BIOSAFETY AND BIOSECURITY INSPECTION SUMMARY ANNEXES 2022-23

Centre for Biosecurity
Public Health Agency of Canada

Table of Contents

Annex A: Abbreviations

CBS	Canadian Biosafety Standard
CMV	Compliance Monitoring and Verification
HAA	Health of Animals Act
HAR	Health of Animals Regulations
HPTA	Human Pathogens and Toxins Act
HPTR	Human Pathogens and Toxins Regulations
PHAC	Public Health Agency of Canada

Annex B: Terminology

Biosafety – Containment principles, technologies, and practices that are implemented to prevent unintentional exposure to infectious material and toxins, or their accidental release.

Biosecurity – Security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and other related assets.

Compliance – The state of conformity of a regulated party with legislative requirements (i.e., the HPTA/R, the HAA/R, and the conditions of Licence).

Compliance Monitoring – Compliance monitoring inspections are routine inspections carried out on facilities that have been issued a Pathogen and Toxin Licence to verify ongoing compliance with regulatory requirements. These include activities to observe, check the progress of, keep record of, watch, track, or check the quality of compliance.

Compliance Verification – Compliance verification inspections are carried out on licensed facilities to verify compliance with specific requirements. These could be follow-up inspections to verify deficiencies identified during a compliance monitoring inspection have been corrected. These include activities to confirm, substantiate, establish the truth of, establish the accuracy of, or establish the reality of compliance.

Deficiency – An observation of non-conformity with the CBS, a Biosafety Directive, a condition of licence, the HPTA/HPTR, or the HAA/HAR.

Facility – Structures or buildings, or defined areas within structures or buildings, where infectious material or toxins are handled or stored.

Inspection – Actions undertaken on-site or virtually, on a predetermined cycle or as required, for the purpose of verifying whether an organization is in compliance with the HPTA, HAA and their respective regulations, or for the purpose of preventing non-compliance.

Inspection Completed Date – The Inspection Completed Date is the date that all deficiencies, if identified, were successfully corrected by the organization. If no deficiencies were identified, the Inspection Completion Date is the last day inspectors were on-site, or the date of the last virtual inspection session. If the outcome is "Referral", the Inspection Completion Date is the date the file was referred for further action related to the licence. No further action required related to the inspection file reference number.

Inspection Start Date –The Inspection Start Date refers to the first day of an inspection, as inspections may be carried out over multiple days. For an on-site inspection, this is the date inspectors first arrived on-site at a facility. For a virtual inspection, this is the date the first virtual session was carried out.

Inspection Type – There are two possible types of inspection, see Compliance Monitoring and Compliance Verification.

Inspector – Any individual designated by the Minister under section 40(1) of the HPTA as an inspector for the administration and enforcement of the HPTA and its Regulations, and/or under section 13(3) of the *Canadian Food Inspection Agency Act* for the purpose of administrating and enforcing the HAA. An inspector's predominant purpose is the monitoring and verification of compliance. A designated inspector is also granted particular powers under the HPTA, as described in sections 41-45 and 51(1) of that Act.

Legal Authority – Documents that convey the PHAC's legal authorities (e.g. HPTA, HAA, licence conditions) or documents that set requirements (e.g. CBS, Biosafety Directives and Advisories).

Licence Number – The Licence Number is a unique number assigned to an organization for the purposes of licensing. The License Number indicated in the dataset reflects only a partial Pathogen and Toxin Licence number assigned to an organization, rather than full number, in order to protect against possible fraudulent use of this information.

Licensed – The inspection has determined the organization complies with the related Acts and Regulations. This outcome can be issued to organizations that have some deficiencies that do not pose an immediate biosafety or biosecurity risk. Activities with human pathogens and toxins may continue as long as the corrective actions are completed within the timeline.

Organization – An institution, company or municipality (including its facilities, and employees), or an individual that is subject to parts of the HPTA and HAR and requires a Pathogen and Toxin Licence under Section 18, and is typically represented by a licence holder and a designated biological safety officer.

Pathogen and Toxin Licence – An authorization to conduct one or more controlled activities with human pathogens or toxins issued by the Public Health Agency of Canada (PHAC) under Section 18 of the HPTA, and/or a permit issued by PHAC for the importation into Canada of indigenous terrestrial animal pathogens, under section 160 of the HAR.

Reference Number – The Reference Number is a unique number assigned by the inspection database when the inspection file is initiated.

Referral – The inspection has determined the organization does not comply with the related Acts and Regulations and has referred the file for further action related to the Licence (activities with human pathogens and toxins may be restricted, suspended or revoked).

Annex C: Frequently Asked Questions About Inspections

1. What are Biosafety and Biosecurity Inspections?

An inspection includes an assessment of a sample of requirements to verify an organization's compliance with the *Canadian Biosafety Standard*, as well as, the conditions of the Pathogen and Toxin Licence as outlined under the *Human Pathogens and Toxins Act* and *Human Pathogens and Toxins Regulations* (HPTA/HPTR), and provisions of the *Health of Animals Act* and *Health of Animals Regulation* (HAA/HAR). Work with pathogens and toxins must meet these standards and conditions.

These inspections allow PHAC to 1) determine if the organization meets the conditions of their Pathogen and Toxin Licence; 2) identify deficiencies; and 3) prevent deficiencies from becoming serious safety risks.

Organizations are required to 1) meet the conditions and requirements of the Pathogen and Toxin Licence; 2) correct biosafety and biosecurity deficiencies; and 3) keep detailed records.

Inspections may be announced or unannounced, on-site or virtual, or a hybrid of on-site and virtual.

2. What are pathogens and toxins?

A pathogen is a microorganism, nucleic acid, or protein capable of causing disease in humans or terrestrial animals.

A toxin, or microbial toxin, is a poisonous substance that is produced or derived from a microorganism and can lead to adverse health effects in humans or animals.

3. What types of organizations are licensed and inspected by PHAC?

The types of organizations working with pathogens and toxins include:

- Laboratories (e.g. diagnostic, research or quality assurance)
- Animal facilities (e.g. research)
- Large scale production companies (e.g. vaccine manufacturers)

4. How often are inspections conducted?

The frequency of inspection is based on PHAC's Policy on Compliance Monitoring, Verification and Regulatory Risk-Based Activities.

5. What are inspectors looking for during an inspection?

Inspectors review a sample of the organization's records and procedure documents, inspect physical facilities, and interview personnel to assess if an organization is following their Pathogen and Toxin Licence conditions, including meeting the *Canadian Biosafety Standard (CBS)* requirements applicable to their type of facility, and their regulatory requirements under the HPTA and HPTR and the HAA/HAR.

Based on the *Canadian Biosafety Standard*, here is an example of the requirements that could be inspected in detail by inspectors:

1. Physical Containment including:
    - Structure and Location
    - Surface Finishes
    - Air Handling Systems
    - Essential Biosafety Equipment
2. Operational Practices including:
    - Entry and Exit of Personnel, Animals and Materials
    - Work Practices
    - Decontamination and Waste Management
    - Records and Documentation
3. Performance and Verification Testing including:
    - Certification of biological safety cabinets (BSC)
    - Maintenance of inward directional airflow
    - Operation of mechanical or electrical door interlocks

6. How are deficiencies defined during inspections?

Inspectors note and categorize the types of deficiencies found during inspections as:

- Do not pose an immediate biosafety or biosecurity risk
- Could pose a biosafety or biosecurity risk if uncorrected
- Pose an immediate or potentially serious biosafety or biosecurity risk

When deficiencies are noted, the organization must implement corrective actions within timelines established by inspectors.

7. What happens if an inspector finds a deficiency posing an immediate or potentially serious biosafety or biosecurity risk?

The following measures could take place if an inspector finds a deficiency posing an immediate or potentially serious biosafety or biosecurity risk:

- The inspector may order the organization to carry out any measure that the inspector considers necessary to reduce or eliminate that danger; and

- There may be a separate process to consider varying, suspending or revoking the licence.

8. What happens after an inspection?

After carrying out an inspection, the inspector issues an inspection report to the organization detailing any deficiencies and corrective action timelines.

The corrective actions for any deficiencies noted during the inspection must be completed within the timeframe given by the inspector and failure to do so may result in further enforcement actions being taken, such as a notice of non-compliance or variation to the licence. PHAC may conduct a follow-up inspection to verify that the corrective actions have been implemented and to prevent further non-compliance.

The possible outcomes of an inspection are:

- Licensed
- Referral

9. Why are categories of deficiencies listed in the inspection summary instead of the actual individual deficiencies?

Individual deficiencies are not listed since the description of the deficiency could include information such as pathogen names, room numbers or locations, or facility services that could pose a biosecurity risk.

10. What are the possible Legal Authorities?

In the dataset, deficiencies are categorized by Legal Authority. A deficiency could be assigned against the CBS, a condition of the Pathogen and Toxin Licence, a Biosafety Directive, the HPTA/HPTR, or the HAA/HAR.

11. Why is the interval between the date an inspection started and the date an inspection is completed much longer for some inspections than others?

Some deficiencies, such as updating documents, may take less time than others to correct. When determining the length of time allotted to correct a deficiency, PHAC takes into account the nature of the deficiency, the administrative policies and procedures in place in an organization, the availability of materials, and the need for qualified off-site contractors, to name a few. PHAC may also grant extensions due to unforeseen circumstances such as the COVID-19 Pandemic. PHAC may require additional interim measures be implemented, such as modifying a procedure or placing a piece of equipment “out of service”, until the corrective actions are completed.

12. If an organization has more deficiencies than another, does it mean that it is less safe?

No, the number of deficiencies is not an indicator of safety. One facility could be assessed as having seven deficiencies related to record management that would not pose an immediate risk to the Canadian public, whereas a second facility may be assessed as having one deficiency for handling a pathogen in an unsafe manner, which could pose a higher safety risk.

13. How often are inspection summary reports updated on the Open Government Portal?

The first inspection summary report was published in early 2022 and included data for inspections completed between April 1, 2021 and December 31, 2021. Inspection summary reports will be updated on a quarterly basis thereafter.