Establishments that Transplant Human Cells, Tissues and Organs – Including Transplant surgeons and Dental Professionals

Frequently Asked Questions

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Canada

Establishments that Transplant Human Cells, Tissues and Organs – Including Transplant surgeons and Dental Professionals – Frequently Asked Questions

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Table of contents

About this document 3
1. Purpose 3
2. Scope 3
3. Frequently Asked Questions 4
4. Additional Information 7
5. Contact Information 8

About this document

1. Purpose

Establishments that process, import, distribute or handle human cells, tissues and organs (CTO) intended for transplantation must comply with the *Food and Drugs Act* (the Act) and the Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations).

The purpose of this document is to address frequently asked questions for establishments that transplant human cells, tissues and organs.

2. Scope

This document applies to all establishments that transplant human cells, tissues and organs, including transplant surgeons and dental professionals.

3. Frequently Asked Questions

3.1 How are human cells, tissues and organs (CTO) for transplantation regulated in Canada?

In Canada, human CTO for transplantation are regulated under the authority of:

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

The CTO Regulations reference specific sections of the General Standard CAN/CSA Z900.1, entitled Cells, Tissues, and Organs for Transplantation: General Requirements. In addition, the CTO Regulations make reference to four of the five subset standards, published by the Canadian Standards Association (CSA) Standards for specific organs and tissue types:

- Lymphohematopoietic Cells for Transplantation
- Perfusable Organs for Transplantation
- Tissues for Transplantation
- Ocular Tissues for Transplantation

These referenced sections have the force of law, which means that establishments must comply with the CTO Regulations and these sections of the CSA Standards.

3.2 What is the scope of the CTO Regulations?

The CTO Regulations apply to all individuals and establishments in Canada that handle, process, distribute, transplant or import human organs, or minimally manipulated cells and tissues for homologous use (performs the same basic function) in transplantation in another individual.

Minimally manipulated means:

- with respect to a structural tissue, the processing does not alter the original characteristics that are relevant to its claimed utility for reconstruction, repair or replacement; and
- with respect to cells and nonstructural tissue, the processing does not alter the biological characteristics that are relevant to their claimed utility.

In the case of demineralized bone product, if the product is only combined with a sterilizing, preservation or storage agent, it would be considered minimally manipulated and regulated under the CTO Regulations.

The purpose of the CTO Regulations is to minimize the potential health risks to Canadian recipients of human CTO by addressing the safety aspects related to the processing and handling of these products.

3.3 Are CTO Establishments required to register with Health Canada?

The following CTO establishments, with the exception of establishments that retrieve and establishments that transplant only are required to register with Health Canada:

- Source establishments: Establishments that are responsible for processing and determining that the CTO is safe for transplantation are referred to as the source establishment. Some examples of source establishments:
    - The organ donation organization (ODO) in the case of organs from deceased donors
    - Eye and Tissue banks in the case of tissues
    - In the case of an organ from a living donor or lymphohematopoietic cells that are not banked, the transplant establishment is considered the source
- It is important to note that foreign source establishments that distribute tissues to Canadian establishments are also required to register with Health Canada
- Establishments that import CTO for distribution within Canada including those within their own health authority
- Canadian establishments that distribute CTO within Canada

3.4 Are establishments that only transplant tissues and establishments that only transplant organs from deceased donors required to register with Health Canada?

No. Establishments that only transplant organs from deceased donors and establishments that only transplant tissues are not required to register with Health Canada. Although they are not required to register with Health Canada, they must follow certain sections of the CTO Regulations (Refer to Question 3.5).

3.5 Which sections of the CTO Regulations apply to establishments that only transplant CTO?

The following sections of the CTO Regulations apply to establishments that only transplant CTO

Section 4 – Prohibition	Transplant establishments must ensure that CTO have been processed by an establishment registered with Health Canada and have been determined safe for transplantation. (Refer to Question3.6 for further details)
Section 40 – 41 – Exceptional Distribution	Health Canada recognizes that transplantations are often urgent and life-saving/life-enhancing. The CTO Regulations provide a mechanism, referred to as Exceptional Distribution, which allows for the distribution of CTO that may not meet all of the regulatory requirements, when fully compliant CTO are not immediately available. The transplant physician or dentist must authorize the exceptional distribution, based on their clinical judgement, and obtain informed consent from the recipient. It is important to note that in the case of tissues, it is unlikely that exceptional distribution could be applied as it is rare that fully compliant tissues are unavailable for transplantation.
Sections 43, 46, 47, 49, 50, 52, 53 and 54 – Errors, Accidents and Adverse Reaction1 Investigation and Reporting	A transplant establishment must immediately report suspected errors/accidents and adverse reactions to the source establishment and quarantine implicated products. The transplant establishment must also report it to the importer, when applicable. The transplant establishment is required to cooperate with the source establishment that is conducting an investigation with any relevant information in its possession with respect to CTO they have transplanted.
Sections 55 - 57 and 60 - 62 –	These sections provide the requirements regarding the records that must be retained by a transplant establishment.

Records	Specifically, the transplant establishment must keep records that include: the establishment from which it received the CTO; a description of the CTO; the donor identification code; the registration number of the source establishment; exceptional distribution information, if any; information that allows the identification of the recipient; and applicable error/accident and adverse reaction information, if any. Applicable records must be retained for 10 years from the date of the transplantation, of the final disposition, or of the expiry of the tissue. Furthermore, the CTO Regulations also require each establishment to maintain traceability throughout the chain of distribution, allowing it to be traced forward to the recipient or back to the donor.

1 "error" means a deviation from the standard operating procedures or applicable laws that could adversely affect the safety of a transplant recipient of the safety, efficacy or quality of cells, tissues or organs.

"accident" means an unexpected event that is not attributable to a deviation from the standard operating procedures or applicable laws and that could adversely affect the safety of a transplant recipient or the safety, efficacy or quality of cells, tissues or organs.

"adverse reaction" means an undesirable response in the recipient to transplanted cells, tissues or organs, including the transmission of a disease or disease agent.

3.6 How can a transplant establishment verify that a source establishment is registered with Health Canada?

Transplant establishments can verify if the source establishment is registered with Health Canada by emailing Health Canada at: CTO_registration@hc-sc.gc.ca

Furthermore, the products must be labelled with the Health Canada registration number and the name of the source establishment. This information must be on the exterior label and package insert of the CTO. The registration number is a six digit number and starts with "1".

4. Additional Information

You should read this document along with:

- the *Food and Drugs Act*

- the Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations)
- relevant sections of the National Standard, including:
    - CAN/CSA Z900.1: *Cells, tissues, and organs for transplantation: General requirements and appropriate subsets*
- *Guidance Document for Cell, Tissue and Organ Establishments – Safety of Human Cells, Tissues and Organs for Transplantation*
- *Inspection Policy for Cell, Tissue and Organ Establishments* (POL-0057)
- *Guidance on Classification of Observations for Inspection of Cells, Tissues and Organs Establishments* (GUI-0101)

5. Contact Information

Any questions concerning the CTO Regulations or the *Guidance Document for Cell, Tissue and Organ Establishments – Safety of Human Cells, Tissues and Organs for Transplantation* can contact: BGTD.OPIC@hc-sc.gc.ca

Additional information can also be obtained by contacting: BPCP_PCPB@hc-sc.gc.ca