CTO Establishment Inspections

'an Atlantic update - Organs'



October 14, 2010

Canada

Scope of Inspections

All CTO establishments must be registered with Health Canada with the exception of establishments that only retrieve, transplant or import directly for transplant (i.e not for further distribution).

All registered Canadian establishments will be inspected

- Source Establishments
- Establishments that importers
- Establishments that distribute, including transplant establishments and dentists that further distribute CTO

Inspection Program - Organs

Source Establishments (SE) for Organs

- In the case of organs from a deceased donor; the relevant organ donation organization

- In the case of organs from a living donor; the relevant transplant program

CTO Inspections

Objectives

- to assess compliance with the CTO Regulations
- to take compliance and enforcement action, as required

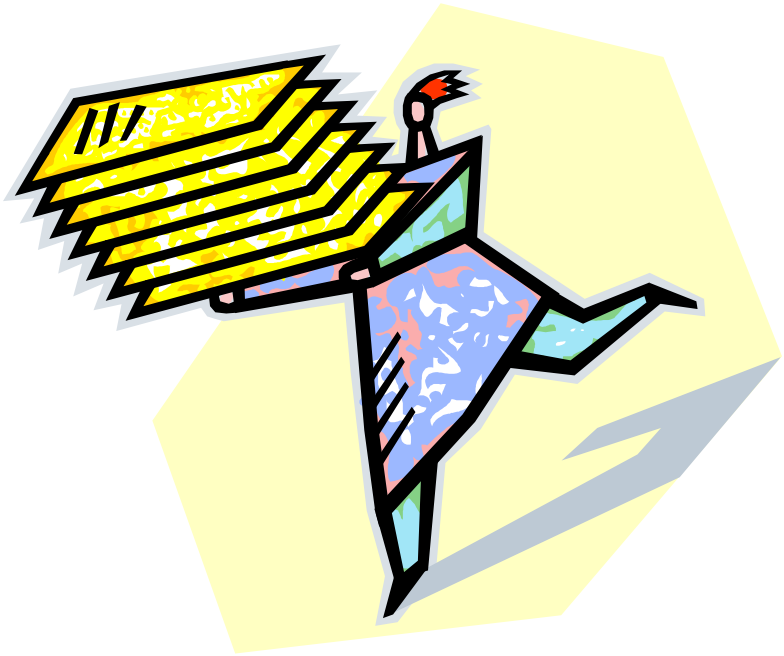
Approach

- performed according to established SOPs based on policies and legislation
- observations of serious nature discussed immediately

Inspection Process

Verification of compliance with all applicable CTO Regulations by

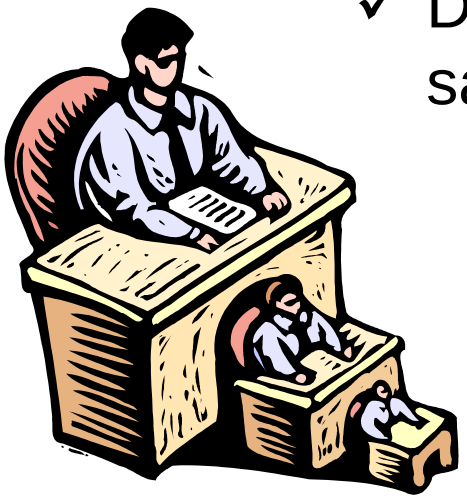
- examining documentation
- discussing the application of existing practices



Inspection - Key Areas

- Establishment Registration
- Prohibitions
- Source Establishment Responsibilities
- Exceptional distribution
- Recordkeeping requirements
- Error and Accident Reporting System
- Adverse Reaction Reporting System
- Records, Personnel, Facilities, Equipment and Supplies
- Quality Assurance System

Source Establishment Responsibilities



- ✓ Determining that the organ is safe for transplantation

- ✓ Processing of the organs, whether the activity is performed by the source establishment or by another establishment on behalf of the source establishment

Processing Activities

a) Donor screening
b) Donor testing
c) Donor suitability assessment
d) Retrieval, except for organs and islet cells
e) Testing & measurements performed post retrieval
f) Preparation for use in transplantation, except for organs
g Preservation
h) Quarantine
i) Banking
j) Packaging and labelling

Donor Screening

“an evaluation based on . . .

- the donor’s medical and social history
- physical examination
- the results of any diagnostic procedures performed

Donor Testing

- Source establishments are responsible for donor testing even if testing is performed by another establishment
- CTO Regulations list the required testing
- Test kits must be licensed by Health Canada (if testing is performed in Canada) or licensed in Canada or US – if testing is performed outside of Canada

Donor Suitability Assessment

“an evaluation based on . . .

- the donor screening
- all donor testing results (live donors)
- the donor testing results that are required at the time of transplantation

Packaging & Labelling

Labelling

- Interior label
- Package insert
- Exterior label

Exceptional Distribution

Source Establishment

- Only the source establishment can determine if an organ can be distributed through exceptional distribution
- All 3 conditions outlined in s. 40 must be met

Transplant Physician

- Authorizes the exceptional distribution of a particular organ

Transplant Establishment

- Obtains informed consent from the recipient

Notice of Exceptional Distribution

- Source Establishment must keep a copy of the notice
- Transplant Establishment must keep a copy of the notice
- What is needed in a Notice of Exceptional Distribution?
  - Name of the transplanted CTO
  - CTO Reg(s) not meet
  - Transplant physician's decision / justification
  - Name of the ODO that distributed CTO
  - Name of the transplant establishment and transplant physician who authorized the distribution
  - Time and date of the written authorization and a copy of the authorization signed by the transplant physician

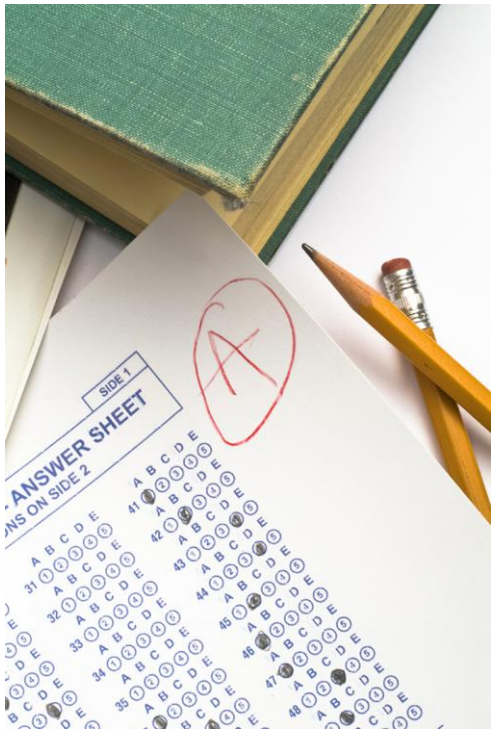
Quality Assurance System

- Management requirements
- Documentation system
- Training program
- Information/ Data control system
- Process control
- Quality control
- Supplies/ Services control process
- Process for investigating E/A, AR
- Audit program

Documentation System

- Records must be kept for at least 10 years, secure, and stored under appropriate conditions
- All documents are uniquely identified and controlled
- Approved SOPs for all activities that could affect the safety of the CTO

Training Program



- Sufficient personnel who are qualified by education, training, or experience to carry out their respective tasks

- A system for orientation and training, both initial and ongoing, of personnel and for the evaluation of their competency

Audit Program

- An audit to verify that the activities it carries out comply with the CTO Regulations and with the establishment's SOPs must be conducted every two years
- Auditor must be a person who does not have direct responsibility for the activities being audited