

OVERCOMING THE CHALLENGES FACED IN IMPLEMENTING THE REQUIREMENTS OF THE CBS, HPTA AND HPTR

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2019 Canadian Biosafety Symposium

September 19, 2019



Universal Biosafety Inc.

Introduction - HPTA & CBSG

- ▶ HPTA 2009
 - ▶ Facility Registration
 - ▶ Assignment of a BSO
 - ▶ Reasonable precautions to protect the health and safety of the public
 - ▶ Prohibition of activities with agents listed in Schedule 5

- ▶ Canadian Biosafety Standards and Guidelines 1st Edition, 2013
 - ▶ Harmonization of the following documents:
 - ▶ Laboratory Biosafety Guidelines (LBG) 3rd Edition
 - ▶ Containment Standards for Veterinary Facilities 1st Edition.
 - ▶ Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms handling Prion Disease Agents 1st Edition.



Introduction - HPTR & CBS

- ▶ HPTR 2015
 - ▶ Enforced all other aspects of the HPTA
 - ▶ Licence with conditions for conducting controlled activities
- ▶ Canadian Biosafety Standards 2nd Edition, 2015
 - ▶ National Standard governing manipulation of human and terrestrial animal pathogens and toxins.
 - ▶ Mandatory physical, operational and performance verification requirements for CL2, CL3, CL4 containment zones
 - ▶ Laboratories, Large scale facilities, Animal zones, SSBA, Prions



Biosafety Compliance History

- ▶ Facilities made an easier transition to HPTR and the CBS
 - ▶ LBG and CBSG guided the development and/or enhancement of biosafety programs
 - ▶ Internal inspections against the requirements of the CBSG
 - ▶ Development of plans for closing gaps identified in inspections
- ▶ Facilities not utilizing the LBG and CBSG in preparation for regulatory changes may experience a more difficult transition.



Biosafety Culture

- ▶ Culture
 - ▶ Values, beliefs, behaviours, practices that support safe science/biosafety irrespective of standards, codes, regulations
- ▶ Facilities having a strong biosafety culture
 - ▶ Greater alignment with good microbiological practices and
 - ▶ Smoother transition to the regulatory requirements
- ▶ Facilities with a weak or non-existent culture may face greater challenges



We've been doing it this way for years... ...and nothing happened!

- ▶ Unaware of hazards associated with controlled activities
 - ▶ Lack or awareness of risks associated with pathogens, toxins and specific activities
 - ▶ Lack of awareness of potential exposures and/or infection
- ▶ Unaware that the HPTA, HPTR, CBS requirements are mandatory



Resistance to change

- ▶ Changing old habits, procedures, culture
 - ▶ Additional resources e.g. financial or additional personnel
 - ▶ ...we've been doing it this way for years
- ▶ Hinders the obligation to protect the health and safety of the public and indeed protection of staff
- ▶ Hinders compliance



The HPTR Licence

- ▶ Conducting controlled activities without a Licence
- ▶ Staff unaware of the existence of the Licence and the associated conditions
 - ▶ Requirements for movements, lost or missing pathogens and toxins.
 - ▶ CFIA requirements for animal products, foreign and emerging animal diseases etc.
 - ▶ Decontamination and record keeping requirements



The BSO & The Licence Holder

- ▶ Both mandatory under the HPTA and HPTR with specific roles and responsibilities
- ▶ The BSO is the Licence Holder
 - ▶ BSO meets the qualifications as per HPTA & HPTR
 - ▶ Fewer challenges
- ▶ The Licence Holder is also the BSO
 - ▶ Licence holder has other responsibilities
 - ▶ Limited biosafety knowledge or experience
 - ▶ May experience greater challenges
- ▶ BSO operates outside of Canada / Corporate BSO
 - ▶ Corporate requirements vs Canadian Biosafety requirements



The Biosafety Program

- ▶ There is no structured biosafety program in place
 - ▶ Some elements may exist
 - ▶ Lacking or limited key program elements
- ▶ Biosafety program does not align with the facility's program intent or activities
 - ▶ Large scale activities - program does not include large scale safety
 - ▶ Animal containment zones - no safe animal-handling techniques included



Biosafety vs Quality

- ▶ Is there a conflict?
- ▶ Can we find synergies?



Biosafety & Quality Key Elements

- ▶ Physical requirements
 - ▶ Access control systems
 - ▶ Structure, location, containment perimeter, surfaces etc
 - ▶ Equipment maintenance
 - ▶ Decontamination technologies e.g. autoclaves, decon in place in equipment
- ▶ Operational requirements
 - ▶ Program management
 - ▶ Medical surveillance
 - ▶ Training
 - ▶ Entry / exit procedures
 - ▶ PPE-Product or personnel protective equipment
 - ▶ Records and documentation



Biosafety & Quality Key Elements

- ▶ Equipment and Facility Performance and Verification Testing
 - ▶ Air handling systems
 - ▶ Equipment maintenance, HEPA filter testing
- ▶ Some are in alignment and some may be in conflict
- ▶ Finding the balance or solutions to achieve objectives.



Risk Assessment

- ▶ Inability to conduct a biological risk assessment
- ▶ Performed by one person
- ▶ Incomplete assessment
 - ▶ Assessing only the agent and not the activities, environment or equipment used for conducting controlled activities.
- ▶ The risk is not identified or described or controls do not match the risk
 - ▶ e.g. risk of exposure via injection - with no sharps precautions
- ▶ The risks and mitigation strategies are not communicated nor implemented.
- ▶ The risk assessment is documented and filed - no action taken



Toxins

- ▶ Included in the HPTA and HPTR
 - ▶ Schedule 1 of the HPTA
 - ▶ SSBA include toxins above trigger quantities
- ▶ “Live vs Non-live”
 - ▶ Live organism is infectious - hazardous
 - ▶ Misconception: Non-live toxin is non-hazardous because it is non-infectious
- ▶ Toxins are not included in the Local Risk Assessment



Equipment Hazards

- ▶ Laminar flow hoods, fume hoods, biosafety cabinets
 - ▶ Not knowing the difference, how they operate or protection provided
 - ▶ Using the wrong device
- ▶ Improper use of biosafety cabinets
 - ▶ Overcrowded, blocked grilles, two people working at one cabinet
- ▶ Autoclaves
 - ▶ Validation vs Verification - what do they mean?
- ▶ Loss of containment from equipment



Training

- ▶ Limited or ineffective biosafety training
 - ▶ Training needs assessment not completed
 - ▶ Basic principles of biosafety or good microbiological practices not included or not understood
 - ▶ Biosafety cabinets in use without training on proper use
 - ▶ Safe animal handling techniques not included for animal zones.
 - ▶ No training on accident reporting and investigation
 - ▶ What is a PSDS?
- ▶ Training not relevant to the type of containment zone
 - ▶ Laboratory, large scale, SA or LA zone etc.
- ▶ Read and review vs performance based



Overcoming the Challenges

- ▶ Understand the HPTA, HPTR & Licence requirements
- ▶ Understand how to use the CBS
- ▶ Country requirements takes precedence over external requirements
- ▶ Communicate the Licence and conditions to staff
- ▶ Do a status check and change the culture
- ▶ Build the program starting with key elements



Overcoming the Challenges

- ▶ Revisit the biological risk assessment
 - ▶ PHAC Guideline on Local Risk Assessment
 - ▶ Include an assessment of equipment and associated hazards
 - ▶ Involve the team and share the assessment
- ▶ Build institutional biosafety capacity
- ▶ Find the synergies between Biosafety and Quality
- ▶ Toxins are hazardous material and some are regulated
- ▶ Training, training, training
 - ▶ Make it performance based and verify competence



Thank you for your attention

Questions????

