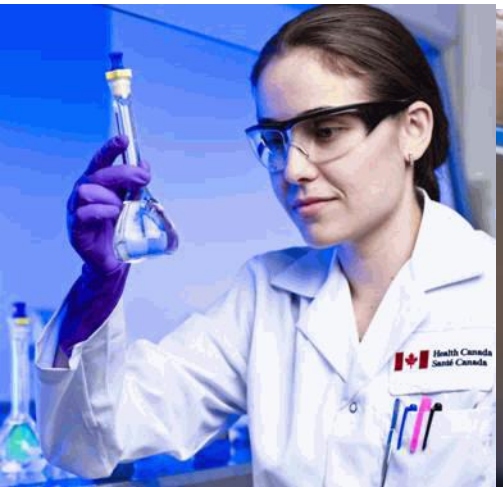
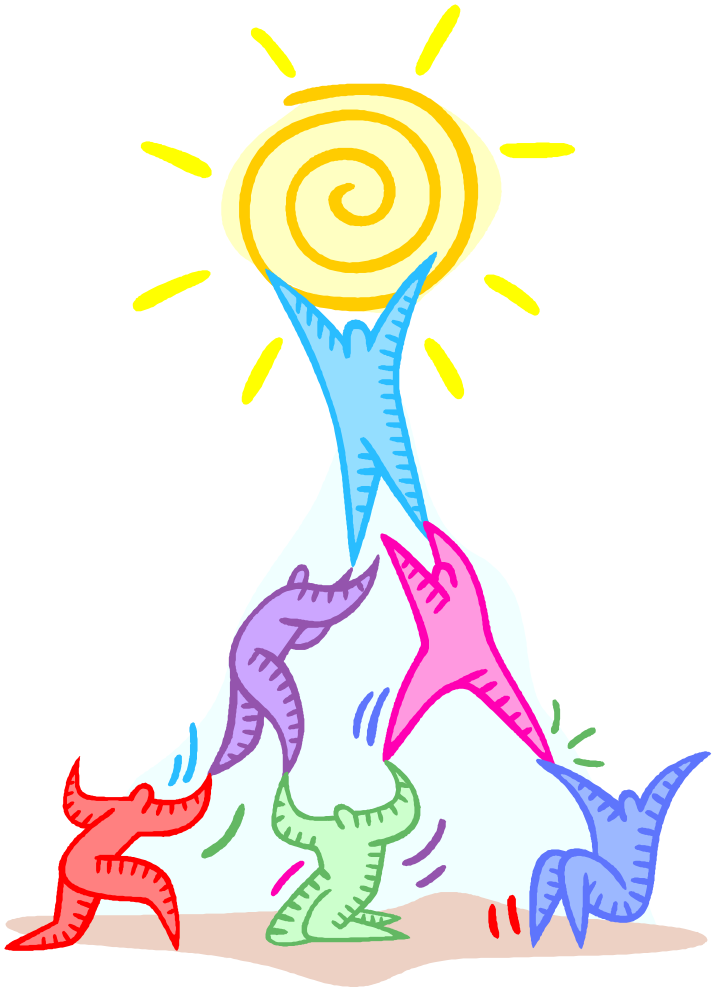
CTO Establishment Inspections

'an Atlantic update - Tissues'



October 14, 2010

Canada



Health Products and Food Branch Inspectorate

L'Inspectorat de la Direction générale des produits de santé et des aliments

Compliance & Enforcement

Deliver a national compliance and enforcement program, pursuant of the *Food & Drugs Act*, for health products such as medical devices, drugs, natural health products, blood, and

- cells, tissues and organs (CTO)

Activities include establishment registration/ licensing, laboratory analysis, compliance verifications, investigations, and inspections.

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 a serious nature discussed immediately

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

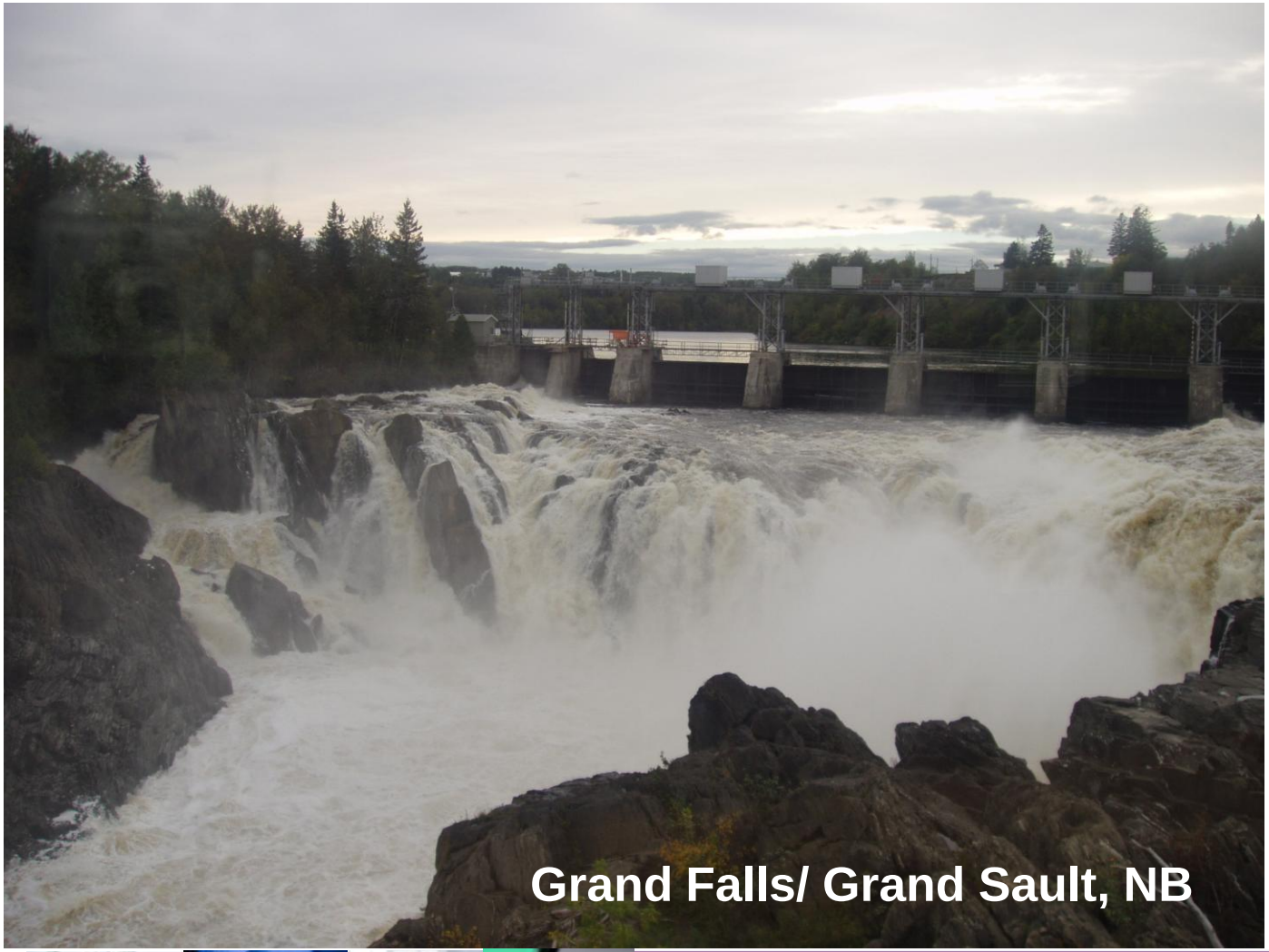
Inspection Program - Tissues

Source Establishments for Tissue

In the case of tissues, the relevant tissue bank

Source Establishment for Adjunct Vessels

In the case of adjunct vessels that are retrieved with an organ and not used immediately in the organ transplantation, the relevant tissue bank



Grand Falls/ Grand Sault, NB

Health Products and Food Branch Inspectorate

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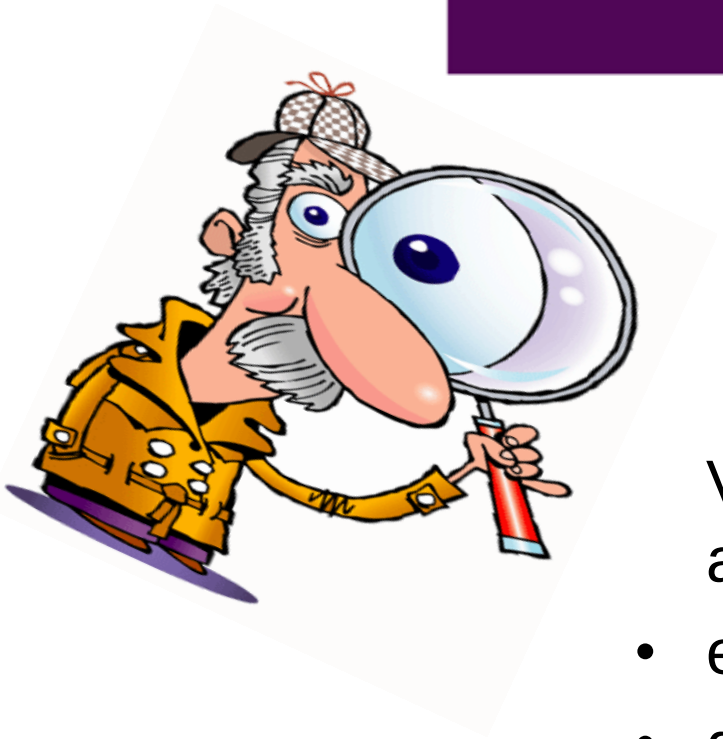
Inspection Process



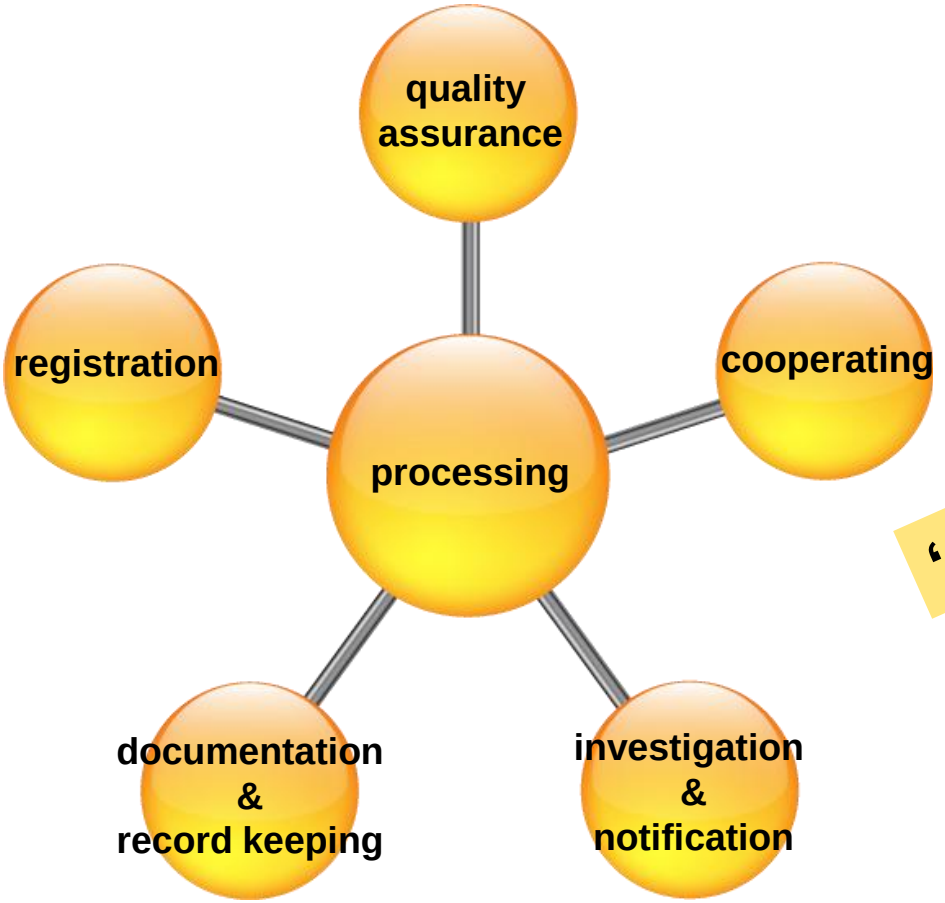
Verification of compliance with all applicable CTO Regulations by

- examining documentation
- direct observation
- 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



‘safe’ for transplantation

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

in vitro diagnostic devices that are used by an establishment in the testing of donor blood for transmissible disease agents or markers under these Regulations must be licensed either

(*a*) in Canada, if the testing is performed in Canada; or

(*b*) in Canada or the United States, if the testing is performed outside Canada

Packaging

An establishment that **packages cells, tissues or organs** must ensure that it uses appropriate packaging materials that are free from damage and capable of maintaining integrity of the cells, tissues and organs

Labelling

An establishment that distributes tissues must ensure that all of the applicable information, as indicated by an “X”, set out in the table accompanying section 31 is provided on the interior label, in the package insert and on the exterior label.

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

Standard Operating Procedures

The standard operating procedures must meet all of the following requirements:

(*a*) be in a standardized format;

(*b*) be approved by the medical director or scientific director;

(*c*) be available for use at all locations where the relevant activities are carried out;

(*d*) have any changes to the procedures approved by the medical director or scientific director before being implemented; and

(*e*) be kept up-to-date.

Error / Accident

A source establishment that has reasonable grounds to believe that the safety of cells, tissues or organs for whose processing it is responsible has been compromised by the occurrence of an error or accident during processing must immediately take all of the following actions:

a) quarantine any implicated tissues

b) send a notice to other involved establishments

c) initiate an investigation

Error/ Accident Notice

The notice must include all of the following information:

(*a*) the reasons for its belief that the safety of the cells, tissues or organs has been compromised;

(*b*) an explanation of how the safety of the implicated cells, tissues or organs may have been compromised, if known;

(*c*) the donor identification codes of all implicated cells, tissues and organs;

(*d*) the name of any suspected transmissible disease or disease agent, if known; and

(*e*) a statement requiring all implicated cells, tissues and organs to be quarantined immediately and until further notice from the source establishment and specifying any other corrective action

Audit

An establishment must conduct an audit every two years of the activities that it carries out to verify that those activities comply with these Regulations and with its standard operating procedures, by a person who does not have direct responsibility for the activities being audited.