



Santé  
Canada

Health  
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Health Products and Food Branch Inspectorate

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



# MEDICAL DEVICE REGULATORY INSPECTION PROGRAM

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# Inspection Process Demonstration of Compliance

- device classification and licensing
- advertising
- labelling
- establishment licensing
- distribution records
- complaint handling
- mandatory reporting
- recalls
- implant registration
- custom-made or special access devices
- devices for investigational testing
- export certificates



# Assessment Device Licensing

## Regulation

- Section 26 - no sale or import of a device unless manufacturer holds a licence or amended licence

## Application

- any person importing or selling a medical device in Canada
- manufacturer's responsibility
- incorrect classification affects compliance



# Assessment Device Licensing

## Assessment

- Inspector reviews classification and licensing of sampled products

### Manufacturers

- no procedure to classify - **observation**
- no procedure for licensing, amending licences - **observation**

### Importers and distributors

- no procedure to verify classification - **observation**
- no procedure to verifying licensing - **observation**

### Manufacturers, importers, distributors

- incorrectly classified device - **may be treated as unlicensed**
- Importation or sale without a valid licence - **noncompliance + stop sale + recall**



# Assessment Advertising

## Regulation

- Section 24 - contraceptive advertising
- Section 27 - no advertising unless
  - manufacturer holds a device licence, or
  - notice in catalogue indicates that not all devices may be licensed

## Application

- any person advertising a class II, III or IV medical device for sale in Canada



# Assessment Advertising

## Assessment

- Inspector samples and reviews advertising material and catalogues
- contraceptive advertising does not meet the requirements - **noncompliance**
- no procedure for review of advertising - **observation**
- advertising unlicensed devices - **noncompliance**
- no statement in catalogues that some devices may not be licensed - **noncompliance**



# Assessment Labelling

## Regulations

- Section 21 - label contents
- Section 22 - format and appearance
- Section 23 - bilingual requirements

## Application

- any person importing or selling medical devices in Canada



# Assessment Labelling

## Assessment

- Inspector samples labels from different products, device classes

### Manufacturers

- no procedure to design and produce labels in compliance with Regulations - **observation**

### Importers and distributors

- no procedure to review labelling for compliance to Regulations - **observation**
- labelling does not meet the requirements; e.g., name, manufacturer, identifier, control number, expiry, directions for use, storage conditions, language - **noncompliance**



# Assessment Establishment Licence

## Regulations

- Section 44 – Prohibition
  - cannot import or sell without MDEL
  - exemptions
- Section 45 – Application
  - requirements of MDEL application
- Section 48 – Notification
  - notification of some changes within 15 days



# Assessment Establishment Licence

## Application

- any person importing or selling a medical device in Canada
- exemptions by Regulation
  - retailer (person selling solely to the ultimate consumer)
  - health care facility
  - manufacturers of class II, III, or IV medical devices
  - manufacturers of class I devices who sell solely through a licensed establishment
  - persons who import a device for their own personal use
  - establishments who import or sell only medical devices for veterinary use
  - dispensers
  - establishments who import or sell only custom-made devices, special access devices, devices for investigational testing



# Assessment Establishment Licence

## Assessment

### Section 44

- absence of medical device establishment licence is normally investigated outside inspection scope

### Section 48

- if company name or address or contact person is different than that on the establishment licence - **noncompliance**



# Assessment Establishment Licence

## Section 45 (a to j)

- establishment name and address incorrect - **noncompliance**
- representative information incorrect - **noncompliance**
- activities (import, distribute, class I manufacturer) incorrect - **noncompliance**
- list of manufacturers incorrect or incomplete - **noncompliance**
- medical specialties for each manufacturer incorrect - **not reviewed**
- class of devices for each manufacturer incorrect - **noncompliance**
- no documented procedures (false attestation) - **noncompliance for each**
- inadequate procedure (major deficiencies) - **noncompliance for each**
- minor deficiencies in procedure - **observation**
- list of sites incorrect or incomplete - **noncompliance**



# Assessment Distribution Records

## Regulations

- Section 52
  - distribution record for each device
- Section 53
  - adequacy of records to permit recall
- Section 55
  - retention, the longer of projected useful life of the device, or
  - 2 years post shipping date
- Section 56
  - timely retrieval



# Assessment Distribution Records

## Application

- manufacturers, importers, distributors
- retailers and health care facilities exempt by Regulation
- attestation by MDEL applicants (sec 45(g))
  - procedure for distribution records



# Assessment Distribution Records

## Assessment

Procedure (sec 45(g))

- no documented procedure - **noncompliance**
- inadequate procedure (major deficiencies) - **noncompliance**
- minor deficiencies in procedure - **observation**

Inspector requests distribution records of a few devices

- cannot retrieve - **noncompliance**
- adequacy of records to permit an effective recall
  - major deficiency - **noncompliance**
  - minor deficiency - **observation**

Retention period too short - **noncompliance**



# Assessment Complaint Handling

## Regulations

- Section 57
  - records of problems regarding performance or safety
  - all actions taken in response to problems
- Section 58
  - documented procedures that enable effective, timely investigation of problems; and
  - effective, timely recalls



# Assessment Complaint Handling

## Application

- manufacturers, importers, distributors
- retailers and health care facilities exempt by Regulation
- attestation by MDEL applicants (sec 45(g))
  - procedure for complaint handling



# Assessment Complaint Handling

## Assessment

Procedure (sec 45(g))

- no documented procedure - **noncompliance**
- inadequate procedure (major deficiencies) - **noncompliance**
- minor deficiencies in procedure - **observation**

Inspector sample and reviews problem report records

- major deficiencies - **noncompliance**
- minor deficiencies - **observation**
- complaint handling procedure not followed - **noncompliance**





# Assessment Mandatory Problem Reporting

## Regulations

- Section 59
  - requirement to report, criteria for reports
- Section 60
  - preliminary report contents, timeframes
- Section 61
  - final report contents and timeframe
- Section 61.1
  - designate importer to report on behalf of manufacturer



# Assessment Mandatory Problem Reporting

## Application

- manufacturer and importer
- attestation by MDEL applicant (sec 45(h))
  - procedure for mandatory problem reporting



# Assessment Mandatory Problem Reporting

## Assessment

Procedure (sec 45(h))

- no documented procedure - **noncompliance**
- inadequate procedure (major deficiencies) - **noncompliance**
- minor deficiencies in procedure - **observation**

Inspector samples and reviews mandatory problem report records

- major deficiencies - **noncompliance**
- minor deficiencies - **observation**
- mandatory problem reports not submitted - **noncompliance**
- reporting procedure not followed - **noncompliance**
- reporting for manufacturer without authorization - **noncompliance**

# Assessment Recall

## Regulations

- Section 58(b)
  - documented procedures that enable an effective and timely recall
- Section 64
  - initial report
- Section 65
  - final report
- Section 65.1
  - designate importer to report on behalf of manufacturer

# Assessment Recall

## Application

- Procedure
  - manufacturer, importer, distributor
- Reporting
  - manufacturer and importer
  - retailers and health care facilities exempt by Regulation
- attestation by MDEL applicant (Sec 45(g))
  - procedure for recalls

# Assessment Recall

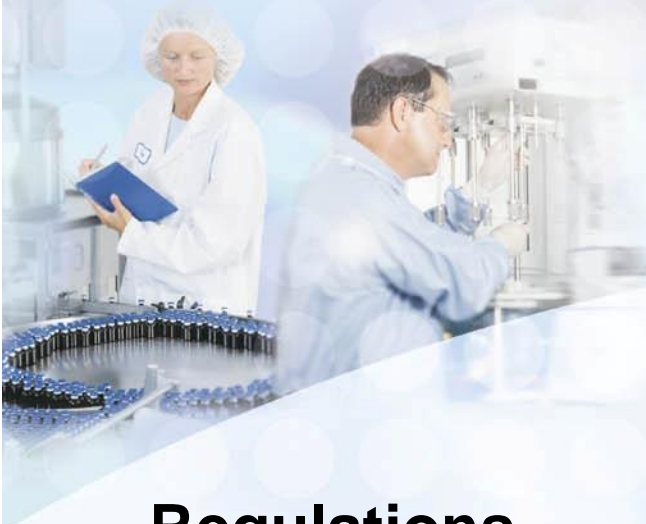
## Assessment

### Procedure

- no documented procedure - **noncompliance**
- inadequate procedure (major deficiencies) - **noncompliance**
- minor deficiencies in procedure - **observation**

### Inspector samples and reviews recall reports

- recalls not reported - **noncompliance**
- recall reporting is late - **noncompliance**
- recall procedure not followed - **noncompliance**
- reporting for manufacturer without authorization - **noncompliance**



# Assessment Implant Registration Cards

## Regulations

- Sections 66 to 68

## Application

- manufacturer
- If an importer or distributor handles a device that requires an implant registration card, the adequacy of the card will be assessed during the inspection
- If an importer or distributor is designated by the manufacturer to collect the implant registration information, this process will be assessed during the inspection



# Assessment Implant Registration Cards

## Assessment

- implant registration card does not meet the requirements - **noncompliance (manufacturer)**
- implant registration information not adequately collected or maintained - **noncompliance (designate)**



# Assessment Custom-Made / Special Access

## Regulations

- Section 70
  - no import or sale without Health Canada authorization
- Sections 71-72
  - authorization issued to designated manufacturer or importer
- Section 75 - labelling
  - statement that device is custom-made or special access device
- Section 76 - distribution records
- Section 77 - reporting of incidents
  - reported to Health Canada, and to manufacturer or importer
- Section 78 - implant registration



# Assessment Custom-Made / Special Access

## Application

- authorization applies to class III or IV custom-made devices, and special access devices
- labelling applies to all classes
- health care professional
  - application for authorization
  - reporting serious incidents
- manufacturer or importer
  - import or sell
  - labelling
  - distribution records
  - implant registration



# Assessment Custom-Made / Special Access

## Assessment

### Procedure

- no documented procedure to control - **observation**
- major or minor deficiencies - **observation**

Inspector samples and reviews custom-made and special access devices, and related records

- Importation / sale without authorization - **noncompliance + stop sale**
- label does not meet requirements - **noncompliance**
- no distribution records - **noncompliance**



# Assessment Investigational Testing

## Regulations

- Section 79
  - investigational devices - human subjects
- Section 80
  - no import or sale without Health Canada authorization
- Section 86 - labelling
  - statement “Investigational Device” in English and French
  - statement “To be Used by Qualified Investigators Only” in English and French



# Assessment Investigational Testing

## Regulations

- Section 87 – advertising
  - must declare that device is subject of investigational testing
- Section 88 - other requirements
  - distribution records (s 52-56)
  - complaint handling (s 57, 58)
  - mandatory problem reporting (s 59-62)
  - recalls (s 63-65)
  - implant registration (s 66-68)



# Assessment Investigational Testing

## Application

- authorization applies to class II, III or IV devices
- qualified investigator
  - follow authorized protocol
  - informed consent of patient
  - report serious incidents
- manufacturer or importer
  - import or sell
  - labelling
  - advertising
  - distribution records
  - complaint handling
  - mandatory problem reporting
  - recalls
  - implant registration





# Assessment Investigational Testing

## Assessment

### Procedure

- no documented procedure to control - **observation**
- major or minor deficiencies - **observation**

Inspector samples and reviews devices subject to investigational testing, and related records

- importation / sale without authorization - **noncompliance + stop sale**
- label does not meet requirements - **noncompliance**
- advertising does not meet requirements - **noncompliance**
- no distribution records - **noncompliance**
- no procedure for complaint handling - **noncompliance**
- mandatory problem reports not submitted - **noncompliance**
- recalls not reported - **noncompliance**



# Assessment Export Certificates

## Act and Regulations

- Section 37, Food and Drugs Act
  - package marked – “Export”
- Sections 89-92, Medical Devices Regulations
  - Export Certificate in Schedule 3 of the Regulations

## Application

- products manufactured solely for export

## Assessment

- export certificates not maintained (5 years) - **noncompliance**
- packages not marked as required by Act - **noncompliance**

# Appendix 1

## Responsibilities

	Manufacturer	Importer	Distributor
<b>Safety &amp; Effectiveness</b>	✓		
<b>Labelling</b>	✓	✓	✓
<b>Advertising</b>	✓	✓	✓
<b>Device Licensing</b>	✓	✓	✓
<b>Establishment Licence</b>	✓ exceptions	✓ exceptions	✓ inc. foreign distributors
<b>Distribution Records</b>	✓	✓	✓
<b>Complaint Handling</b>	✓	✓	✓
<b>Mandatory Problem Reporting</b>	✓ exceptions	✓	
<b>Recall Reporting</b>	✓ exceptions	✓	





## Appendix 2

### Documents Reviewed by Inspector

- Medical Device Establishment Licence
  - activities
  - class of devices
  - manufacturers
- Procedures
  - distribution records
  - complaint handling
  - recall
  - mandatory problem reporting (if applicable)
  - handling, storage, delivery (if applicable)
  - installation, servicing (if applicable)
  - corrective action (if applicable)



## Appendix 2 Documents Reviewed by Inspector

- Optional Procedures
  - device classification
  - device licensing
  - label review
  - advertising review
  - establishment licensing
  - control of special access devices
  - control of devices for investigational testing



## Appendix 2

### Documents Reviewed by Inspector

- Device Labelling
  - label
  - package insert
  - implant registration cards (if applicable)
- Advertising Material
  - product brochures
  - catalogues
  - internet site (if applicable)



## Appendix 2

### Documents Reviewed by Inspector

- Other Documents (as applicable)
  - authorization for special access
  - authorization for investigational testing
  - distribution records
  - complaint reports
  - recall notifications
  - mandatory problem reports
  - records of storage conditions
  - service records
  - corrective action reports
  - export certificates