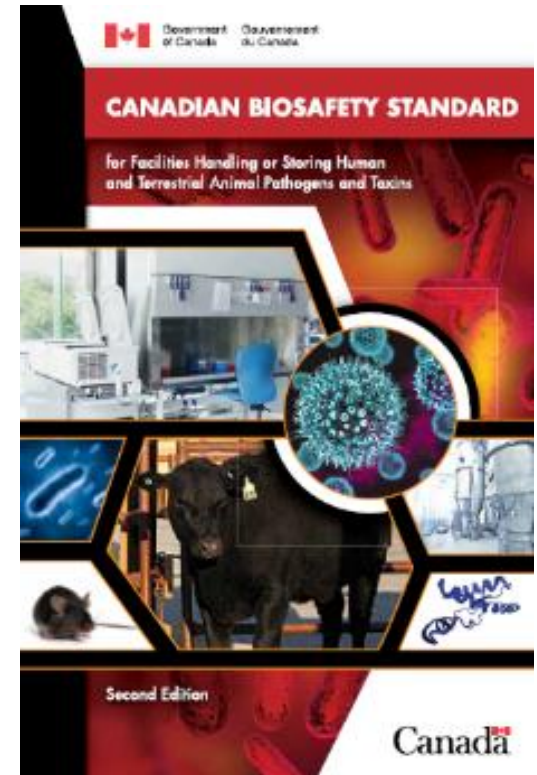
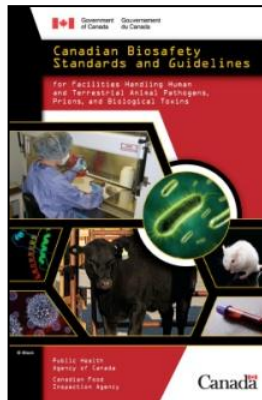
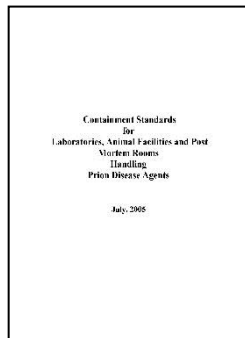
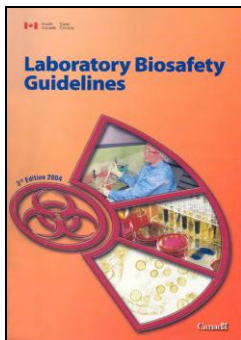
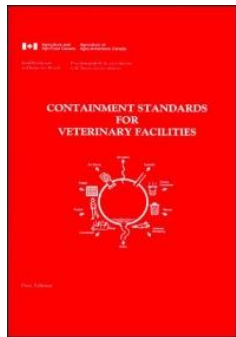


Why the need for the HPTA?



- “Human pathogens and toxins are inherently dangerous - capable of causing disease and death in humans.”
- 9/11/2001 and international pressure to provide safeguards against bioterrorism (Australia Group)
- *Human Pathogens Importation Regulations* (HPIR) did not regulate human pathogens or toxins if domestically acquired
- HPIR punishment inconsequential
- Domestically acquired human pathogens and toxins were subject to voluntary guidelines only (*Laboratory Biosafety Guidelines*-established 1990)

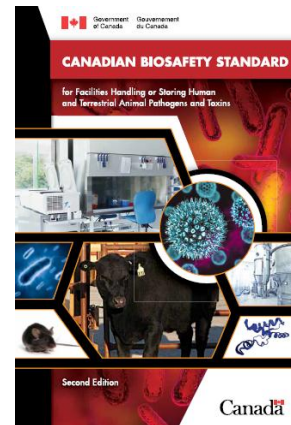
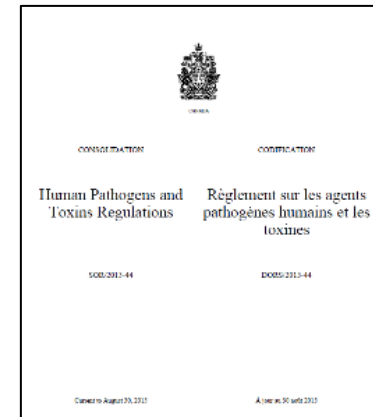
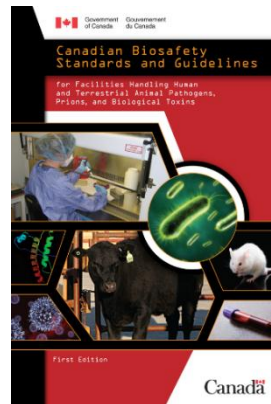
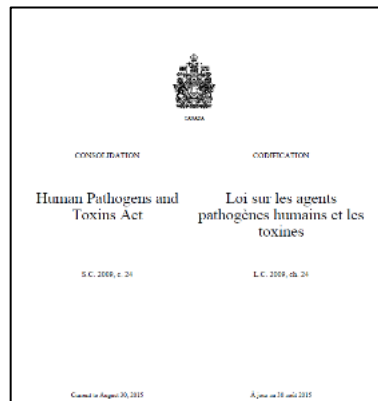
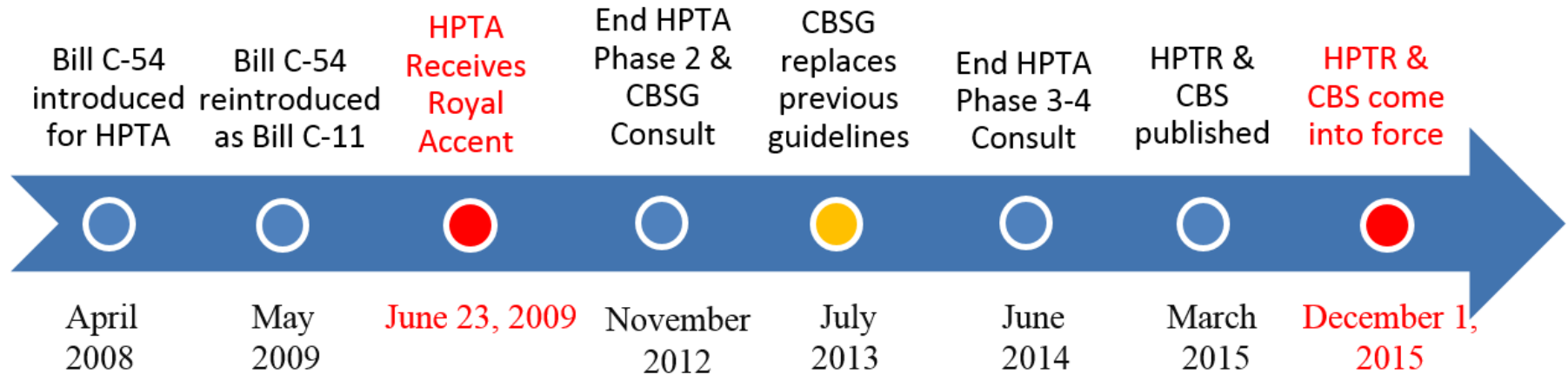
CBS 2nd Ed.-Development



June 1, 2013
CBSG, 1st Ed.

Dec 1, 2015
CBS 2nd Ed.

Timelines for the HPTA/HPTR/CBS?



Applicable Federal Legislation

Health Canada

- *Hazardous Products Act (WHMIS/GHS)*

Public Health Agency of Canada

- *Human Pathogens and Toxins Act*
- *Human Pathogens and Toxins Regulations*
- *Canadian Biosafety Standard, 2nd Ed (includes terrestrial animal pathogens)*
- *Biosafety Directives, Advisories and Notifications*

Applicable Federal Legislation

Canadian Food Inspection Agency

- *Health of Animals Act (HAA)*
- *Import Program (pathogens causing foreign animal and emerging animal diseases)*

Environment Canada

- *Canadian Environmental Protection Act (CEPA)*
- *New Substances Notification Regulations (Organisms)*

Transport Canada

- *Transportation of Dangerous Goods Act & Regulations*

Applicable Provincial Legislation

Ministry of Labour

- *Occupational Health and Safety Act*
- *O.Reg. 67/93 Health Care and Residential Facilities*
- *O.Reg 833 Control of Exposure to Biological or Chemical Agents*
- *O.Reg 851 Industrial Establishments*

Ontario Ministry of the Environment

- *Environmental Protection Act*
- *Guideline C-4 Management of Biomedical Waste*

Other:

- *International Law*
 - *USA Select Agent Law*
 - *Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH)*
- *National Institute of Health (NIH)*
 - *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

HPTA



“An Act to promote safety and security with respect to human pathogens and toxins.”

- **Human pathogen** means a micro-organism, nucleic acid or protein (including synthetic form) that is listed in schedules 2-4 or falls into Risk Group 2, 3 or 4;
- **Toxin** means a substance (including synthetic form) that is listed in Schedule 1 or in Part 1 of Schedule 5



HPTA-Prohibitions

No persons shall conduct the following” **controlled activities”(CA)** with human pathogens or toxins without a licence:

Possession	Production
Storage	Permitting access to
Importing	Exporting
Release or abandonment	Disposal



HPTA-Does Not Apply to:

A human pathogen or toxin that is in an environment in which it naturally occurs if it has not been cultivated or intentionally collected or extracted, including a human pathogen or toxin that:

Is in or on a human suffering from a disease

Has been expelled by a human suffering from a disease

Is in or on a cadaver, a body part or other human remains

A drug in dosage form whose sale is permitted or otherwise authorized under the *Food and Drugs Act* or a human pathogen or toxin contained in such a drug.

HPTA



- **Licences:**

- All persons shall comply with the licence conditions.

- **Security Clearances**

- **Biological Safety Officer (BSO)** qualifications, obligations, power, functions

- **Administration and Enforcement**

- Offences and Punishment

HPTA



- *Every person who contravenes this Act or the regulations is guilty of an offence and liable, on summary conviction,
 - ...in the case of a contravention with respect to a human pathogen that falls into Risk Group 2 (ii) for a subsequent offence, to a fine of not more than \$500,000 or to imprisonment for a term of not more than six months, or to both.
- ...creates a risk to the health or safety of the public is guilty of an indictable offence and liable to imprisonment for a term of not more than five years.

HPTR



- **Licence Details**

- Duration related to Risk Group Licence conditions related to controlled activities and
 - Persons must inform BSO
- **Biosafety Officer qualifications, Functions, Powers**
- **Security Sensitive Biological Toxins Table 1 (Sec 10 (2))**
- **Security Clearance Process/Requirement details**

HPTR-Biological Safety Officer (BSO)



Qualifications: Knowledge of:

- Microbiology/risks,
- Act, Regulations and other Federal/Provincial legislation,
- Applicable biosafety and biosecurity practices

• Functions:

- Communicate with Minister
- Report to Minister: (exposures, inadvertent possession, etc.)
- Conduct inspections/audits
- Develop biosafety manual

• Power:

- To Obtain records to support functions

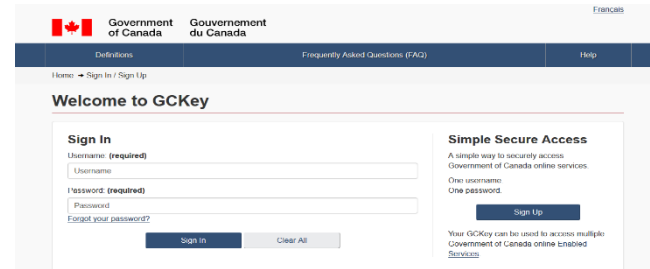
HPTR-Exemptions



27 (1) A person who carries out laboratory analyses or diagnostic testing with a human pathogen that is neither a prion nor a prescribed human pathogen is exempt from the application of section 7 of the Act on condition that

(a) they do not cultivate or otherwise produce a human pathogen;

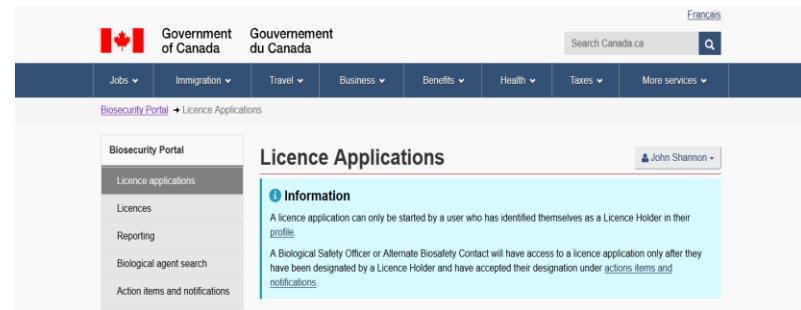
Licence



The screenshot shows the GCKey login interface. At the top, there is a header with the Government of Canada logo and the text 'Government of Canada' and 'Gouvernement du Canada'. Below this is a navigation bar with links for 'Definitions', 'Frequently Asked Questions (FAQ)', and 'Help'. The main content area is titled 'Welcome to GCKey'. It features a 'Sign In' section with fields for 'Username (required)' and 'Password (required)', a 'Forgot your password?' link, and 'Sign In' and 'Clear All' buttons. To the right, there is a 'Simple Secure Access' section with a description of the service, a 'Sign Up' button, and a note about GCKey's use for multiple Government of Canada online services, with a 'Services' link.

- Administered by PHAC via Biosecurity portal (web-based)
- Includes HPTA, HPTR and sections under HAA (terrestrial animal pathogens)
- Required for all parties conducting controlled activities
- Party must identify a “Licence Holder” and the “Biological Safety Officer (BSO)”
- Only Licence Holder and BSO can access Biosecurity portal.
- *Plan for Administrative Oversight (POA) for Pathogens and Toxins in a Research Setting* is required for scientific research

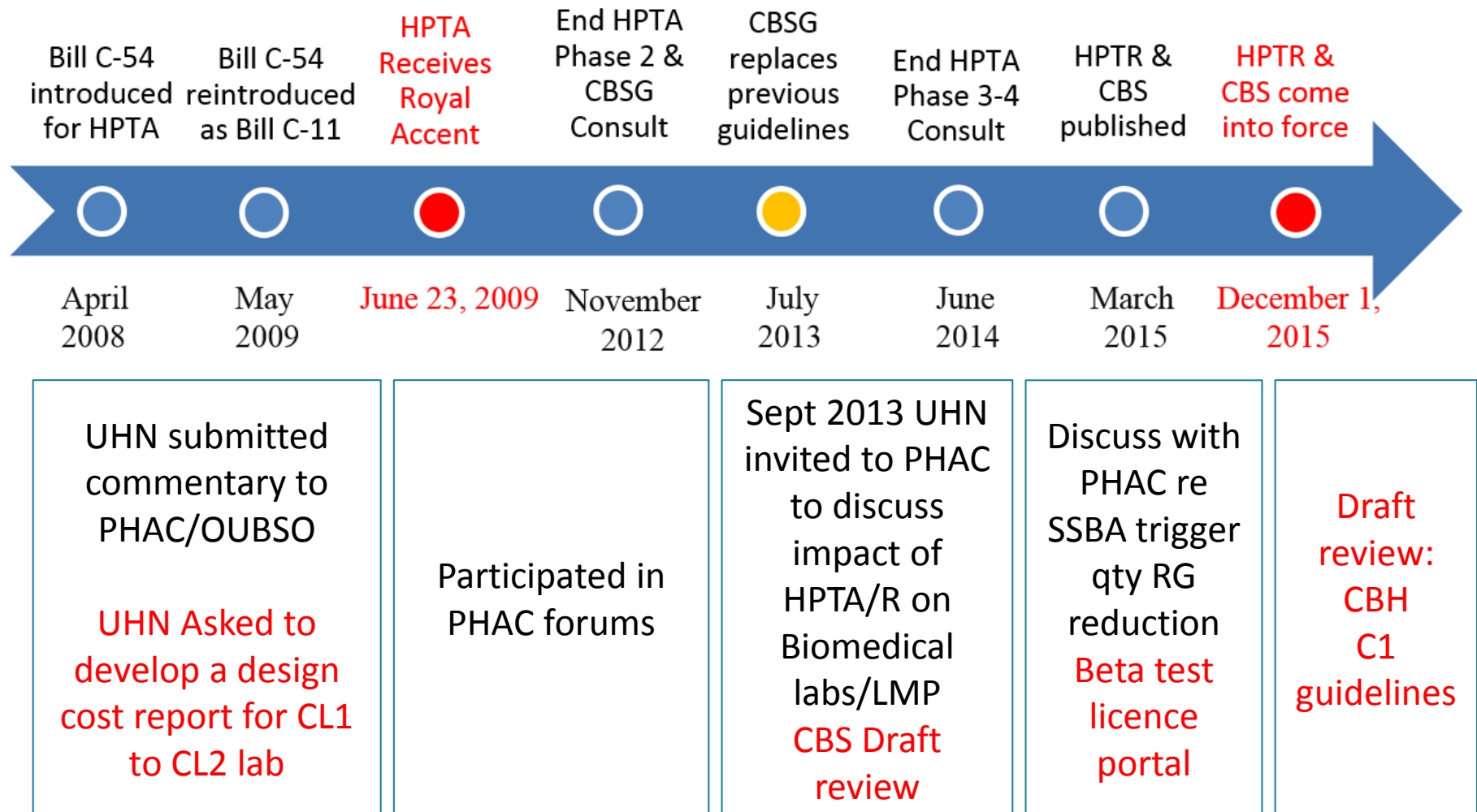
Licence



Plan for Administrative Oversight (POA) for Pathogens and Toxins in a Research Setting:

1. Management Commitment
2. Roles and Responsibilities
3. Key Contact
4. Identification of Biosafety and Biosecurity Risk
5. Assessment of Biosafety and Biosecurity Risk
6. Management & Control of Biosafety and Biosecurity Risk
7. Description of Work Areas Covered by Plan
8. Description of Individuals Covered by Plan
9. Summary of Communication Plan
10. Plan Review and Monitoring

UHN Involvement HPTA/HPTR/CBS



Implementation of HPTA at UHN?

Communication:

Method	Description
UHN Intranet	<ul style="list-style-type: none"> • Policies, UHN Research Biosafety Manual, general program information, SOP's, templates, guidance documents, etc. • Special news stories
Email Program Updates	<ul style="list-style-type: none"> • Broadcast emails • Directed emails to PI's, supervisors, personnel, etc.
Mandatory Training	Mandatory orientation, eLearning and in-class Wet-Laboratory Safety Training
In-Lab Orientation	PI's are responsible for ensuring new personnel are provided in-lab orientation/training on laboratory-specific procedures/SOP's and emergency procedures.

Implementation of HPTA at UHN?

Communication (continued):

Method	Description
Principal Investigator (PI) Onboarding	All new PI's assigned a RFPS Safety Coordinator to assist one-on-one with laboratory start-up and biosafety and biosecurity program compliance,
Special Information Sessions	UHN conducted multiple information sessions
Inspection & Audit	UHN Inspectors (Safety Coordinators/BSO): <ul style="list-style-type: none"> • Provide literature information • Provide direct feedback on reports
Committee Reports/Debriefs	RFPS/BSO provided ongoing updates senior management, council, committees and departments

Key Highlights of HPTA and HPTR

Governance

**Legislation
Alignment**

**Reporting
Requirements**

**Security Sensitive
Biological Agents
(SSBAs)**

Biosecurity

**Medical
Surveillance**

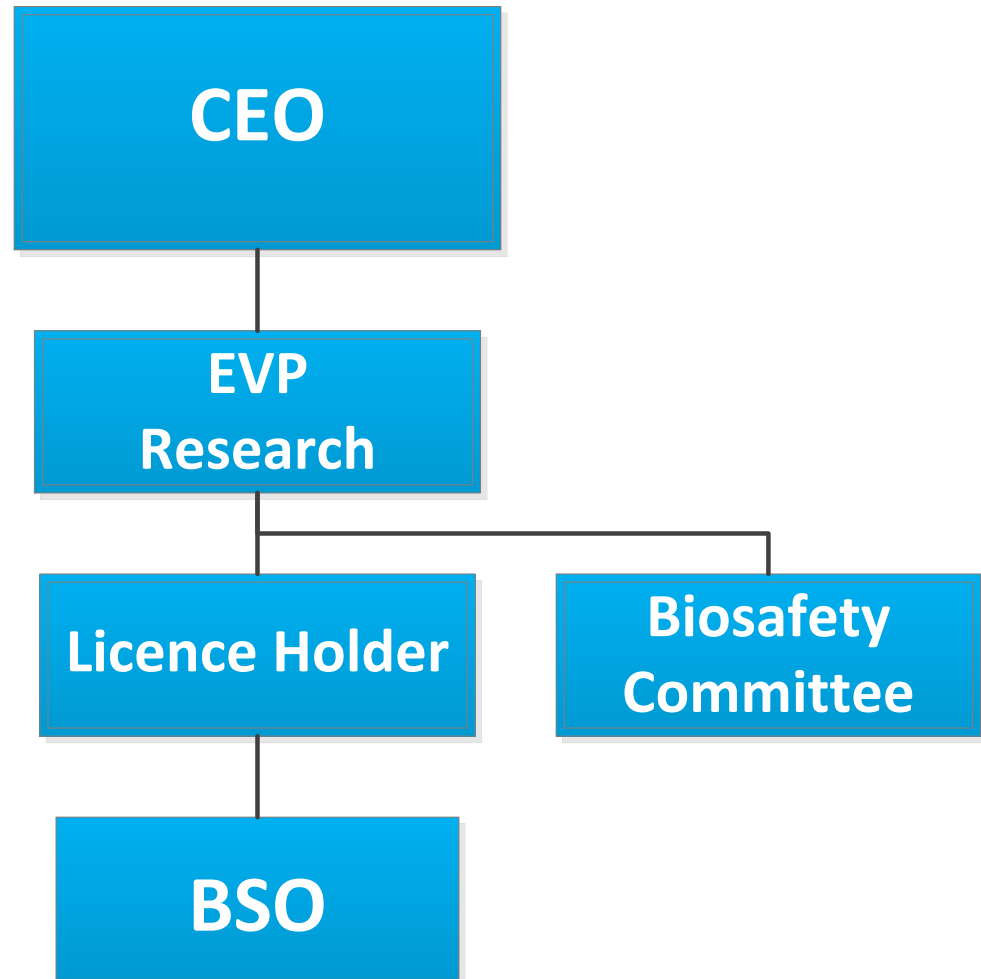
Training

Governance

- Laboratory Medicine Program exempt as it does not cultivate/produce Human pathogen
- Licence administered under UHN Research Safety program
- Licence Holder-Ian McDermott
- Biological Safety Officer (BSO)-John Shannon
 - Previously 3 BSO's: Principle Investigators representing 3 institutes
 - Change to Biosafety Committee
 - Forming Clinical Research Biosafety Committee

Implementation of HPTA at UHN?

- REPORTING STRUCTURE:



Legislation Alignment

- HPTA only regulates RG2 and greater human pathogens and toxins
 - Biomedical laboratories (basic and clinical) conduct research with human blood/tissues
 - UHN's biosafety program treats human tissue as RG2
 - Personnel health and safety under OHSA
-
- HPTA only regulates microbiological toxins yet non-microbiological toxins (i.e ricin from castor bean, tetrodotoxin from puffer fish) have health, safety and security implications and are regulated under USA Select agent law

Legislation Alignment

Continued:

- NIH has regulatory guidelines for use of recombinant DNA/synthetic DNA research-impacts to Clinical trials (HPTA exempts drug form)
- Terminology :human pathogens and toxins vs biological agents

Reporting Requirements

New Requirements to REPORT TO PHAC:

- **Exposure reporting**
 - Requirement to report all incidents to BSO without delay
 - Existing requirement to report to OHS, OHS also notifies BSO
- **Inadvertent acquisition**
- **Accidental Release**

Reporting Requirements

Continued:

New Requirements to REPORT TO BSO/Licence Holder:

- **Importing or Exporting**
- **Receiving**
- **Transferring** (i.e Core facilities)
- **Increasing pathogenicity, toxicity, communicability, etc.**

Must be included on UHN Biosafety Certificate, transfer forms, notification requirements in policy/UHN Research Biosafety Manual Agreements with 3rd party importers (i.e. Cedarlane, Sigma)

Security Sensitive Biological Agents (SSBAs)

Control of Trigger Quantities

- Audit of inventories and actual storage quantities
- Accurate central inventory
- Managed parts of a facility via notification and biosafety certificate program and space information to stay below trigger quantities
- Biosafety certificate special conditions
- HR and security clearance HR, job description etc.

Toxin	Trigger Quantity (mg)
Alpha toxin	5
<u>Botulinum</u> neurotoxin	0.5
Cholera toxin	20
<u>Clostridium</u> <u>botulinum</u> C2 and C3 toxins	5
<u>Clostridium</u> <u>perfringens</u> Epsilon toxin	5
<u>Hemolysin</u>	10
Shiga-like toxin (<u>verotoxin</u>)	1
<u>Shigatoxin</u>	1
Staphylococcal enterotoxins, Type B (SEB)	1
Staphylococcal enterotoxins, types other than Type B	10
<u>Staphylococcus</u> <u>aureus</u> Toxic shock syndrome toxin	5

Biosecurity

- New term!
- Overarching risk assessment
- Reassessment of large open concept labs and containment zones
- Locking closing doors –blitz campaign
- Change in behavior

Medical Surveillance

- As determined by risk assessment and as may be required by UHN Research Biosafety Certificate
- OH&S provides medical expertise
- Update to OHS onboarding
- OHS resource issue

Training

Canadian Biosafety Standard Training Requirements:

- Biosafety Manual
- Standard Operating Procedures
- Demonstrate knowledge and proficiency*
- Hazards-symptoms of disease/precautions
- Containment zone/systems*
- Use and operation of primary containment devices

Training

Canadian Biosafety Standard Training Requirements:

Continued:

- Use of restraints for animal work
- Visitors, maintenance, janitorial staff, contractors
- Refresher Training-annual for emergency response*
 - Labs to review internal ERP, new eLearning launched

UHN Program Active Elements

1. Management Commitment
2. Identification of Biosafety and Biosecurity Risk
3. Assessment of Biosafety and Biosecurity Risk
4. Management & Control of Biosafety and Biosecurity Risk
5. Communication Plan
6. Plan Review and Monitoring

Questions?

