# Inspection Policy for Cell, Tissue and Organ Establishments

POL-0057

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Canada

# Inspection Policy for Cell, Tissue and Organ Establishments (POL-0057)

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# About this document

## 1. Purpose

Health Canada inspects establishments that process, distribute or import human cells, tissues and organs (CTO) for transplantation. These inspections help monitor establishments that handle CTO for transplant in order to minimize the potential health risks to Canadian recipients of human CTO.

This policy describes the inspection process we use to assess whether a CTO establishment is complying with the:

- *Food and Drugs Act* (the Act)
- *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (CTO Regulations)

Health Canada's authority to inspect CTO establishments comes from sections 22(1) and 23 of the Act.

## 2. Scope

This policy applies to any Canadian CTO establishment registered with Health Canada whose activities are governed by the CTO Regulations.

Specifically, it applies to establishments that do any of the following activities with CTO for transplantation into another person:

- processing
- distributing
- importing

# 3. Inspection process

## Before an inspection

In most cases, Health Canada gives notice to an establishment before an inspection takes place. An inspector contacts the establishment to schedule the inspection and then sends a communication confirming the inspection's date and time. The establishment may also receive a pre-inspection package, which gives more details about the inspection process.

Unannounced inspections may be conducted if:

- there is an immediate risk to health and safety, or
- this approach will more accurately assess the establishment`s compliance with the Act and CTO Regulations.

## During an inspection

During an inspection, our inspectors observe and discuss the CTO establishment's existing processes and review its records, documents and procedures. They look carefully at many different areas to assess compliance, including but not limited to:

- processing
- quality system assurance
- inventory
- importation
- distribution
- exceptional distribution
- error, accident and adverse reaction investigation and reporting
- staff training
- equipment maintenance
- use of critical supplies

### Risk observations

Inspectors make observations when they note areas where the establishment is not adequately meeting its regulatory requirements. Each observation is classified by level of risk:

- critical
- major
- minor

Inspectors will communicate their findings to the establishment during the course of the inspection. It may be possible for the establishment to correct the observations during the inspection itself. If not, the establishment must take corrective actions after the inspection to address the observations.

Health Canada assigns inspection ratings based on the *Guidance on Classification of Observations for Inspection of Cells, Tissues, and Organs Establishments* (GUI-0101).

## After an inspection

After completing an inspection, the inspector creates a report (Exit Notice) that:

- documents the observations
- issues an overall inspection rating to the establishment

The overall rating indicates whether the establishment is compliant or non-compliant with the requirements of:

- the  Act
- CTO Regulations

The rating is based on observations noted by the inspector and includes:

- the number of observations
- risk level of each observation

A **compliant (C)** rating means the establishment is complying with the Act and CTO Regulations. Getting a compliant rating does not mean there were no issues during the inspection.  An

establishment will still need to take corrective actions to address any deficiencies noted against the Act and the CTO Regulations.

A **non-compliant (NC)** rating could mean that the establishment:

- has not shown that its activities comply with the Act and CTO Regulations
- will need to take immediate corrective actions

Health Canada may cancel an establishment's registration in some cases.

Establishments have 20 working days to provide a written response to the Exit Notice. This written response must be sent directly to the inspector.

When an establishment is given a non-compliant rating, it must address the deficiencies by creating and implementing a detailed corrective action plan. The plan must include target dates for completion.

Health Canada may also consider enforcement options following a non-compliant rating. Options are outlined in the *Compliance and Enforcement Policy* (POL-0001).

### Inspection report cards

Health Canada posts report cards for CTO inspections. Each inspection report card summarizes the inspection observations and ratings, and makes them available to the public. You can find them here:

- Drug and Health Product Inspections Database

# 4. Inspection frequency and duration

## How often we conduct inspections

CTO establishments are inspected within 24 months of registering with Health Canada. After this initial inspection, we use the following steps to determine how often an establishment will be inspected:

1. We assess the level of risk of the establishment's activities: high, medium or low.

High: The processing of CTO is considered to be a high risk activity. Establishments that are responsible for processing CTO and determining if they are safe for transplantation are known as “source establishments.”

A CTO establishment is considered a source establishment if it is:

- an organ donation organization (for organs from deceased donors)
- a tissue bank (For tissues or for adjunct vessels retrieved with an organ and not used immediately in organ transplantation)
- a transplant establishment (for organs from a living donor or lymphohematopoietic cells that are not banked)
- a cell bank (banked lymphohematopoietic cells)
- an establishment that prepares cells for use in transplantation (for islet cells)

Processing of CTO can include:

- donor:
    - testing
    - screening
    - suitability assessment
- banking
- quarantine
- preservation
- packaging and labelling
- retrieval (except in the case of organs and islet cells)
- preparation for use in transplantation (except for organs)
- testing and measurements performed on CTO after they are retrieved

Medium: Importers and distributors are responsible for storing and transporting CTO that have already been deemed safe for transplantation. For this reason, their activities are considered medium risk.

Low: Currently, no activities related to CTO are considered low risk.

2. We review the overall rating of the last inspection(s).
    - Establishments conducting high risk activities with a compliant rating at the last inspection will be inspected within 24–36 months.
    - Establishments conducting medium risk activities with a compliant rating at the last inspection will be inspected within 30–36 months.
    - Establishments with a non-compliant rating at the last inspection will:

- have the scope and timeline of the re-inspection determined by the inspector but is generally re-inspected within 6-12 months

- Establishments that received a non-compliant rating at one inspection and then a compliant rating at the next inspection will be inspected within 12–24 months.

Establishments may be inspected more often if Health Canada believes there is a potential risk to the health and safety of Canadians.

### How long inspections last

In general, inspectors determine the length of each inspection on a case-by-case basis.

The average time for an inspection varies depending on the:

- complexity and number of an establishment's activities
- number of inspectors
- size of the establishment

## 5. Contact information

For questions about the inspection process, please contact the Biological Product Compliance Program: BPCP_PBPB@hc-sc.gc.ca

# Appendices

## Appendix A – Glossary

These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Food and Drugs Act* or CTO Regulations, the definition in the Act or Regulations prevails.

**Compliance –** The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement.

**Enforcement –** Actions that may be taken to induce, encourage or compel compliance with the FDA and its associated Regulations.

**Inspection –** Monitoring and assessment of compliance against any of the applicable requirements of the *Food and Drugs Act* and its associated Regulations by a designated inspector. Inspections are conducted at pre-determined intervals or on a risk basis.

# Appendix B – References

## Laws and regulations

*Food and Drugs Act*

Safety of Human Cells, Tissues and Organs for Transplantation Regulations

National Standard of Canada CAN/CSA-Z900 – Cells, Tissues and Organs for Transplantation

## Guidance documents and policies

*Guidance Document for Cell, Tissue and Organ Establishments: Safety of Human Cells, Tissues and Organs for Transplantation*

*Guidance on Classification of Observations for Inspection of Cells, Tissues and Organs Establishments* (GUI-0101)

*Compliance and Enforcement Policy* (POL-0001)