



**Health Canada Medical Device
Establishment Licence (MDEL) –
Inspections, Audits and Compliance**


June 2009



Intent of the medical device establishment licensing requirements in the *Medical Devices Regulations*

1. To ensure the Inspectorate is made aware of the following to protect the Canadian consumer:

- a) Who is importing and/or selling medical devices in Canada
- b) The identity of the manufacturers of the devices sold by the holder of the MDEL (licence holder), as well as the classification of those devices
- c) The identity of manufacturers of Class I medical devices

 To require licence holders to provide some assurance to the Inspectorate that they have met the regulatory requirements and have documented procedures in place, where applicable, related to the following with respect to the medical devices they sell.

- distribution records
- complaint handling
- recalls
- mandatory problem reporting
- handling, storage, delivery, installation and servicing

Definitions (as per the guidance document)

Medical Device - a device within the meaning of the *Food and Drugs Act*, but does not include any device that is intended for use in relation to animals. Includes used devices, parts and accessories.

Device – any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings ~~or animals~~
- b) restoring, correcting or modifying a body function or the body structure of human beings ~~or animals~~
- c) the diagnosis of pregnancy in human beings ~~or animals~~
- d) the care of human beings ~~or animals~~ during pregnancy and at and after birth of the offspring, including care of the offspring

and includes a contraceptive device but does not include a drug

Definitions (as per the guidance document)

- Distributor – a person, other than a manufacturer, an importer or a retailer, who sells a medical device in Canada for the purpose of resale or use, other than for personal use. A person outside of Canada selling medical devices into Canada is also considered to be a distributor.
- Importer - a person, other than the manufacturer of a device, who causes the medical device to be brought into Canada for sale.
- Manufacturer – a person who sells a medical device under their own name, or a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

NOTE: The **name** on the medical device label **IS** the manufacturer

Definitions (as per the guidance document)

Retailer - persons who sell a device, or a service utilizing a device, solely to the ultimate consumer.

Example: A person selling a medical device to a healthcare facility or a provider (i.e. ADP) is NOT a retailer but a distributor.

Example: A central purchasing and distribution facility that supplies medical devices to a chain of retail outlets that are individually owned and operated (independently or under a franchise agreement) is NOT a retailer but a distributor.

Sell - offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

Ultimate consumer – individual who purchases or receives a medical device for their own personal use (including use within their household) or receives treatment or diagnosis with a medical device from a health care facility or provider.

Who needs a Medical Device Establishment Licence?

Any person who imports into Canada, or sells in Canada, a medical device for human use requires an establishment licence with the exception of

- A retailer
- A healthcare facility
- A manufacturer of Class II, III or IV medical devices that only sells
 - Medical devices for which they hold a valid licence, or
 - Medical devices subject to Parts 2 and 3 of the *Regulations*
 - Part 2 - Custom-made and Special Access
 - Part 3 - Investigational Testing
- A manufacturer of a Class I medical device who sells solely through a licensed establishment
- A person solely selling medical devices subject to Parts 2 and 3 of the *Regulations*
- A dispenser

What is your classification according to Health Canada?

- You can be more than 1 classification with Health Canada.
 - Example: Sunrise Medical Canada Inc.
 - Class I – patient lifters, wheelchairs
 - Class II – air floatation mattresses, respiratory equipment
 - Need to determine product class accurately (refer to slide 14)

| | Distributor / Distributeur | Importer / Importateur | Manufacturer of Class I devices / Fabricant d'instruments médicaux de classe I |
|--------------------|-------------------------------|---------------------------|---|
| Class / Classe I | X | X | X |
| Class / Classe II | X | X | |
| Class / Classe III | | | |
| Class / Classe IV | | | |

Attestations

A senior officer of the establishment applying for an establishment licence shall submit an application to the Minister that contains attestations based on the activities conducted by this establishment. The establishment has documented procedures in place regarding:

All establishments:

- distribution records
- complaint handling
- recalls

Importers & distributors of Class II, III or IV devices

- handling, storage, delivery
- installation
- corrective action
- servicing

Importers


- mandatory problem reporting

Guidance on the Medical Device Inspection Programme (pages 12-15)

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/md_insp_prog_prog_insp_mm-eng.pdf

What is required for compliance?

- Standard Operating Procedures (SOP) related to the activities of your establishment
 - Indicate ownership, dates of creation, revision history and document control information (change number)

| | | |
|---|---------------------------------|------------------------------------|
|  SUNRISE MEDICAL SUNRISE CANADA | Document No.: CA.9.1.2 | Revision: A |
| | Change No.: 622 | Effective Date: 11-JUL-06 |
| | Document Owner: Quality Manager | Document Approver: Quality Manager |
| RECALL PROCEDURE | | Page 1 of 8 |

| REVISION HISTORY | | | |
|------------------|-----------------------|----------------|----------|
| Revision | Description of Change | Effective Date | Change # |
| A | Initial Release | 11-JUL-06 | 622 |
| | | | |
| | | | |
| | | | |

What is required for compliance?

- Proper Device Classification

- You are responsible for establishing the correct class of a device based on the rules found in the *Regulations*. Failure to classify devices correctly may result in non-compliance with the device licensing or other regulatory requirements.

Guidance for the risk based classification system

- http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/risk5_risque5-eng.pdf

Guidance for the risk based classification system of *in vitro* diagnostic devices

- http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/ivd-rsk_idiv-rsq-eng.pdf

Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices

- http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motscles2-eng.pdf

To verify the classification of your device, please contact
DEVICE_LICENSING@hc-sc.gc.ca.

What is required for compliance?

- Proper Labeling of all medical devices
 - includes information affixed to a device or the packaging but also manuals, package inserts, brochures and leaflets

Guidance for the Labeling of Medical Devices, Section 21 to 23 of the Medical Devices Regulations

- http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/labl_etiq_dv10-eng.pdf

Guidance for the Labeling of *In Vitro* Diagnostic Devices

- http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/labl_etiq_ivd_div-eng.pdf

What is required for compliance?

- Device Advertising (part of labeling)
 - Class II Example
 - In a brochure distributed in Canada, you must clearly identify which items are licenced for sale in Canada otherwise it is considered to be misrepresentation
 - Options:
 - Identify the licence number on the brochure
 - Include a statement on a sticker or printed on the brochure
“The devices advertised in this catalogue may not have been licensed in accordance with Canadian law.”
 - Print a local Canadian brochure and include only licenced products

What is required for annual renewals?

- Update supplier listing
 - Search changes in manufacturer (ownership) so it reflects HC database
 - Check MDALL (Medical Device Active Licence Listing) for device class and existence of licence
 - <http://webprod.hc-sc.gc.ca/mdll-limh/index-eng.jsp>
 - Check for product changes which manufacturer is required to update via amended licence

NOTE: The manufacturer is responsible for notifying distributors and importers of ANY significant changes to their products and medical device licence
- Check keyword index for possible classification changes
 - http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motscles2-eng.pdf
 - Sharon Klassen - Phone: 613-946-1494
E-mail: Sharon_Klassen@hc-sc.gc.ca
- Update procedures to reflect attestations.













What to expect from an inspection/audit? (Overview)

Inspection - a systematic and independent examination of **objective** evidence to determine compliance with the *Act* and *Regulations*.

- Initial phone contact followed by written confirmation of visit
- Conducted on site by one inspector
- Procedures to be sent to inspector in advance for review
- Opening meeting to discuss inspection plan and review of basic company info
- Tour of the facility may be requested
- To gather the objective evidence the inspector may interview staff, review procedures and examine records
- If non-compliances are identified, the associated risk is estimated and appropriate corrective and preventative action is requested to mitigate the risk and achieve compliance.
- Draft inspection report discussed at closing meeting
- Final report prepared and sent to company with timelines for response with a corrective action plan
- Re-inspection may be conducted depending on non-compliances and response

What to expect from an inspection/audit?

Assessing Compliance:

-  Device classification
-  Safety and Effectiveness assessed only if significant health risks are suspected
-  Labeling Requirements for Class I and II
-  Advertising
-  Importation, sale & advertising conditional on device licensing (Class II, III, IV)
-  Terms and conditions of device licences
-  Establishment Licensing
-  Distribution Record requirements (mock recall)
-  Complaint Handling requirements
-  Recalls – procedure and notification
-  Mandatory Problem Reporting
-  Implant Registration (if applicable)

Important Links

Medical Device Establishment Licensing information

- <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index-eng.php>

The above link will direct you to these headings:

Medical Devices

- [Medical Device Establishment Licences](#)
- [Medical Devices Establishment Licence Listing \(MDEL\)](#)
- [Guidance on Medical Device Compliance and Enforcement\(GUI-0073\)](#)
- [Guidance on Medical Device Establishment Licensing](#)
- [Guidance on the Medical Device Inspection Programme](#)
- [Inspection Strategy for Medical Device Companies](#)
- [Medical Device Establishment Licence: Fee Reduction Request](#)
- [Medical Devices Establishment Licence Application Form](#)

For MDEL application related questions

- LEPIM@hc-sc.gc.ca

Important Links

Medical Devices Regulations (current to May 27, 2009)

- <http://laws.justice.gc.ca/PDF/Regulation/S/SOR-98-282.pdf>

Food and Drugs Act

- <http://laws.justice.gc.ca/PDF/Statute/F/F-27.pdf>

Possible Follow-up Topics

Searching Medical Device Licensing

Preparing the annual MDEL renewal package (August each year)

Complaint Handling (internal vs. regulatory reporting)

Complying with a manufacturer's product recall