Regulation of Medical Devices by Health Canada

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Medical Devices Bureau – Outline

• Stakeholders
• Regulatory Framework
  ➢ History
  ➢ Provisions/ prohibitions
  ➢ Classification
  ➢ Application Requirements
• Other access routes
Medical Device Stakeholders

Help Canadians maintain, improve health
Brief History of the Canadian Medical Device Regulatory Framework

1975
Medical Devices Regulations (MDR) come into force on September 2.

1977
MDR amended to include premarket review for some devices.

1991
Medical Devices Review Committee (MDRC) created to assess regulation.

1992
MDRC publish their report which includes several recommendations.

1997
The Medical Devices Bureau is unified under one Directorate.

1998
The new MDR comes into effect, making licensing a requirement.

2018
More than 4000 licenses renewed annually.
Roles and Responsibilities

THERAPEUTIC PRODUCTS DIRECTORATE
TPD

MARKETED HEALTH PRODUCTS DIRECTORATE
MHPD

HEALTH PRODUCTS & FOOD BRANCH INSPECTORATE
HPFBI

REGIONS & PROGRAMS BUREAU
RAPB

MEDICAL DEVICES BUREAU

MARKETED PHARMA & MD BUREAU

RISK MANAGEMENT BUREAU

LICENSEING & INSPECTION BUREAU

POST-MARKET SAFETY SURVEILLANCE, ASSESSMENT OF SIGNALS & SAFETY TRENDS, AND RISK COMMUNICATIONS

POST-MARKET COMPLIANCE MONITORING AND ENFORCEMENT ACTIVITIES SUPPORTED BY AN ESTABLISHMENT LICENSING SYSTEM

PRE-MARKET ASSESSMENT OF MEDICAL DEVICE SAFETY, EFFECTIVENESS, & REGULATORY COMPLIANCE, SUPPORTED BY A LICENSING SYSTEM INTENDED TO REGULATE MARKET ACCESS

MEDICAL DEVICES COMPLIANCE UNIT

ESTABLISHMENT LICENSING UNIT

BORDER INTEGRITY UNIT

ATLANTIC

QUEBEC

ONTARIO

PRAIRE

BC

HPFBI SERVICE DELIVERY FUNCTION (FIELD INSPECTION)
Health Canada’s Regulatory Tools

Legislation

Medical Devices Regulations

Guidance Documents & Policies

Regulations

Policy
What is a Device?

Section 2 of the **Food & Drugs Act**:

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“device” means 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, or

(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;
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**Medical Device = humans only**
Regulatory Provisions

• All devices offered for sale in Canada must comply with the Food and Drugs Act:
  ➢ Cannot advertise or represent by label a treatment for a Schedule A disease or disorder (Section 3)
  ➢ Cannot sell or advertise a device that may cause harm
  ➢ Cannot sell or advertise a device in a misleading or deceptive way

• All medical devices (those used on human beings) must also comply with the Medical Devices Regulations
Regulatory Provisions

A manufacturer:

- Sells a medical device under their own name, trade-mark, design, trade name or other name owned or controlled by the person
- Is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, assigning it a purpose
- Performs or has someone perform on their behalf

Manufacturer = Name on the label
Class I
post-market oversight based on compliance to applicable sections of the MDR pertaining to Distribution Records, Complaint Handling, Problem Reporting & Recalls.

Class II
- certification that device is manufactured according to international Quality Management System standard.
- manufacturer’s attestation that device satisfies the safety, effectiveness in MDR; labelling reviewed.

Class III
- certification that device is designed & manufactured according to international Quality Management System standard (ISO 13485).
- evidence of safety, effectiveness & labelling reviewed to validate compliance with MDR.

Class IV
- certification that device is designed & manufactured according to international Quality Management System standard (ISO 13485).
- evidence of safety, effectiveness & labelling reviewed to validate compliance with MDR. More stringent review than Class III.

Risk-Based Regulatory System

Premarket regulatory oversight based on a licensing system whereby market authorization is granted to manufacturers who demonstrate conformity to the requirements set out in the MDR

Post-market oversight based on a surveillance system intended to enforce, and promote compliance with the MDR
Classification based on indicators of Risk

- Non IVDDs
  
  Degree of Invasiveness
  
  Duration of contact
  
  Systemic effects on body
  
  Body system affected
  
  Special/unique factors
Classification based on Indicators of Risk

- IVDD’s
- Specific disorder/condition or risk factor
- Technical/scientific/medical expertise of user
- Criteria ie mode of transmission, efficacy of transmission,
- Nature of disease and available treatments
- Impact of diagnostic test to individual/public health
- Important patient related factors ie unnecessarily delaying or subjecting individual to treatment (false diagnosis)
Classification of Medical Devices

• To determine the classification of a device, you must apply all of the rules in Schedule 1 of the Medical Devices Regulations.

  **PART 1**
  MEDICAL DEVICES OTHER THAN IN VITRO DIAGNOSTIC DEVICES

  **PART 2**
  IN VITRO DIAGNOSTIC DEVICES

• You must consider the labelled indications for use, or claims made for the device; this includes any marketing material.
Definitions

• “Invasive device” means a medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface.

• “Surgically invasive device” means an invasive device that is intended to enter the body through an artificially created opening that provides access to body structures and fluids.
Definitions

• “Active device” means a medical device that depends for its operation on a source of energy other than energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device.
Definitions

• “Active Diagnostic Device” means an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity.

• “Active Therapeutic Device” means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury.
How Software Fits the Definition of a Device

• Dedicated software that is part of the device or is used in association with higher risk devices has been generally viewed as a medical device
  eg. Software programs for pacemakers, defibrillators, infusion pumps

• Standalone software that is used as a diagnostic tool has been generally viewed as a medical device
  eg. PACS, image guided surgery

• Software Applications developed for mobile platforms
  eg smart phones, tablets
Software as a Medical Device

• Generally standalone software is considered to fall within the definition of an active device.

• Software would fall within the classification rules that apply to active diagnostic devices.
**Middleware**

Health Canada has defined “middleware” as follows:

“middleware” means a piece of software that connects two or more software applications so that they can exchange data. This includes software systems that facilitate the interaction of disparate components through a set of commonly defined protocols. The purpose is to limit the number of interfaces required for interoperability by allowing all components to interact with the Middleware using a common interface.
**ACTIVE DEVICES**

**Rule 8:**

(1) Subject to subrules (2) and (3), an active device intended to emit ionizing radiation, including any device or software intended to control or monitor such a device or directly influence its performance, is classified as Class III.

(2) A device described in subrule (1) that is intended to be used in radiographic mode is classified as Class II.

(3) Despite subrule (2), an active device that is intended to be used for mammographies is classified as Class III.

**Rule 9:**

(1) Subject to subrules (2) and (3), an active therapeutic device, including any dedicated software, intended to be used to administer or withdraw energy to or from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.

(3) A device described in subrule (2) that is intended to control the treatment of a patient’s condition through a closed loop system is classified as Class IV.

**Rule 10:**

(1) Subject to subrule (2), an active diagnostic device, including any dedicated software, that supplies energy for the purpose of imaging or monitoring physiological processes is classified as Class II.

(2) A device described in subrule (1) that is intended to be used to monitor, assess or diagnose a disease, a disorder, an abnormal physical state or a pregnancy, if erroneous readings could result in immediate danger, is classified as Class III.
Application Service Providers

- ASPs (application service providers) do not fall within the scope of the Regulations since no sale of a medical device is taking place.

However, if the ASP has purchased a medical device with which the ASP is providing a service, the manufacturer of the device is still required to comply with the requirements of the Medical Devices Regulations and obtain the appropriate licence prior to the sale to the ASP.
Figure H-1: Sample folder structure for IMDRF TOC

- **License Name**
  - 1 REG ADMIN
    - 1.01 Cover Letter
    - 1.04 Application Form - Administrative Information
    - 1.06 Quality Management System, Full Quality System or Other Regulatory Certificates
    - 1.09 Pre-Submission Correspondence & Previous Regulator Interactions
    - 1.14 Other Regional Administrative Information
  - 2 CONTEXT
    - 2.4 Device Description
      - 2.4.4 Reference & Comparison to Similar & or Previous Generations of the Device
  - 5 LABELLING
    - 5.01 Chapter Table of Contents
    - 5.02 Product-Package Labels
    - 5.03 Package Insert-instructions for use
    - 5.04 e-Labelling
    - 5.05 Physician Labelling
    - 5.06 Patient Labelling
    - 5.07 Technical-Operator Manual
    - 5.08 Patient File Stickers-Cards & Implant Registration Cards
    - 5.09 Product Brochures
    - 5.10 Other Labelling & Promotional Material

* A letter 'm' followed by 6 digits
Licence Type

- What type of licence do I apply for?
  - Single Medical Device
  - Medical Device Family
  - Medical Device Group
  - Medical Device Group Family
  - Medical Device System (IVDD/Non IVDD)
  - Test Kits (IVDD)
New Applications – Class II Requirements

6. **ATTESTATIONS**

Specific to Part 1, section 32(2), item (c), (d), and (e) of the *Medical Devices Regulations* relevant to the licensing of Class II medical devices, a senior official shall submit an application to the Minister that contains the following attestations as applicable: Check (√) the relevant attestations.

- I, the Manufacturer of this device, have objective evidence to establish that this device meets the safety and effectiveness requirements set out in the *Medical Devices Regulations*, Part 1, sections 10 through 20.
- I, the Manufacturer of this device, have met all the labelling requirements set out in the *Medical Devices Regulations*, Part 1, sections 21 through 23.
- The device IS a near patient IVDD (*In Vitro Diagnostic Device*). I, the Manufacturer of this device, have evidence of investigational testing of this device using human subjects representative of the intended users and under conditions similar to the intended conditions of use of the device.
- The device IS NOT a near patient IVDD.

I, as a senior official of the manufacturer named in Item 2 of this application, hereby attest that I have direct knowledge of the items checked above and declare that these identified statements are true and that the information provided in this application and in any attached documentation is accurate and complete.

Where a person is named in Item 3 of this application, I hereby authorize that person to submit this application to the Minister on my behalf. I further authorize the Medical Devices Bureau to direct all correspondence relating to this application to the person named in Item 3 of this application.

Name: ___________________________ Title: ___________________________

Signature: _________________________ Date: ____________________________
Application Process – Class II

1. Submission Receipt
2. Administrative Screening
3. Application Creation
4. Validation Screening
5. Record Creation
6. Finance
7. Licence Generation
Application Process – Class III & IV

1. Submission Receipt
2. Administrative Screening
3. Application Creation
4. Validation Screening
5. Technical Screening
6. Record Creation
7. Financial Processing
8. Review
9. Further Information Request
10. Licence Generation
SAFETY AND EFFECTIVENESS REQUIREMENTS

10. A medical device shall be designed and manufactured to be safe, and to this end, the manufacturer shall, in particular, take reasonable measures to
   (a) identify the risks inherent in the device;
   (b) if the risks can be eliminated, eliminate them;
   (c) if the risks cannot be eliminated,
      (i) reduce the risks to the extent possible,
      (ii) provide for protection appropriate to those risks, including the provision of alarms, and
      (iii) provide, with the device, information relative to the risks that remain; and
   (d) minimize the hazard from potential failures during the projected useful life of the device.

11. A medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety.

12. A medical device shall perform as intended by the manufacturer and shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented.

13. During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected.

14. The characteristics and performance of a medical device shall not be adversely affected by transport or conditions of storage, taking into account the manufacturer’s instructions and information for transport and storage.

15. Reasonable measures shall be taken to ensure that every material used in the manufacture of a medical device shall be compatible with every other material with which it interacts and with material that may come into contact with it in normal use, and shall not pose any undue risk to a patient, user or other person.

16. The design, manufacture and packaging of a medical device shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including
   (a) flammability or explosion;
   (b) presence of a contaminant or chemical or microbial residue;
   (c) radiation;
   (d) electrical, mechanical or thermal hazards; and
   (e) fluid leaking from or entering into the device.

17. A medical device that is to be sold in a sterile condition shall be manufactured and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated.

18. A medical device that is part of a system shall be compatible with every other component or part of the system with which it interacts and shall not adversely affect the performance of that system.

19. A medical device that performs a measuring function shall be designed to perform that function within tolerance limits that are appropriate for the medical conditions, purposes and uses for which the device is manufactured, sold or represented.

20. If a medical device consists of or contains software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated.
Premarket Review Document Requirements

(3)4.3 Device Description
   (3)4.3.1 General Description
   (3)4.3.2 Licence Amendments
   (3)4.3.3 Drugs

(3)4.4 Design Philosophy

(3)4.5 Indications for Use and/or Intended Use and Contraindications

(3)4.6 Device Labels, Package Labelling, and Documentation

(3)4.7 Marketing History
   (3)4.7.1 Canada and International
   (3)4.7.2 Incident Reports and Recalls

Safety and Effectiveness

(3)5.1 Standards

(3)5.2 Preclinical Studies
   (3)5.2.1 Physical and Mechanical Bench Tests
   (3)5.2.2 Software Verification and Validation
   (3)5.2.3 Biocompatibility Tests
   (3)5.2.4 Pyrogenicity
   (3)5.2.5 Animal Studies

5.3 Clinical Evidence

5.4 Sterilization
   (3)5.4.1 Sterilization Validation
   (3)5.4.2 Residual Toxicity

5.5 Packaging

5.6 Shelf Life Validation
   (3)5.6.1 Shelf Life of the Product
   (3)5.6.2 Shelf Life of the Packaging

Class IV Specific

4.9 Manufacturing and Quality Control
   (4)4.9.1 Material Specifications
   (4)4.9.2 Devices Containing Biological Material or Derivatives
      (4)4.9.2.1 Animal Tissue
      (4)4.9.2.2 Human Tissues
      (4)4.9.2.3 Recombinant and Fermentation Products
   (4)4.9.3 Device Specific Quality Plan
   (4)4.9.4 Manufacturing Process and Quality Control Activities
   (4)4.9.5 Process Validation Studies
Quality Management System

• All medical device manufacturers are required to use a quality system certificate, ISO 13485:2003, as evidence of compliance to regulatory quality systems
• Class II Medical devices must be manufactured according to this standard
• Class III & IV Medical devices must be designed and manufactured according to this standard
<table>
<thead>
<tr>
<th>Requirement</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Class IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Device Licence</strong></td>
<td>exempt</td>
<td>must hold active licence</td>
<td>must hold active licence</td>
<td>must hold active licence</td>
</tr>
<tr>
<td>(manufacturer)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Safety &amp; Effectiveness</strong></td>
<td>keep objective evidence</td>
<td>keep objective evidence &amp; provide attestation</td>
<td>submit objective evidence for review</td>
<td>submit objective evidence for review</td>
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<tr>
<td>(manufacturer)</td>
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</tr>
<tr>
<td><strong>Labelling</strong></td>
<td>compliant label</td>
<td>compliant label (submit for review)</td>
<td>compliant label (submit for review)</td>
<td>compliant label (submit review)</td>
</tr>
<tr>
<td>(all parties engaged in importation or sales activities)</td>
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</tr>
<tr>
<td><strong>Quality Management System Certificate</strong></td>
<td>exempt</td>
<td>ISO 13485 certified (for manufacturing activities)</td>
<td>ISO 13485 certified (for design and manufacturing activities)</td>
<td>ISO 13485 certified (for design and manufacturing activities)</td>
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<tr>
<td>(manufacturer)</td>
<td></td>
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<tr>
<td><strong>Distribution Records</strong></td>
<td>maintain record</td>
<td>maintain record</td>
<td>maintain record</td>
<td>maintain record</td>
</tr>
<tr>
<td>(manufacturer, importer &amp; distributor)</td>
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<tr>
<td><strong>Complaint Handling</strong></td>
<td>maintain record</td>
<td>maintain record</td>
<td>maintain record</td>
<td>maintain record</td>
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<tr>
<td>(manufacturer, importer &amp; distributor)</td>
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<tr>
<td><strong>Mandatory Problem Reporting</strong></td>
<td>submit preliminary &amp; final report</td>
<td>submit preliminary &amp; final report</td>
<td>submit preliminary &amp; final report</td>
<td>submit preliminary &amp; final report</td>
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<tr>
<td>(manufacturer &amp; importer)</td>
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<td><strong>Recall</strong></td>
<td>submit recall notice</td>
<td>submit recall notice</td>
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<td>submit recall notice</td>
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<tr>
<td>(manufacturer &amp; importer)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Establishment Licence</strong></td>
<td>must hold active licence</td>
<td>must hold active licence</td>
<td>must hold active licence</td>
<td>must hold active licence</td>
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<tr>
<td>(class I manufacturer, importer &amp; distributor)</td>
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</table>
Other Regulatory Provisions

- Special Access – Part 2 of the regulations: provides Health Care Professionals with access to devices for emergency use if conventional therapies have failed, are unavailable or are unsuitable.

- Investigational Testing – Part 3 of the regulations: provides access for clinical trials involving human subjects for devices that have not yet met the safety and effectiveness requirements listed in sections 10-20 of the Regulations.
Did you know?

• There are 35,639 active Class II, III and IV Medical Device Licences:
  • 73% are Class II
  • 23% are Class III
  • 4% are Class IV

• Health Canada receives approximately 12,000 new and amendment applications each year.

• Licenses are held by 3,672 different manufacturers, 55% are US, 10% are from Germany and 8% are Canadian
Contact Information

• For classification & licensing assistance, please contact:
  
  device_licensing@hc-sc.gc.ca

• Medical Devices Regulations


• For Medical Device Guidance Documents

Thank You

More Questions?