How to Survive of a PHAC Inspection

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Overview

- Summary of the Public Health Agency of Canada (PHAC) inspection of the May 2018 at the University of Saskatchewan

- Provide an overview of the PHAC inspection process
  - Before, during, and after

- Provide a summary of the lessons learned from the inspection
Regulatory Requirements

- PHAC performs:
  - Compliance monitoring and verification activities to verify whether regulated activities are carried out by a facility in accordance with the Human Pathogens and Toxins Act and Regulations (HPTA/R); and
  - Monitors compliance with the Human Pathogens and Toxins Act and Regulations (HPTA/R) and certain provisions of the Health of Animals Act and Regulations.
U of S Biosafety Program - Overview

- 22,000 students and 7000 Faculty and staff
- 205 risk group (RG) 2 biosafety permits and some RG3 permits (HIV and blastomyces)
- May 2018: 1-RG2 HPTR licence and 1-RG3 HPTR Licence
- Conduct biosafety audits every 4 years: 55-60/year (scheduled)
- Conduct targeted site specific visits 1-2 times/month (unscheduled)
Company is coming

- In April, 2018, received phone message from PHAC of upcoming inspection
- Initial conversations with PHAC inspector provided basic information regarding the upcoming inspection:
  - Potential dates;
  - Inspection team; Scope of inspection (e.g. locations);
  - PPE and any specific entry requirements.
- Officially received via email letter of intent to the BSO and licence holder (attestation required by licence holder)
  - Complete PHAC Onsite Inspection Planning form
Company is coming ........ Why?

- PHAC chosen the U of S based on RG 3 Licence as they are required to inspect every 3 years; and simultaneously conduct the inspection for the RG2 licence requirements.

- Based on risk based criteria of:
  - Compliance history;
  - Program robustness; and
  - Oversight complexity.
Setting the Scene

- PHAC provided preparation checklist of upcoming inspection requirements:
  - Requirement of meeting room;
  - Provide list of potential inspection sites (listed on RG2 and RG 3 licences);
  - Distribution of any documents for pre-review (based on locations/facilities nominated); and
  - Agenda development (scheduling).
Setting the Scene – Inspection Site Selection

- Agriculture Building (two containment level (CL) 2 labs)
Setting the Scene – Inspection Site Selection

- Western College of Veterinary Medicine (WCVM) (two CL 2 and one CL2–Ag facility)
Setting the Scene – Inspection Site Selection

- Vaccine and Infectious Disease Organization (VIDO) (CL2 Ag facility and paddock outdoor areas)
Setting the Scene – Inspection Site Selection

- Health Sciences Building (one CL 2 lab working with HIV and two CL 2 lab and CL2 small animal facility)
Setting the Scene – Site Visit only

- Saskatchewan Centre for Cyclotron Sciences (SCCS)
Setting the Scene – Document Review

- Required to send PHAC following documents for each inspection site/nominees:
  - Biosafety plans (U of S site specific biosafety manuals);
  - Standard Operating Procedures;
  - Inventory;
  - Training records;
  - Emergency response plans;
  - Audit/inspection reports;
  - Copies of U of S biosafety permit;
  - Animal use protocols, etc.
Setting the Scene – Agenda Development

- After reviewing list of potential inspection sites/nominees, PHAC recommended **three-day** visit due to complexity and size of the university and selected the inspection nominees
  - PHAC selected the inspection nominees from provided list
Setting the Scene – Agenda Development

- Agenda included:
  - Day 1: Opening Meeting (introductions, attendance forms, format of inspection, review of agenda)
  - Day 1-3 plan include:
    - Document Review – morning
    - Walkthrough and verification of selected inspection sites – afternoon
  - Day 3: Site visit to Cyclotron and Closing Meeting
Getting Ready, Company is coming

- Notify the selected inspection nominees of upcoming PHAC inspection and invite to opening meeting

- Check your backyard
  - Conduct pre-PHAC site visits of the areas being inspected (conduct internal biosafety audit)
  - Physical walkthrough of lab/facility
  - Help get to get “house” in order
Getting Ready, Company is coming

- Prior to sending docs to PHAC, have inspection nominees conduct a quick internal review of documents to check if updates are required
  - Final review by BSO
  - Print off copies of docs for your own reference
  - Sent 115 files to PHAC via 11 emails

- Participated in PHAC webinar course, “What to Expect when Inspected”
  - Available today online the PHAC eLearning centre
    https://training-formation.phac-aspc.gc.ca/
Getting Ready, Company is Coming

- Recommend to invite to opening meeting:
  - Selected Inspection nominees;
  - Licence holder; and
  - Institutional biosafety committee chairs and members.
Hi my name is ........Inspection Day

- Opening Meeting
  - Introductions – Inspectors wearing vests with inspection badges
  - Overview of PHAC inspection mandate and process
  - Agenda overview
Inspection Time

- Document review sessions by PHAC Inspectors
  - Inspectors review documents amongst themselves in meeting room
  - If questions or clarifications required, inspectors will come and get you
  - Good time to catch up on emails during this time 😊
Inspection Time

- Walkthrough of selected inspection sites with inspectors, nominees, and BSO
  - Professional tour guide – lots of note taking and pictures taken
  - Interactive – lots of questions (verification and clarification) and ask for demonstrations (e.g. working in BSC, entry/exit into CL2-AG containment room)
The Good, the Bad, and the Ugly

- Inspectors meet amongst themselves to compile summary of observations and findings during inspection

- Closing Meeting – the Big Reveal
  - Same attendees from Opening Meeting participating
  - Inspectors disclose summary of inspection observations and findings
  - Discussions about observations and findings – allows for clarifications and questions
  - Discussion on next steps – final inspection report
Inspection Time – The Big Reveal

- Inspectors met amongst themselves to discuss and compile summary of observations and findings from inspection

- Closing Meeting:
  - Attended by same individuals from Opening meeting
  - Inspectors disclose their findings – the good, the bad, and the ugly
  - Open discussions about findings – allows for clarifications and questions
  - Discussion of next steps
    - Final Inspection Report and corrective action timelines
And we thought we were done........

- After the inspectors leave:
  - PHAC Final inspection Report
    - Provided to BSO and licence holder 30 days after inspection for each licence (electronic copy)
    - Provides greater details and clarifications for any reported deficiencies
    - Send attestation of receipt of final report by licence holder and BSO
  - Acknowledgement of Receipt Report
    - Have 3 months from the date of receipt of the final report to complete and acknowledge the action plans to resolve any deficiencies
Final Inspection Report – Current Status

- U of S Observations and Findings:
  - No Serious/Dangerous of Major non-compliance reported 😊

  - Minor non-compliances observed:
    - Add RG to site specific inventory for each biological material;
    - Develop plan to describe autoclave validation procedure;
    - Physical building deficiencies (e.g. exposed wood on cupboard);
    - Develop plan for biosafety audit follow-ups;
    - Ensure safety glasses worn during surgery for CL2-AG.
Final Inspection Report – Current Status

- U of S Observations and Findings:
  - Recommendations:
    ✓ Remove, replace, or resurface fabric chairs;
    ✓ Expiry date of preparation of ethanol;
    ✓ 2-way communications in Cl2-Ag containment zone;
    ✓ Do not recap needles in CL2-Ag;
    ✓ Integrate centrifuge o-ring and bioseal checks as part of centrifuge maintenance program;
    ✓ Use secondary transport container when transporting infectious material between BSC and incubator for HIV work; and
    ✓ Add personnel suitability and reliability into biosecurity assessment.
Final Inspection Report – Current Status

- Currently, in progress of completing the acknowledgement report, which summarizes the action plans for the deficiencies reported
  - Implementation of action plan stated
Conclusion - Lessons Learned

- Do not offer bribes
- Be prepared –
  - Meet with the inspection nominees in advance
  - Print off a copy readily available of documents
- Take notes and pictures
- Be professional, approachable, and transparent
- It’s ok no to know everything, if you don’t know, you will get back to them
- Expect the unexpected, such as potential exposure incident while the inspectors are there
Conclusion - Lessons Learned

- Embrace it and have some fun doing it
Any questions??

Thanks!