

## Software Regulated as a Medical Device - Frequently Asked Questions

### 1. What software is regulated as a medical device?

Software regulated as a medical device:

- (1) provides the only means and opportunity to capture or acquire data from a medical device for aiding directly in diagnosis or treatment of a patient; or
- (2) replaces a diagnostic or treatment decision made by a physician.

Software that fits part (1) of this definition would be picture archiving and communication system (PACS) and other types of software that have traditionally been licensed since they are adjuncts or accessories to medical devices.

### 2. Is Remote Patient Monitoring Software a medical device?

Software used by a patient in the patient's home (or other locations outside of a healthcare setting) to transmit data received from a medical device (for example: blood pressure monitor, blood glucose monitor) would be a medical device. If the software is intended for analyzing device-provided data for the purpose of directly aiding in the treatment or diagnosis of a patient, this would be Class II software. If the software only transmits and stores the data, it would be a Class I medical device.

### 3. Is software that is connected to a medical device also a medical device?

Software that controls, or is embedded in a medical device, or receives information directly from a medical device would be an accessory to a medical device, and therefore a medical device itself, if it is intended for diagnostic or therapeutic use.

### 4. What medical device software is considered to be Class I?

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 of a patient, would be Class I medical devices.

### 5. What does a manufacturer of Class I medical device software device need to do to sell this product in Canada?

All Class I medical devices are exempt from the device licensing requirements of Sections 26 to 43 of the *Medical Devices Regulations (Regulations)*. However, it is the manufacturer's

responsibility to ensure that Class I devices imported for sale, or sold in Canada comply with the remaining sections of the *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)

All Class I Devices must also comply with the requirements of Sections 3 and 19 to 21 of the *Food and Drugs Act*.

Pursuant to Section 44 of the *Regulations*, manufacturers, importers or distributors of Class I medical devices are required to hold a Medical Device Establishment Licence unless one of the following exemptions apply:

- (a) a retailer;
- (b) a health care facility;
- (c) in the case of a Class II, III or IV medical device, the manufacturer of the medical device; or
- (d) in the case of a Class I device, the manufacturer of the medical device, if the manufacturer imports or distributes solely through a person who holds an establishment licence.

For information on how to obtain a Medical Device Establishment Licence, please contact the Medical Devices Establishment Licensing Unit by e-mail at [MDEL\\_questions\\_LEPIM@hc-sc.gc.ca](mailto:MDEL_questions_LEPIM@hc-sc.gc.ca)

More information can also be found on the Health Products and Food Branch Inspectorate Website at:

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

## **6. What medical device software is considered to be Class II?**

Medical device software that is an adjunct to another medical device and is involved in data manipulation, data analysis, data editing, image generation, determination of measurements, identification of a region of interest in an image, or identification (by an alarm or alert) of results from a monitor that are outside of an established range, is a Class II medical device if it:

- (1) provides the only means and opportunity to capture or acquire data from a medical device for aiding directly in diagnosis or treatment of a patient; or
- (2) replaces a diagnostic or treatment decision made by a physician.

## **7. What does a manufacturer of a Class II software device need to do to sell this product in Canada?**

To sell or import Class II devices in Canada, the manufacturer must obtain a Class II Medical Device Licence. To obtain a licence, the manufacturer must submit an application form, fee

and a copy of a valid ISO 13485:2003 quality system certificate. The certificate must be from one of the registrars on the list on our website at [http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list\\_liste\\_regist-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php) and must also contain the logo from the SCC (Standards Council of Canada) and a statement of CMDCAS (Canadian Medical Devices Conformity Assessment System) recognition.

Devices imported or sold in Canada must meet eleven fundamental safety and effectiveness requirements (Sections 10 to 20 of the *Regulations*, inclusive) and must be labelled in accordance with specified labelling requirements. Pursuant to part one of the *Regulations*, all manufacturers wishing to import, sell, or distribute Class II medical devices in Canada are required to have a Class II medical device licence.

### **8. Is Middleware a medical device?**

For the purposes of this document, “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 meet the definition of a medical device.

### **9. Are Electronic Medical Records (EMRs), Electronic Patient Records (EPRs), and Electronic Health Records (EHRs) medical devices?**

A software product that simply replaces a patient’s paper file does not meet the definition of a medical device if it is only intended to store and view patient information (for example: age, weight, notes about a patient’s appointment, patient test results, order processing, scheduling, or managing patient movement).

Components of iEHRs, iEMRs and iEPRs that replace a diagnostic or treatment decision made by a physician are software products that are regulated as medical devices.

### **10. Are application service providers (ASP) subject to the *Medical Devices Regulations*?**

ASPs (application service providers) do not fall within the scope of the *Regulations* since no sale of a medical device is taking place. If the software manufacturer has the software hosted by a third party on their behalf, this is also not considered to be a sale. 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 *Regulations* and obtain the appropriate licence prior to the sale to the ASP.

**11. Health Canada has stated all Class I Medical Device Software sold after February 1, 2011 and Class II Medical Device Software sold after September 1, 2011 are expected to be compliant with the *Regulations*. What about software sold prior to these dates?**

The implementation dates for Class I and Class II Medical Devices Software were selected and previously communicated to allow manufacturers sufficient time to obtain the necessary establishment licences and/or device licences in order to comply with the Medical Devices Regulations. Medical Device Software sold after the implementations dates without the necessary licences will be subject to compliance and enforcement actions in accordance with Policy 0001 of the Health Product and Food Branch Inspectorate.

Unless a safety issue is identified, Health Canada's compliance approach for medical device software that are not compliant with the requirements of the *Regulations* will be to prioritize compliance and enforcement actions in accordance with the Health Products and Food Branch Inspectorate's *Compliance and Enforcement Policy* POL-0001.

Neither servicing, maintenance nor use of a device is subject to the *Regulations*. Upgrading to a new version of the software, if the functionality, intended uses, or nomenclature of the system is altered would be considered a new medical device and the new version would need to be licensed.

**12. If I have questions as to whether a software product is or is not a medical device, or am unsure of the classification, who can I ask?**

For questions on classification of medical device software, please contact:

Device Licensing Services Division  
Medical Devices Bureau  
Therapeutic Products Directorate  
Health Canada  
Health Canada 2934 Baseline Road, Tower B  
Address Locator: 3403A  
Ottawa, Ontario K1A 0K9

Telephone: (613) 957-7285  
Facsimile: (613) 957-6345  
E-mail: [device\\_licensing@hc-sc.gc.ca](mailto:device_licensing@hc-sc.gc.ca)