Ontario
Trillium Gift of Life Network

Clinical Process Instruction Manual

Health Canada Registration Process Instruction

Policy:

Every establishment must be registered under Health Canada regulations. The Cell, Tissue, Organ (CTO) registration requirements provide Health Canada with information regarding the identity of the establishment, and programs that reside within establishments, the types of products being processed, distributed or transplanted and the types of activities being carried out.

Senior Leadership is responsible for ensuring any changes to registration information is captured on the registration form. The Director Quality or designate is responsible for ensuring any changes to registration information are communicated to Health Canada within 30 days.

Process:

Application for Registration

1. In the event a new program (e.g. recovery partner or organ type) must be registered, the "Application for Registration Form" from Health Canada will be completed following the process described in *Health Canada's Guidance Document for Cell, Tissue and Organ Establishments*.

Registration Renewal

2. TGLN is responsible for maintaining CTO registration for both organ and tissue donor programs in the province of Ontario.

3. CTO Registration numbers expire on December 31 of the year <u>following</u> the year it was issued.

4. In September, prior to the renewal, the Quality Assurance Lead or designate will complete a registration form indicating "Registration Renewal."

5. Notice of the requirement to complete an application for renewal will be provided by the Biological Product Compliance Program of Health Canada prior to the expiry date of the issued certificate of registration.

    5.1. Forms are also available electronically on Health Canada's website.

6. The following information must be included on the application:

    6.1. Establishment name and civic address

    6.2. Name and telephone number of responsible person to contact for further information (i.e. Director Quality)

    6.3. Description of cells, tissues and organs that are processed, distributed or imported

    6.4. Description of types of processing, distribution or transplantation activities

    6.5. Period during which the establishment has been in operation

    6.6. Statement signed and dated by the CMO-Donation and CMO-Transplant that attests the establishment is in compliance with the regulations

    6.7. Completed registration form is sent to Health Canada

Registration Certificates

7. Received certificates from Health Canada are stored electronically.

Registration Information Updates

8. It is a requirement to notify Health Canada within 30 days of any changes to the information provided on the registration form.

    8.1. Ideally, TGLN will notify within 7 days prior to a change or as soon as possible after, up to 30 days.

9. Notification may be made using an updated application form.

10. The date on which the change or cessation became effective needs to be reflected on the contents of notice.

11. Updated notice must be signed and dated by the CMO-Donation and CMO-Transplant.

12. Completed notice is sent to Health Canada.

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Health Canada Registration Certificate		Quality Department	Quality Department	16 years

References:

Safety of Human Cells, Tissues and Organs for Transplantation Regulations. Canada Gazette Part II.

Health Canada Guidance Document for Cell, Tissue and Organ Establishments. Safety of Human Cells, Tissues and Organs for Transplantation.