



 Health Canada / Santé Canada

Therapeutic Products Directorate / Direction des produits thérapeutiques

Health Products and Food Branch / Direction générale des produits de santé et des aliments





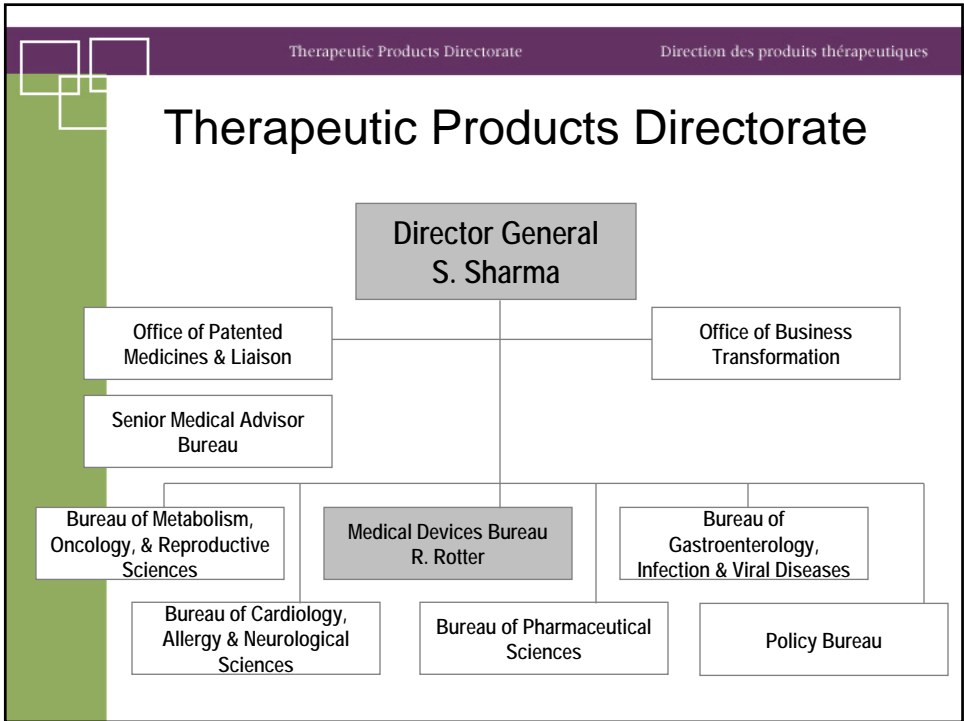


Patient Management Software

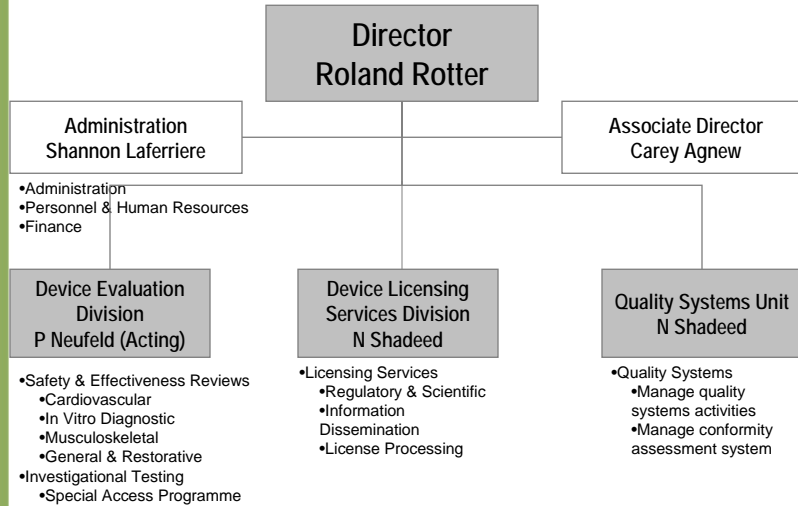
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Medical Devices Bureau



Regulatory Framework

- Canada has captured successful elements from other regulatory systems
 - Risk based classification system – EU
 - Post-Market – USFDA
 - Quality System Requirement – EU
 - Pre-Market Licensing – USFDA

Regulatory Provisions: Essentials

- Health Canada regulates the advertising, manufacture and sale of medical devices in Canada.
- The *Food and Drugs Act* and *Medical Devices Regulations* are the tools used to ensure that safe and effective devices are available.
- Manufacturers of devices apply to Health Canada to receive either a Licence or an Authorization to sell their devices.

Regulatory Provisions: Essentials

- The *Regulations* apply to:
 - The sale and advertising for sale of a medical device
 - The importation of a medical device for sale or for use on individuals, other than importation for personal use

Regulatory Provisions: Essentials

- A manufacturer in the *Regulations*:
 - 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

Sale of Medical Devices

...no person shall import or sell a Class II, III or IV medical device unless the manufacturer of the device holds a licence in respect of that device or, if the medical device has been subjected to a change described in section 34, an amended medical device licence

Regulatory Framework

- Class I (low risk) → Class IV (high risk)
- Pre-market resources apply primarily to Class III & IV
- Product Licensing applies to Class II, III & IV
- QS requirements apply to Class II, III and IV
- Post-market requirements apply to all Classes
- Establishment Licensing applies primarily to importers / distributors / Class I manufacturers

Class IV – 5%

Class III – 15%

Class II – 40%

Class I – 40%

(NB: almost 800K individual devices currently “licensed”)

Other Regulatory Provisions

- Mandatory Problem Report
- Recalls
- Complaint Handling / Distribution Records
- Special Access - devices for emergency use or if conventional therapies have failed, are unavailable or are unsuitable
- Investigation Testing – clinical trials involving human subjects.

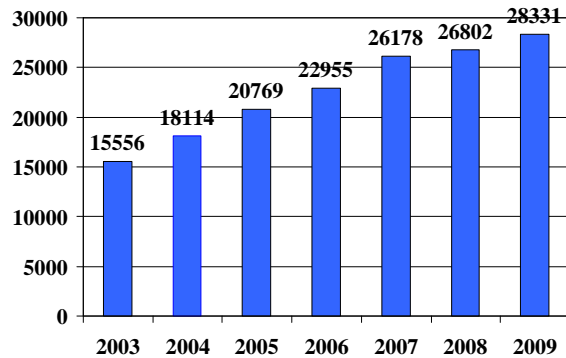
Regulatory Framework

- Licensing – need to know the industry / products we regulate – however – needs to be done in a timely / efficient manner
(Class II – 15 days, Class III – 75 days, Class IV – 90 days)
- Class II devices – “attestation” device meets requirements – responsibility rests with manufacturer
- QS (ISO 13485) – partnered with Standards Council of Canada – established third party auditing program – paid for by industry – program is still evolving but remains a “model” for regulators
- Annual Licence Renewal – accurate information as to what products are on the Canadian market (legally)

Examples of Classified Devices

- Class I : Reusable surgical instruments, bandages, cell culture media
- Class II: Blood pressure monitors, electrodes, contact lenses, pregnancy test kits, single use surgical instruments, catheters
- Class III: Ventilators, cardiac monitors, hip implants, knee implants, lasers, Chlamydia test kits, glucose meters
- Class IV: Defibrillators, pacemakers, coronary stents, HIV test kits, neurosurgical shunts

Licences Renewed Annually



Definition of a Device

“**DEVICE**” means any article, instrument, apparatus of 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.

Definition of a Device

- 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.

“MEDICAL DEVICE” means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals

Definition of Patient Management Software

- provides the only means and opportunity (meaning in real time) to capture or acquire data from a medical device for aiding directly in diagnosis or treatment
- or
- replaces a diagnostic or treatment measurement or calculation made by a professional

Classification of a Medical Device



The degree of regulatory oversight assigned to a medical device is dependent upon its classification

Schedule 1 – The Classification Rules

- To determine the classification of a device, you must apply all of the rules in Schedule 1
 - Part 1 applies to devices in general
 - Part 2 applies to in Vitro Diagnostic Devices
- You must consider the labelled indications for use, or claims made for your device

The Underpinning Logic of the System

- NON-IVDD's
 - Large number of variables
 - Rapid technological advances
 - Classification criteria based on
 - The human body
 - Inherent device related potential hazards
 - Customary device use (O.R., I.C.U., N.I.C.U.)

Active Devices

- “**Active Device**” means a medical device that depend for its operation on a source of energy other than energy generated by the human body or gravity....

Active Devices

- **“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

Rule 12

Rule 12 – Other Active Devices

- Any other active device is classified as Class I

Class I Software

- Any patient management software that is intended to be used to view images, or other real time data, as an adjunct to the monitoring device itself, for the purpose of aiding in treatment or diagnosis, is considered a Class I medical device based on Rule 12 of the *Medical Devices Regulations*.

Manufacturer/ Importer / Distributor

- Importers / Distributors / Manufacturers of Class I devices not employing a “licensed” importer / distributor require an Establishment Licence

Establishment Licensing

- Manufacturer's responsibility to ensure that Class I devices imported for sale or sold in Canada comply with the remaining sections of the *Medical Devices Regulations*, which include:
 - Safety and effectiveness (Sections 10 to 20)
 - Labelling (Sections 21 to 23)
 - Distribution records (Sections 52 to 58)
 - Mandatory problem reporting (Sections 59 to 62)
 - Recall requirements (Sections 63 to 65)

Rule 10

Rule 10 – Active Diagnostic Devices

- 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.

Class II Software

Any patient management software that is intended to analyze data for the purpose of directly aiding in a diagnosis or treatment (ex. locating a region of interest in an image to aid in diagnosis, or perform calculations to lead to a treatment plan) would be a Class II medical device

Class II Software

This includes any patient management software involved in:

- data manipulation,
- data analysis,
- data editing,
- image generation,
- determination of measurements,
- graphing,
- flagging of results,
- identifying a region of interest
- performing calculations.

Class II Software

Only software performing analysis/calculations/etc. that directly impact diagnosis and/or treatment of a patient merits a Class II designation.

Software not intended by the manufacturer to be used for those medical purposes is not considered a medical device.

Examples of non-medical device software include:

- applications which perform administrative calculations and manipulations (such as determining time between appointments, or workflow management)
- the Wii Fit video game
- personal BMI calculators and pedometer software used for fitness.

Device Licence Class II

Identification Information



Attestation of Compliance with:

- Safety and Effectiveness (S&E)
- Intended Use/Purpose to verify class
- Application Type



ISO 13485:2003
Quality System



Certificate from
CMDCAS
"recognized"
auditing
organization

Amendments to Class II licences

Amendments for Class II licences are only necessary if the manufacturer proposes to make a change in:

- the name of the manufacturer
- the name of the device
- the device identifier
- the medical conditions, purposes or uses for which the device is manufactured, sold or represented (see section 34 of the *Medical Devices Regulations*).

The amended licence is required to be issued prior to the modified device being sold or imported for sale in Canada.

FAQ – Sale of a Device

The term “sell” does not have a different meaning within the context of patient management software. From the *Food & Drugs Act*, sell is defined as follows:

“sell” includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration;

Medical devices developed and used exclusively in-house by healthcare providers do not fall within the scope of the *Regulations* as they do not meet Section 2:

- 2. These Regulations apply to**
- (a) the sale and advertising for sale of a medical device; and
 - (b) the importation of a medical device for sale or for use on individuals, other than importation for personal use.

FAQ – Middleware

With respect to Patient Management Software, “middleware” is defined 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.

As defined above middleware would not fit the definition of a medical device.

FAQ – Legacy Systems

With respect to Patient Management Software, “legacy system” is defined as follows:

“legacy system” is software that was designed, sold and deployed prior to February 1, 2011 (Class I) or September 1, 2011 (Class II).

Since Class II legacy systems have been previously sold without immediate risks to public health having been identified, they have not been prioritized for compliance with this prohibition until September 1, 2011. For Class I legacy systems, compliance with that requirement to hold an establishment licence has similarly not been prioritized until February 1, 2011.

After that date the import or sale of a legacy system device without an EL will be prioritized for compliance as any other similar device (according to Policy 001 of the Health Product and Food Branch Inspectorate).

Neither servicing, maintenance nor use of a device is governed by these Regulations. Upgrading to a new version of the software, if the functionality, intended uses, or nomenclature of the system is altered, would be a “sale” of a medical device, and the new version would need to be licensed.

FAQ – Application Service Providers (ASP)

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.

FAQ – EHR

EHR Definition from Canada Health Infoway (2006):

An Electronic Health Record (EHR) provides each individual in Canada with a secure and private lifetime record of their key health history and care within the health system. The record is available electronically to authorized health providers and the individual anywhere, anytime in support of high quality care. This record is designed to facilitate the sharing of data – across the continuum of care, across healthcare delivery organizations and across geographies.

Based on the above definition, an EHR is not a medical device.

Examples

As software product is intended to transmit results received from a monitor directly to the nurses' workstation within a hospital.

Is this a medical device? If so, which class?

Examples

An electronic medical record is intended to store a patient's age, weight, notes about a patient's appointment, order processing, scheduling, and managing patient movement.

Is this a medical device? If so, which class?

Examples

A patient takes their blood pressure and heart rate from home. The the results are up-loaded directly to the patient's computer. Through a software application, the patient's physician is notified (by a flag/alarm) if the results are out of range.

Is this a medical device? If so, which class?

Contact Information

For classification and licensing assistance, please contact:

- Fax: (613) 957-6345
- E-mail: device_licensing@hc-sc.gc.ca

For additional information regarding Quality System Certificates

- ISO13485_CMDCAS_SCECIM@hc-sc.gc.ca

Medical Devices Regulations:

<http://laws.justice.gc.ca/en/showtdm/cr/SOR-98-282>