Health Canada Santé Canada

December 3, 2010

Notice

Our file number: 10-125797-779

Subject: Software Regulated as a Class I or Class II Medical Device

Attention: Manufacturers, importers and distributors of medical device software and facilities that purchase this software.

Software that is intended or represented for use in the diagnosis or treatment of an abnormal physical state of a patient meets the definition of a medical device under the *Food and Drugs Act* and must therefore comply with the requirements of the Medical Devices *Regulations*. Software associated with higher risk devices is generally well characterized and the regulatory requirements are generally understood. However, there appears to be uncertainty about the classification and regulatory requirements for software in the lower risk classes.

This notice clarifies what medical software is regulated as a Class I or Class II medical device, how the Schedule 1 Classification Rules are applied to software, and Health Canada's approach to bringing Class I and Class II medical device software products into compliance with the *Regulations*.

Application

This notice applies to:

- Software that meets the definition of a medical device and is classified as a Class I or Class II device under the Schedule 1 Classification Rules.

- Note that the Regulations apply to Free and Open-Source (FOSS) device software, since the definition of "sell" in the *Food and Drugs Act*, includes transactions without compensation.

This notice does not apply to:

- Software related to *in Vitro* Diagnostic Device (IVDD), including those software systems that are used to control IVDDs or analyze results from IVDDs, i.e., software products classified via Part 2 of Schedule 1, Classification Rules in the *Medical Devices Regulations*.

Definitions

As defined in the *Food & Drugs Act* (the "Act"):

"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 sate, 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.

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

As defined in the *Medical Devices Regulations (the Regulations):*

"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. (*instrument medical*)

"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. (*instrument actif*)

"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. (*instrument diagnostique actif*)

"manufacturer" means a person who sells a medical device under their own name, or under 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, labelling, 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. (*fabricant*)

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Context

Regulatory Classification of Medical Software as a Medical Device

The regulatory classification of software as a medical device is dependent on the manufacturer's labelled intended use for the product. When the intended or represented use of software is for one or more of the medical purposes set out in the definition of a device as stated in the *Act*, that software qualifies as a medical device.

Examples of software that does not meet the definition of a medical device includes applications that 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.

Classification of Medical Device Software

Medical device software that meets the definition of a medical device must therefore be classified in accordance with the classification rules for medical devices as stated in the Regulations. The Medical Devices Bureau uses the following guidelines in order to ensure that the potential risk of a medical device software is reflected in its classification:

Medical device software is considered to be an active device because it relies on a source of energy other than energy generated by the human body or gravity.

Software 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 considered a Class II medical device and therefore requires a licence. This classification is based on Rule 10 (1) of the *Regulations*.

> Rule 10:
> (1) Subject to sub-rule (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.
>
> Software intended to be used to view images or other real time data, and is an accessory to the monitoring device itself, is a Class I medical device based on Rule 12 of the *Regulations*.
>
> Rule 12:
> Any other active device is classified as Class I.

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These software systems are considered active diagnostic devices because they are used for the purpose of monitoring a physiological condition, state of health, illness or congenital deformity. Pursuant to the *Regulations*, it is the manufacturer of a device who is required to hold a licence in respect of that device. In order to determine who is responsible for holding a medical device licence, please refer to the definition of manufacturer above.

Regulatory Requirements for Class I and Class II Devices

Section 9 of the *Medical Devices Regulations*, outline a manufacturer's responsibilities to ensure that the device meets the safety and effectiveness requirements outlined in sections 10 to 20 of the Regulations, and to keep objective evidence to establish that those requirements are met.

The device and the manufacturer are also subject to the following regulatory requirements:

* Labelling (Sections 21 to 23)
* Distribution Records (Sections 52 to 58)
* Mandatory Problem Reporting (Sections 59 to 62)
* Recall Requirements (Sections 63 to 65)

Finally, manufacturers, importers or distributors of Class I medical devices must hold a Medical Device Establishment Licence, as per section 44 of the Regulations 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.

In addition to the above, manufacturers of Class II devices are subject to the device licensing requirements set out in Sections 26 to 43 of the *Medical Devices Regulations* (*Regulations*). The device licence application must include a copy of a valid ISO 13485:2003 quality system certificate issued by a registrar recognized by Health Canada[1] under section 32.1 of the *Medical Devices Regulations* and must also carry the logo from the Standards Council of Canada and a statement of Canadian Medical Devices Conformity Assessment System (CMDCAS) recognition.

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[1]http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php

Compliance Approach

In recent years, medical device software has evolved rapidly and the risk class of many of these devices has changed with the capabilities of the software. On August 31, 2009, and May 21, 2010, Health Canada issued Notices to manufacturers to clarify that some medical device software is a Class II medical device and therefore requires a device licence. With this additional clarification, Health Canada expects all Class I Medical Device Software to be compliant with the Regulations by February 1, 2011. All Class II Medical Devices Software must hold a valid device licence by September 1, 2011.

Unless a safety issue is identified, Health Canada's compliance approach 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, on medical device software that is not compliant with the requirements of the *Regulations*.

Amendments to Class II Medical Device Software Licences

With respect to medical device software that is already licenced, 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 or 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. This applies to any medical device software modifications and upgrades that fit the above criteria.

For guidance on Class II device licence applications, please refer to the following website: http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index-eng.php

Additional Information

For additional information on software regulated as a medical device, please refer to the Frequently Asked Questions document "Software Regulated as a Medical Device - Frequently Asked Questions"

To determine what medical devices and companies hold medical device licences, please consult the Medical Devices Active Licence Listing.
(http://webprod5.hc-sc.gc.ca/mdll-limh/index-eng.jsp)

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For information regarding Quality System Certificates, please visit the website or contact the following:

Website: http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/index-eng.php
Phone: (613) 952-8250
E-mail: ISO13485_CMDCAS_SCECIM@hc-sc.gc.ca

For outstanding questions on medical device software, please contact:

Device Licensing
Medical Devices Bureau
Therapeutic Products Directorate
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