

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

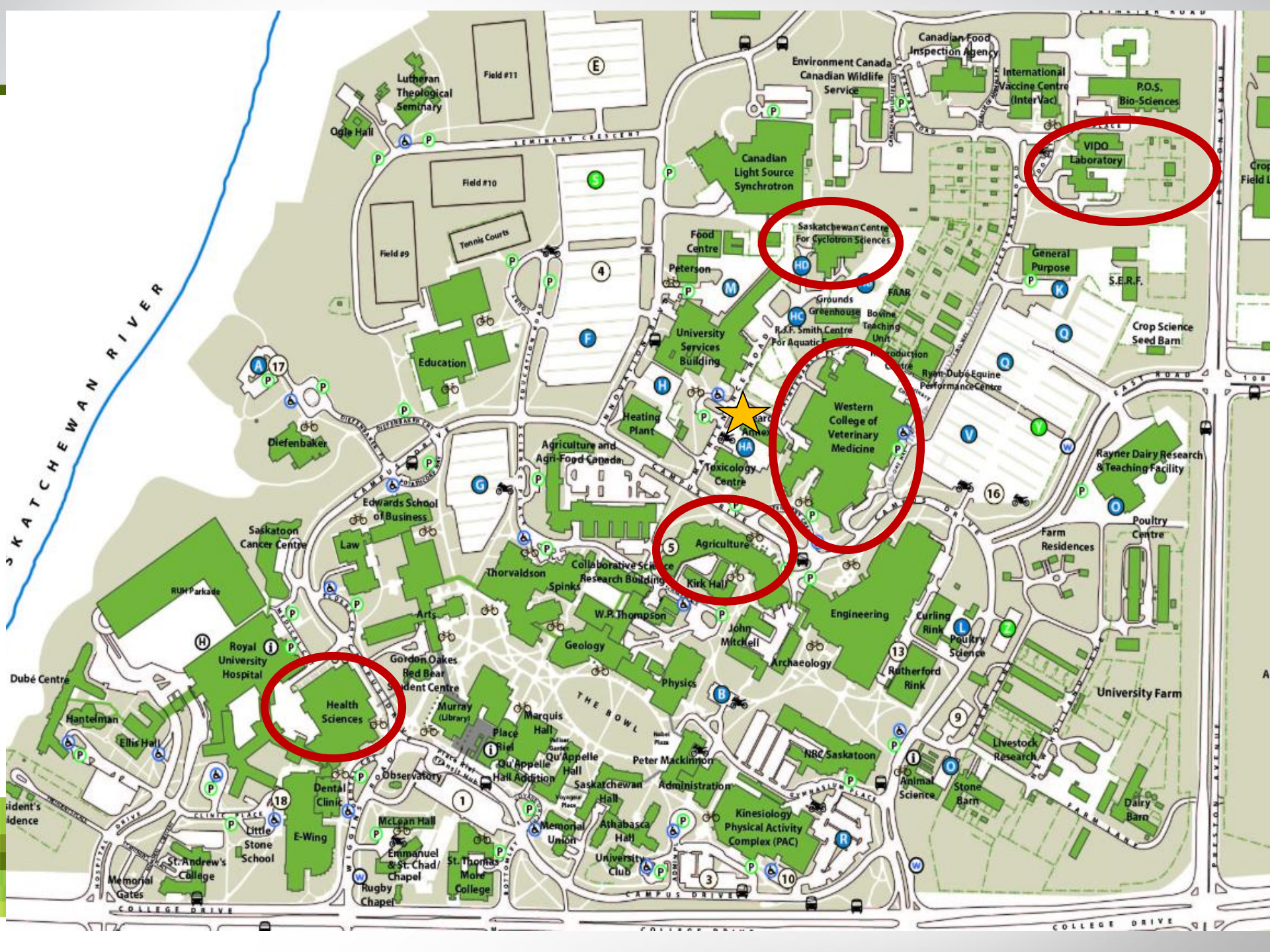
- Health Sciences Building (one CL 2 lab working with HIV and two CL 2 lab and CL2 small animal facility)



Setting the Scene – Site Visit only

- Saskatchewan Centre for Cyclotron Sciences (SCCS)





Health Sciences

Agriculture

Western College of Veterinary Medicine

Saskatchewan Centre For Cyclotron Sciences

VIDO Laboratory

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 isInspection Day

- Opening Meeting

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

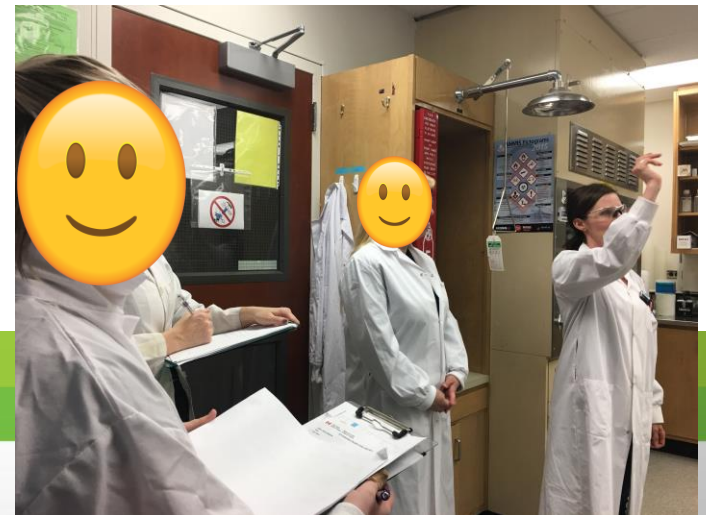


Inspection Time

- 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 or 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

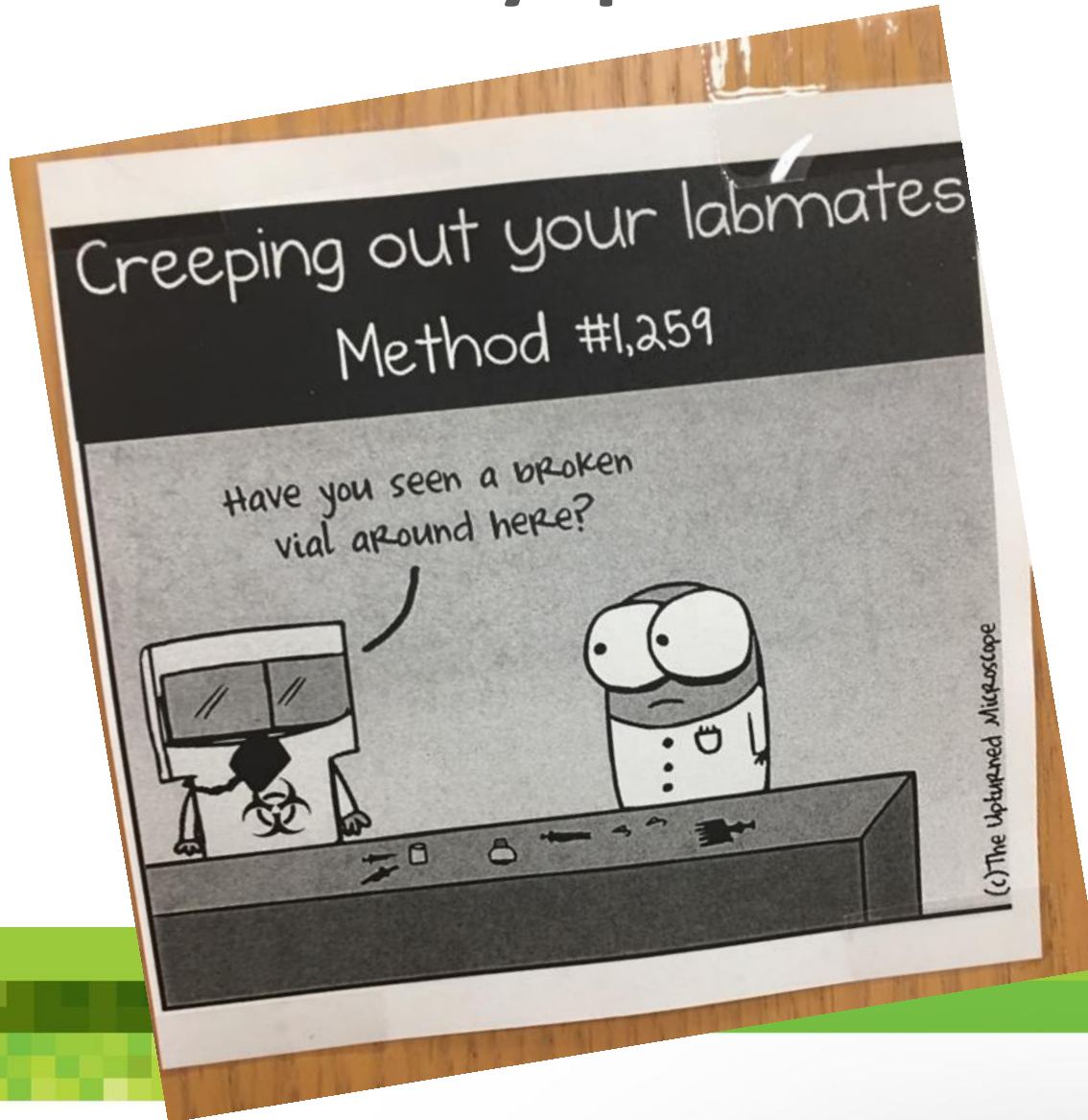


Conclusion - Lessons Learned

- Embrace it and have some fun doing it



Any questions??



Thanks!