INFORMATION TECHNOLOGY
ASSOCIATION OF CANADA

ASSOCIATION CANADIENNE
DE LA TECHNOLOGIE DE L'INFORMATION

Frequently Asked Questions (FAQ) About Patient Management Software Licensing

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About ITAC

The Information Technology Association of Canada (ITAC) is the voice of the Canadian information and communications technologies (ICT) industry. ITAC represents a diverse ICT community spanning telecommunications and internet services, ICT consulting services, hardware, microelectronics, software and electronic content. ITAC's community of companies accounts for more than 70 per cent of the 572,000 jobs, $140.5 billion in revenue, $6.0 billion in R&D investment, $31.4 billion in exports and $11.4 billion in capital expenditures that the ICT industry contributes annually to the Canadian economy. ITAC is a prominent advocate for the expansion of Canada's innovative capacity and for stronger productivity across all sectors through the strategic use of technology.

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1. Background

1.1. *What is ITAC Health?*

ITAC Health is the health division of the Information Technology Association of Canada (ITAC). ITAC is the national association of Canada's information and communications technology (ICT) industry. ITAC represents more than 300 member companies in the ICT industry in Canada, many of who provide products and services to the health sector.

1.2. *Why has ITAC Health published this FAQ?*

ITAC Health has published this *FAQ about Patient Management Software Licensing* in response to concerns expressed by members about the availability of information concerning Health Canada's notice on the *Classification of Medical Devices Class I or Class II patient management software* dated August 31, 2009.

This FAQ is intended to help companies obtain the information they need to kick-start their licensing programs. It must be stressed that each situation is different and companies should look to their own expert consultants, accredited registrar and to Health Canada to determine their precise medical device licensing requirements.

1.3. *How was this FAQ developed?*

This FAQ was developed based on frequently asked questions by ITAC Health members and customer organizations. In responding to the questions, ITAC Health conducted a review of documentation published by Health Canada on its website, presentations by Health Canada officials, ISO 13485:2003 and various guides to ISO 13485:2003 published on the Internet. ITAC Health also interviewed officials from Health Canada, accredited registrars, Provincial Chief Information Officers (CIOs), CIOs from major health care organizations, and expert consultants. Comments on a draft of this document were also provided by MEDEC members (Canada's Medical Device Association) with experience working with Health Canada on the regulation of devices including devices that are stand alone software.

1.4. *Is the information in this FAQ accurate?*

ITAC Health has tried to ensure that the information published in this FAQ is accurate and has confirmed the accuracy of the information with the original sources. However, the licensing of patient management software is a work in progress. There are a number of issues associated with the complex technical and business arrangements that are part of the eHealth and EHR infrastructures being developed by Canada Health Infoway and

provincial jurisdictions. There will undoubtedly be new information and advice coming from Health Canada and Registrars as they work through these complex arrangements.

ITAC Health will endeavor to keep this FAQ up-to-date and will publish updates on its *Patient Management Software Licensing Working Group* Blog at www.itachealth.blogspot.com.

1.5. *Do the answers in this FAQ represent official Health Canada responses to the questions?*

No. The answers in this FAQ ***do not*** represent ***official*** Health Canada responses to these questions. We have tried to the best of our ability to accurately represent the responses by Health Canada to our queries. The answers have been reviewed with Health Canada and many are based on Health Canada legislation, regulations and policy published on the Health Canada website, in notices and in guidance documents. If you have any doubt or concern about a response, please contact Health Canada directly.

1.6. *I found a mistake in this FAQ. What should I do?*

If you find a mistake or if you find that any information is not clear or is confusing, please send an email to bseaton@itac.ca. We will review the Q&A and correct the situation if necessary. Updated or amended answers will be published on our blog at www.itachealth.blogspot.com and will be included in future versions of the FAQ.

1.7. *I have a question that isn't covered in this FAQ. Who can I ask?*

If you have a question that isn't covered in this FAQ, send an email to bseaton@itac.ca. We will try to find the answer and will get back to you. We will also publish the Q&A on our blog at www.itachealth.blogspot.com and in future versions of the FAQ.

Alternatively, you can address your question directly to Health Canada, an accredited registrar, or your expert consultant.

1.8. *What is ITAC Health's stance on the licensing and certification of Health ICT products and services?*

ITAC Health recognizes the need for vendors to demonstrate to the public and to health care providers that ICT products and services are safe, effective, will address privacy and security concerns and will interoperate with an integrated health care delivery system.

ITAC Health supports the development and implementation of national licensing and certification programs that have the following characteristics:

1. The program provides real value to patients, health care providers and vendors.

2. Criteria for licensing and certification are technically feasible and economically viable.

3. Criteria for licensing and certification are based to the greatest extent possible on recognized international and national standards.

4. Criteria for licensing and certification are developed and approved in an open and transparent manner ensuring that the needs, interests and requirements of all users and vendors of ICT products and services are taken into consideration.

5. There is coordination between licensing, certification and conformance bodies to avoid duplication of effort and excessive costs to vendors and their customers and to ensure that implementation schedules do not place unreasonable burdens on vendors and their customers.

2. Patient Management Software Licensing

2.1. *Why all the fuss about Patient Management Software Licensing?*

On August 31, 2009, Health Canada issued a notice confirming that "patient management software" is considered a medical device and is subject to the *Medical Devices Regulations (SOR/98-282)* and the *Food and Drugs Act*.

In simple terms,

- Organizations[1] that import, sell or otherwise distribute Class I or Class II patient management software must have an establishment licence[2].
- Organizations that manufacture Class II patient management software for sale or distribution must have a medical device license for each patient management software product sold.
- In order to obtain a medical device licence, manufacturers must hold a quality management system (QMS) certificate issued by an accredited registrar showing that the QMS is compliant with *ISO 13485: 2003 Medical devices – Quality management systems – requirements for regulatory purposes*.
- Organizations are also required to perform certain post-market responsibilities such as maintaining distribution and complaint handling records, mandatory problem reporting and recalls.

Organizations and their officers who do not comply can be ordered to stop selling and distributing unlicensed products and could be subject to sanctions under the Food and Drugs Act including fine and/or imprisonment.

2.2. *Does the licence apply to the product or the organization?*

A ***medical device licence*** for a Class II patient management software product ***applies to the software product*** itself. In the medical device licence application a company will provide the product name and identifier, the purpose or intended use of the product, and attest that it meets the safety and effectiveness and labeling requirements.

In order to obtain a medical device licence for its product, a manufacturer must hold a valid quality management system certificate issued by an accredited registrar showing that their QMS is compliant with *ISO 13485: 2003*. ***The QMS Certificate applies to the organization***.

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[1] "Organization" can mean a corporation, partnership or association and can include public sector organizations such as hospitals or provincial Ministries of Health.
[2] An exception to this rule is that a manufacturer of Class II patient management software whose product has a medical device licence does not require an establishment licence to sell their own software. See footnotes in question 3.1 for more information.

An ***establishment license applies to an organization*** that imports, sells or distributes Class I or Class II patient management software products.

2.3. *What is "Patient Management Software"?*

Patient management software is any software sold for diagnostic or therapeutic purposes. Patient management software can be classified as a Class I or Class II medical device.

Any patient management software used only for storing, acquiring, transferring or viewing information or images is considered a Class I medical device. Although Class I devices do not require a medical device license, manufacturers, distributors and importers are required to obtain an ***establishment license*** if they sell or distribute Class I software in Canada.

Patient management software that is used for the purpose of monitoring a physiological condition, state of health, illness or congenital deformity and is involved in data manipulation, data analysis, data editing, image generation, determination of measurements, graphing, flagging of results, identifying a region of interest or performing calculations is considered a Class II medical device. Only calculations that directly impact diagnosis and/or treatment of a patient merit a Class II designation for the software in which they are utilized. Calculations and manipulations, which are used to perform only administrative functions such as determining time between appointments, do not result in a Class II software classification.

2.4. *When is this ruling effective?*

This ruling is in effect now. However, most suppliers and users of patient management software products are not compliant with the regulations at this time. ITAC Health and other stakeholders have asked Health Canada to grant an amnesty period to allow time for organizations that manufacture patient management software to obtain ISO 13485:2003 certification and to meet the other requirements of the regulations. ***Health Canada has not yet issued a notice concerning any amnesty period***.

ITAC Health encourages manufacturers and distributors of class II patient management software to proceed immediately to obtain their ISO 13485:2003 certification and apply for medical device licenses for their Class II patient management software products. Importers and distributors of all classes of patient management software as well as manufacturers of class I patient management software that do not sell through a licensed establishment (i.e. an importer or distributor that already has an establishment licence) should apply for and obtain an establishment license from Health Canada. Note that manufacturers of Class II patient management software do NOT need an establishment licence in addition to their medical device licence in order to sell their own licensed Class II software in Canada.

2.5. *What is Health Canada's authority for imposing this requirement on software developers and distributers?*

Health Canada has the authority to impose and enforce these requirements under the Food and Drugs Act. The Act gives the Minister of Health the authority to establish regulations to give effect to the principles in the Act. This includes the *Medical Devices Regulations* (SOR/98-282).

2.6. *Does this notice apply to my organization?*

The notice applies to you, your organization and your patient management software products if you manufacture, sell, import or distribute patient management software in Canada.

2.7. *Does the notice only apply to software that is "sold"?*

The notice applies to patient management software that is imported and/or sold in Canada. The definition of "sell" in the Food and Drugs Act is very broad. The Act states *"sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration*."

This means that any distribution of any patient management software, even if there is no financial transaction, constitutes a sale. This would include patient management software developed by one organization and provided to another organization with or without financial charge or other consideration.

2.8. *Who is a "manufacturer" of patient management software?*

As defined in the Canadian *Medical Devices Regulations* (SOR/98-282):

"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, 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.

"Person" includes a partnership and an association.[3]

[3] "Person" includes any legal corporate entity including corporations, partnerships and associations.

2.9. *My company develops and sells billing and scheduling software. Are these medical devices?*

No. Only Patient management software has the ability to affect diagnosis, treatment and overall well being of a patient fits the definition of a medical device. Software used ***exclusively*** for administrative purposes such as billing, scheduling, materials management, and financial management are not medical devices, even if those software products collect, process and retain personal health information.

2.10. *Does this notice apply to application service provider (ASP) services?*

The application of the notice to application service provider services is not clear at this time. A request for clarification has been sent to Health Canada. When received, the response will be published on the ITAC Health Patient Management Software Licensing Working Group blog at www.itachealth.blogspot.com and in future versions of this FAQ.

It is recommended that you contact Health Canada directly by email at DEVICE_LICENSING@hc-sc.gc.ca if this question applies to your situation.

2.11. *How does this notice apply to legacy systems?*

The application of the notice to legacy systems (i.e. systems in production at the present time that are using unlicensed patient management software products) is not clear at this time. A request for clarification has been sent to Health Canada. When received, the response will be published on the ITAC Health Patient Management Software Licensing Working Group blog at www.itachealth.blogspot.com and in future versions of this FAQ.

It is recommended that you contact Health Canada directly by email at DEVICE_LICENSING@hc-sc.gc.ca if this question applies to your situation.

2.12. *How does Health Canada enforce the Medical Devices Regulations (SOR 98/282)?*

For enforcement of the regulations respecting Class II licenses, Health Canada relies primarily on complaints (problem reports) from users and from other vendors (such as competitors who may have successfully completed the licensing process).

Enforcement is the responsibility of Health Canada's Inspectorate. While their inspection program largely focuses on Establishments (companies that hold medical device establishment licenses), they may also inspect Class II, III, or IV manufacturers.

Health Canada also relies on the CMDCAS recognized registrars to audit all Class II-IV manufacturers to verify that they have a valid ISO 13485:2003-conforming quality

management system (QMS) that is compliant with all applicable sections of Part 1 of the *Medical Devices Regulations* (SOR/98-282). Manufacturers who do not conform to ISO 13485:2003 and the applicable Part I requirements of the Canadian *Medical Devices Regulations* (SOR 98/282) will not be eligible to receive an ISO 13485:2003 certificate under the CMDCAS program. Existing certificate holders may lose or have their certification suspended, if they do not maintain compliance to the requirements.

2.13. *What are the consequences of not complying with the Medical Devices Regulations and Food and Drugs Act?*

Companies that do not comply with the *Medical Devices Regulations* (SOR/98-282) and the *Food and Drugs Act* will be prohibited from advertising and/or importing and/or selling their patient management software products in Canada. Companies and their officers could be subject to sanctions under the *Food and Drugs Act* including fine and/or imprisonment.

2.14. *Are there any consequences for individuals and organizations that use or purchase unlicensed patient management software products?*

Health Canada regulates the manufacture, importation, distribution, advertising and sale of medical devices under the *Medical Devices Regulations* (SOR 98/282). It does not regulate the use of medical devices. Health Canada will not stop any health care professional or organization from using unlicensed software. However, health care organizations may not license[4] the use or distribute copies of the unlicensed software to other organizations.

Health Canada has issued a Notice titled ***Purchase of Licensed Medical Devices for Use in Health Care Facilities***[5] directed at Hospital Administrators, Hospital Risk Managers, Hospital Infection Control Practitioners, Hospital Purchasing Departments, Hospital Biomedical Engineering Departments, and Provincial and Territorial Ministries of Health. The guidance document states in part "*Before entering into any contractual agreement with a manufacturer, we strongly recommend that health care facilities verify that the medical device is licensed by Health Canada".* While Health Canada will not prevent a health care organization from purchasing an unlicensed product, vendors are prohibited from offering such products for sale.

There may be legal liability issues for individuals and organizations that use unlicensed software. One of the principal reasons for applying the *Medical Devices Regulations* (SOR 98/282) to patient management software was to address issues of patient safety arising from its use. If a patient is harmed and it is alleged that the use of an unlicensed

[4] License in this instance refers to software licenses, not medical device licenses.
[5] The Health Canada Notice titled ***Purchase of Licensed Medical Devices for Use in Health Care Facilities*** can be found at the following URL: http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/purchase_md_achat_im_let-eng.php .

patient management software product contributed to the harm, both the user and the manufacturer could be subject to civil legal action. The licensing requirement, in essence, may affect the standard of care required of health care providers in Canada.

It is recommended that individuals and organizations that purchase and use unlicensed patient management software consult their legal counsel for advice.

2.15. *Will Medical Device Licensing be a mandatory requirement for RFPs issued by provincial government departments, agencies and health care organizations?*

Provincial and hospital CIOs contacted while researching this FAQ indicated that they are all looking at the impact of the Health Canada notice on procurement practices. Most indicated that licensing will become a mandatory requirement for RFPs for patient management software products.

In its Notice titled ***Purchase of Licensed Medical Devices for Use in Health Care Facilities,*** Health Canada states in part:

> *"Advertising Class II, III or IV medical devices for sale prior to obtaining a medical device licence is prohibited. A manufacturer's response to a Request for Proposal (RFP) is also considered to be an "offer for sale;" therefore, if a manufacturer responds to a RFP with a submission of an unlicensed medical device, it would be in contravention of the Regulations."*

According to the CIOs contacted, if Health Canada grants an amnesty period, RFP issuers will likely require evidence that any licensing requirements will be satisfied by the end of the amnesty period. Advantage may go to those vendors who can demonstrate that they already meet licensing requirements.

ITAC Health has asked Health Canada to ensure that the prohibition against the proposal of unlicensed software by vendors in response to RFPs be clearly addressed in any notice concerning an amnesty period. As indicated in the response to question 2.4, Health Canada has not yet issued any revised notice concerning an amnesty period.

2.16. *Do the Medical Devices Regulations apply to patient management software products downloaded from other countries off the Internet?*

The application of the notice to patient management software products downloaded from other countries off the Internet is not clear at this time. A request for clarification has been sent to Health Canada. When received, the response will be published on the ITAC Health Patient Management Software Licensing Working Group blog at www.itachealth.blogspot.com and in future versions of this FAQ.

It is recommended that you contact Health Canada directly by email at DEVICE_LICENSING@hc-sc.gc.ca if this question applies to your situation.

2.17. *How will Health Canada enforce the Medical Devices Regulations for unlicensed patient management software downloaded from the Internet if the manufacturer or distributor is in another country?*

Health Canada has not indicated how it will enforce the *Medical Devices Regulations* (SOR 98/282) for unlicensed patient management software downloaded from the Internet where the manufacturer or distributor is in another country. A request for clarification has been sent to Health Canada. When received, the response will be published on the ITAC Health Patient Management Software Licensing Working Group blog at www.itachealth.blogspot.com and in future versions of this guide.

It is recommended that you contact Health Canada directly by email at DEVICE_LICENSING@hc-sc.gc.ca if this question applies to your situation.

2.18. *How does this notice apply to open source software?*

The same regulatory requirements apply for Free and Open-Source Software (FOSS) as for other forms of patient management software. "Sell" under the *Medical Devices Regulations* (SOR 98/282) is not restricted to commercial and money transactions and includes transactions without compensation. In order to determine who is responsible to hold a medical device license, please refer to the definition for "manufacturer" in question 2.8. The manufacturer, importer and distributor must comply with all regulatory requirements. The onus is on the open-source software user to confirm that the device is properly licensed prior to using the product. As indicated in question 2.14, the user could be exposed to legal liability for the use of unlicensed software.

2.19. *Does each new release of a patient management software product require its own license?*

With respect to patient management software devices already licensed, amendments for Class II licences are 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* (SOR 98/282)). 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 patient management software modifications and upgrades that fit the above criteria. If the manufacturer chooses to identify their software product by version number (device identifier), an amendment will be required each time the version number changes.

If you are uncertain whether or not a new licence application or an amendment to an existing licence is required, it is recommended that you contact Health Canada directly by email at DEVICE_LICENSING@hc-sc.gc.ca.

2.20. *My company develops and sells a suite of integrated products as components of a comprehensive hospital information system. Does each product require a separate license?*

There are several "types" of licenses that are issued by Health Canada. These are defined in sections 28 to 31 of the *Medical Devices Regulations* (SOR 98/282) and include *single*, *system*, *group* and *family* type licenses. A manufacturer could obtain a "system" licence for software modules that all work together if they are sold under the same unique name.

If the components are stand-alone software modules that do not all bare the same unique name, these components would require their own "single" or "family" type licence. In order to be considered a medical device, the software must meet the definition of a device on its own, although this product will likely interact with other devices (software or otherwise).

For more information on licence type, please refer to the following guidance document entitled *Guidance for the Interpretation of Sections 28 to 31: Licence Application Type* at the following URL: http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/apptype_typedem-eng.php

It is recommended that you contact Health Canada directly by email at DEVICE_LICENSING@hc-sc.gc.ca if this question applies to your situation.

3. The Medical Device Licensing Process – General

3.1. *I'm starting from scratch. What are the steps in the medical device licensing process?*

If you are manufacturing or distributing software that you think may require a medical device license, you should:

1. Determine if your software qualifies as a Class I or Class II device. If there is any doubt, you can contact Health Canada for assistance in determining the appropriate class for your software.

2. Apply for an establishment license[6] if you sell or distribute Class I or Class II medical devices.[7] In order to qualify for an establishment license you must:

    a. Ensure that you have documented procedures in place for maintenance of distribution and complaint handling records, mandatory problem reporting and recalls.

    b. Ensure that you have documented procedures in place for storage, handling, delivery, installation and servicing of software product if you sell Class II software.

    c. Ensure that the manufacturer has obtained a medical device license for the software product if you sell Class II devices.

    d. Complete the Medical Devices Establishment License Application Form. This form is available on the Health Canada website at the following URL http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/form/frm_mdel-leim_20051216_tc-tm-eng.php .

    e. Include the appropriate fee with the application (see question 3.8).

3. Apply for a medical device license if you manufacture Class II medical devices. In order to qualify for a medical device license you must:

    a. Document your Quality Management System and ensure that it complies with ISO 13485:2003 and applicable sections of Part I of the *Medical Devices*

[6] Health Canada has published a document titled ***Guidance on Medical Device Establishment Licensing*** that is available at the following URL http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/gui_mdel-doc_aeim_20051117-eng.pdf

[7] If a vendor both manufactures and sells a Class II device and has a medical device license, you do not need an establishment license to sell the licensed device. If however the vendor also sells patient management software manufactured by another vendor (e.g. a standalone piece of software that MAY BE USED with their product), then they require an establishment license to sell the other vendor's product.

Regulations (SOR/98-282). You may want to engage a qualified consultant to assist you in documenting your system and filling in any gaps.

b. Engage a registrar accredited by the Standards Council of Canada and Health Canada[8].

c. Obtain a Quality Management Certificate from your registrar confirming compliance with ISO 13485:2003 and the *Medical Devices Regulations* (SOR/98-282)[9].

d. Complete the application for the medical device license. Application forms can be found on the Health Canada website at the following URL http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/licapp_demhom_cla2-eng.php

e. Prepare a description of the medical conditions, purposes and uses for which the patient management software is manufactured, sold or represented.

f. List any standards applied in the manufacture of your software product to meet the safety and effectiveness requirements.

g. Have a senior official of your company attest that you meet the safety and effectiveness requirements as defined in the regulations. Be prepared to present objective evidence to this effect.

h. Have a senior official of your company attest that you meet the labeling requirements defined in the regulations.

i. Include the appropriate fee with the application (see question 3.8).

3.2. *How do I contact Health Canada to determine the class of device?*

To initiate an action for a ruling on which class of device your patient management software product falls into, send an email containing a basic description of your company and the software in question (include a description of the intended indications for use and any proposed labeling to aid Health Canada in making a classification decision) together

[8] Health Canada publishes a list of accredited registrars on its website at the following URL http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php

[9] See Also Health Canada's Guidance Document, GD210 - ISO 13485:2003 Quality Management System Audits Performed by Health Canada Recognized Registrars (at http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_audit13485_2-eng.php) for requirements of ISO 13485 and Canadian *Medical Devices Regulations*, as well as GD207 - Guidance On The Content Of ISO 13485 Quality Management System Certificates Issued By Health Canada Recognized Registrars (at http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_accep_cert13485_2-eng.php) for appropriate scope of ISO 13485:2003 certificate.

with contact information for someone in your company who can discuss the application with Health Canada. The email can be sent to: DEVICE_LICENSING@hc-sc.gc.ca. Health Canada will contact you to discuss the process and any additional information required.

3.3. *What are the safety and effectiveness requirements?*

The safety and effectiveness requirements are defined in sections 10 to 20 of the *Medical Devices Regulations* (SOR 98/282). Note that not all of the requirements will apply to patient management software (e.g. Section 17 - requirement for sterilization). Manufacturers should review each of the requirements and determine whether or not they apply to the product in question. Where requirements are excluded, manufacturers should document the reasons for the exclusion. The safety and effectiveness requirements from the Regulations are as follows (note that numbering below is the numbering in the Regulation itself):

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.

3.4. *What objective evidence would we have to produce to demonstrate that we meet the safety and effectiveness requirements?*

Objective evidence must be produced in the event that Health Canada conducts an inspection or requests the information in support of an application. It does not have to be provided with the application.

Objective evidence includes technical documentation, installation and maintenance procedures, software verification and validation (e.g. test programs and results, change management documentation), user manuals, threat and risk assessments, risk registers, revision history, and problem reports and their resolution.

Objective evidence may be created by an external resource, such as an auditor or expert consultant, or by internal resources who document compliance with clinical, technical and business specifications appropriate to the medical conditions, purposes and uses for which the patient management software is manufactured, sold or represented.

3.5. *What are the labeling requirements?*

Labeling requirements are defined in sections 21 to 23 of the *Medical Devices Regulations* (SOR 98/282). The labeling requirements from the Regulations are (note that numbering below is the numbering in the Regulation itself):

21. (1) No person shall import or sell a medical device unless the device has a label that sets out the following information:
    - (a) the name of the device;
    - (b) the name and address of the manufacturer;
    - (c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
    - (d) in the case of a Class III or IV device, the control number;
    - (e) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units;
    - (f) the word "Sterile" if the manufacturer intends the device to be sold in a sterile condition;
    - (g) the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;
    - (h) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use;
    - (i) the direction for use, unless directions are not required for the device to be used safely and effectively; and
    - (j) any special storage conditions applicable to the device.

    (2) The information required pursuant to subsection (1) shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.

22. (1) Subject to subsection (2), if a medical device is intended to be sold to the general public, the information required by subsection 21(1) shall
    - (a) be set out on the outside of the package that contains the device; and
    - (b) be visible under normal conditions of sale.

    (2) Where a package that contains a medical device is too small to display all the information in accordance with section 21, the directions for use shall accompany the

device but need not be set out on the outside of the package or be visible under normal conditions of sale.

23. (1) Subject to subsection (3), the information required by subsection 21(1) shall, as a minimum, be in either English or French.
(2) Subject to subsection (3), where the directions for use are supplied in only one official language at the time of sale, directions for use in the other official language shall be made available by the manufacturer as soon as possible at the request of the purchaser.
(3) In respect of a medical device to be sold to the general public, the information required by paragraphs 21(1)(*a*) and (*e*) to (*j*) shall, as a minimum, be in both English and French.

3.6. *How do we apply the labeling requirements to patient management software products?*

Manufacturers need to examine the labeling requirements in sections 21 to 23 of the Regulations to determine which apply to their products. Labeling information can be placed on a box, in a CD/DVD casing or other media casing, a paper notice accompanying the product, on a splash screen or in an "About" file that is accessible to the user and gives information about the software product. Directions for use can be included in a user manual or other user documentation.

3.7. *What standards should we list to show that our products meet the safety and effectiveness requirements?*

Health Canada periodically publishes a list of recognized standards to assist manufacturers in meeting the safety and effectiveness requirements of the Act. These standards are listed on the Health Canada website at the following URL: http://www.hc-sc.gc.ca/dhp-mps/md-im/standards-normes/md_rec_stand_im_norm_lst_2-eng.php .

Conformance with recognized standards is voluntary for manufacturers. A manufacturer may choose to demonstrate conformance with a recognized standard or may elect to address the relevant issues in another manner.

Only one standard in the current list of recognized standards applies specifically to medical device software. This standard is *IEC 62304 Ed.1.0 b: 2006 Medical device software - software life cycle processes*.

3.8. *What are the fees for medical device and establishment licensing?*

The current fee payable to Health Canada for a class II medical device license is $200.00. This licence is renewed annually. If the vendor is planning to continue importation

and/or sale of a class II medical device, the cost is $100/licence/year. For an establishment license the fee is $2120/year.

Health Canada publishes a guide titled *Guidance Document on Cost Recovery, Fees in respect of Medical Devices Regulations* that provides complete details of fees and applications for fee reductions. It is available at the following URL: http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/guidedoc_feesmd_docorient_fraisim-eng.php .

Note that these fees do not include the cost of ISO 13485:2003 certification or the costs of coming into compliance with ISO 13485:2003 and other requirements of the Regulations.

3.9. *How long does it take Health Canada to process a license application?*

Health Canada's published performance target for processing applications for Class II medical device licenses, that are complete and received with all necessary documentation, is 15 calendar days. This may be longer due to application backlog or if any questions are asked due to deficiency of information provided in the licence application.

Note that this time does not include the time needed for ISO 13485:2003 certification or the time required to come into compliance with ISO 13485:2003 and other requirements of the Regulations.

The turnaround time for establishment licenses is 4 to 6 weeks.

4. ISO 13485:2003 Certification

4.1. *What is ISO 13485:2003?*

ISO 13485:2003 is a quality management standard for medical devices. Its proper title is ***ISO 13485:2003 Medical devices – Quality management systems – requirements for regulatory purposes***. ISO 13485:2003 builds upon ISO 9001 but includes quality management requirements unique to the design, development, manufacture and maintenance of medical devices.

4.2. *What is CMDCAS?*

The Canadian Medical Devices Conformity Assessment System (CMDCAS) was established by Health Canada and the Standards Council of Canada to support the accreditation of registrars and the design of their processes to audit medical device manufacturers under ISO 13485:2003 and the *Medical Devices Regulations* (SOR/98-282). More information on CMDCAS can be found on Health Canada's website at the following URL: http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_syst_pol-eng.php

4.3. *Our software has been classified as a Class I medical device. Do we need ISO 13485:2003 certification?*

No. Only companies that manufacture Class II, III, and IV medical devices require ISO 13485:2003 certification.

4.4. *My organization is already ISO 9001 certified. Do we need ISO 13485:2003 certification as well?*

Yes. If your patient management software product has been classified as a Class II medical device, then you require ISO 13485:2003 certification, even if you have already been ISO 9001 certified. ISO 13485:2003 contains some requirements not included in ISO 9001.

If the registrar who issued your ISO 9001 certificate is recognized by Health Canada /SCC as CMDCAS accredited registrar, you simply need to address the gaps, and upgrade to the new standard. If your current registrar is not accredited under CMDCAS, then you should consider a transfer to one who is.

4.5. *Are there additional requirements to obtain a ISO13485:2003 certification under the CMDCAS program?*

Yes. The manufacturer's QMS needs to be certified to ISO13485:2003 AND must comply with applicable sections of the Canadian *Medical Devices Regulations* (SOR/98-282). See Health Canada's Guidance Document, GD210 - ISO 13485:2003 Quality Management System Audits Performed by Health Canada Recognized Registrars (at http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_audit13485_2-eng.php) for requirements of ISO 13485 and Canadian *Medical Devices Regulations,* as well as GD207 - Guidance On The Content Of ISO 13485 Quality Management System Certificates Issued By Health Canada Recognized Registrars (at http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_accep_cert13485_2-eng.php) for appropriate scope of ISO 13485:2003 certificate.

4.6. *What does ISO 13485:2003 cover?*

ISO 13485:2003 covers in detail the following subjects (note that numbering below is the numbering in the standard itself)

4. Quality management system
    - 4.1 General Requirements
    - 4.2 Documentation Requirements
5. Management responsibility
    - 5.1 Management commitment
    - 5.2 Customer focus
    - 5.3 Quality policy
    - 5.4 Planning
    - 5.5 Responsibility, authority and communication
    - 5.6 Management review
6. Resource management
    - 6.1 Provision of resources
    - 6.2 Human resources
    - 6.3 Infrastructure
    - 6.4 Work environment
7. Product realization
    - 7.1 Planning of product realization
    - 7.2 Customer-related processes
    - 7.3 Design and development
    - 7.4 Purchasing
    - 7.5 Production and service provision
    - 7.6 Control of monitoring and measuring devices
8. Measurement, analysis and improvement
    - 8.1 General

8.2 Monitoring and measurement
8.3 Control of nonconforming product
8.4 Analysis of data
8.5 Improvement

4.7. *Do we have to include design processes in our QMS?*

Section 32 (2) (f) of the *Medical Devices Regulations* (SOR 98/282) states that the manufacturer of a Class II device must provide the following:

> "a copy of the quality management system certificate certifying that the quality management system under which the device is manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485:2003:03, Medical devices — Quality management systems — Requirements for regulatory purposes"

Although it is not stated in the Regulations that for Class II medical devices the quality management system certificate must also certify the quality management system under which the device is designed, it is strongly recommended that design be included in the scope of the ISO 13485:2003:2003 certification when the device is a software product.

If a manufacturer submits a Class II application with a valid ISO 13485:2003:2003 certificate that excludes design, Health Canada will not reject the application for that reason.

4.8. *Where can I get a copy of ISO 13485:2003?*

You can purchase a copy of ISO 13485:2003 in hardcopy or for download from the Standards Council of Canada's website at the following URL: https://www.standardsstore.ca/eSpecs/index.jsp.

Another useful reference is *ISO 14969:2004 Medical devices -- Quality management systems -- Guidance on the application of ISO 13485: 2003*, which is available at the same URL.

4.9. *We are a large diversified company. Does the certification apply to the whole organization?*

Your registrar will help you to determine the precise scope of your ISO 13485:2003 certification. At a minimum, those parts of your organization involved in the development, marketing and support of your patient management software products must be included in the scope of certification.

4.10. *Should we hire a consultant to help us set up our quality management system?*

Experienced consultants can expedite the process of establishing and documenting your quality management system. Good consultants come with a wealth of experience and often have templates to ensure that your documentation conforms to accepted standards of practice. If your company has no experience with quality management systems, then there may be value in contracting for this external expertise.

However, companies must take ownership of their quality management processes and should not outsource the function entirely. A hybrid approach involving both experienced consulting resources and staff resources is recommended. This provides the opportunity for knowledge transfer enabling the company to build the in-house expertise needed to manage the quality management system over time.

4.11. *We need help to set up a quality management system and license our products. What are the qualities of a good consultant?*

You should consider the following qualities when selecting a consultant or a consulting firm to assist with the development of your quality management system, certification under ISO 13485:2003 and the licensing of your patient management software products:

- Extensive experience helping to prepare companies for ISO 13485:2003 certification under the CMDCAS program (i.e. experience with ISO 13485:2003 and Part I of the Canadian *Medical Devices Regulations* (SOR/98-282)).
- Extensive experience in the development of quality management systems for the design, development, deployment and support of software.
- Experience in and understanding of software design, development, deployment and support processes.
- Good working relationships and evidence of regular contact with accredited registrars and Health Canada.
- Extensive experience in medical device licensing and other regulatory affairs matters.
- Experience submitting applications for Class II medical devices to Health Canada.
- Positive references from companies whom they have helped to successfully achieve ISO 13485:2003 certification and licensing of patient management software products.

4.12. *How long does it take to set up a quality management system?*

According to the consultants and registrars consulted, it could take anywhere from 30 days to 12 months to set up an ISO 13485 compliant quality management system depending on the size and complexity of your organization, the current state of your quality processes and the availability of resources to commit to the project.

4.13. *What does it cost to set up a quality management system?*

The cost to set up a quality management system will vary depending on a number of factors:

1. The extent to which quality management processes are already in place in your organization.
2. The current state of quality management process documentation.
3. Whether the company will use external resources or in-house staff to develop the quality management processes and documentation.
4. Training employees to utilize the quality management system.

It is obvious that a company starting from scratch will incur greater costs than a similar company that is already ISO 9001 certified and needs only to adapt its current quality management system. Discuss the total cost of setting up the quality management system with your consultant.

4.14. *How long should the quality management system be up and running before calling in the registrar?*

Registrars will require evidence that your operations conform to your quality management system documentation. If you are implementing a new quality management system, you can't implement your system on one day and then call the registrar in the next. Discuss the required time period with your registrar. Your registrar may accept historical evidence of quality management processes even if those processes pre-date your quality management system.

4.15. *How do we find an accredited registrar?*

A list of accredited registrars is posted on the Health Canada website at the following URL: http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php.

Registrars are accredited by the Standards Council of Canada and Health Canada, and conform to ISO standards for certification bodies and to the *Canadian Medical Devices Conformity Assessment System* (CMDCAS)[10].

Registrars who audit medical device manufacturers within the scope of CMDCAS are responsible for assessing the conformity of a medical device manufacturer's quality management system to ISO 13485:2003 and applicable sections of Part I of the Canadian *Medical Devices Regulations* (SOR/98-282).

[10] More information on CMDCAS can be found on Health Canada's website at the following URL: http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_syst_pol-eng.php.

4.16. *When should we engage our registrar?*

Given the anticipated demand for certification services as a result of the Health Canada notice, companies should engage an accredited registrar as soon as possible.

4.17. *What are the steps in the certification process?*

Each registrar has its own process for 13485:2003 certification, which may vary slightly from one to the other. In most cases the following generic steps apply.

1. Prior to calling in your registrar you should ensure that your quality manual has been written and implemented, and any required training delivered. You should conduct your own internal audit to ensure that you comply with all of the requirements of ISO 13485:2003 and present the results of the audit to your organization's management team or audit committee in a management review.

2. You should notify your registrar at least 30 days in advance of your planned audit so that the registrar can schedule the necessary audit resources.[11] During this period you may ask your registrar to conduct an optional introductory or preliminary visit to help determine the scope of the audit and to discuss weak spots or concerns in your quality management program.

3. Your registrar will conduct a Stage 1 assessment or readiness review. This stage will usually involve a verification of scope and will determine if procedures have been developed, written and meet the intent of the standards. A brief tour of the facility is made to ensure readiness for the Stage 2 audit. The principle outcome of the stage 1 assessment is an audit plan detailing issues and gaps that must be addressed and the dates for the Stage 2 audit.

4. After you have addressed all of the issues and gaps identified in Stage 1, the registrar will conduct a Stage 2 audit. This review will include a detailed review of your quality management documentation, a review of evidence that your quality management system is functional, a review of internal audits and training records, a facility tour and a management review meeting to review the audit findings. The auditor may interview your managers and staff.

5. At the end of the Stage 2 audit, if all issues and gaps have been appropriately addressed, the registrar will issue a quality management certificate. The certificate is valid for a period of 3 years.

6. During the validity period for the certificate, your registrar will conduct annual audits to ensure continuing compliance with ISO 13485.

[11] Depending upon the demand for registration services, your registrar may require more notice in order to schedule the required audit resources. Discuss this with your registrar on engagement.

7. Upon expiry of the quality management certificate after 3 years, the company must be recertified.

4.18. *How long does it take to go through the certification process?*

Registrars report that it usually takes between 1 and 45 days to complete the stage 1 and stage 2 audits and issue a certificate[12]. The primary variables are the number of issues and gaps identified in the stage 1 report and the time required for a company to adequately address those issues and gaps. According to the registrars contacted, the actual audits themselves typically take one to two days for Stage 1 and one and a half days to five days or more for stage 2 depending on the size of the facility and the number of sites.

4.19. *How much does the certification process cost?*

The fees charged by a registrar for certification will vary depending upon the number of employees in the organization and the number of sites associated with the development, marketing and support of patient management software products. Registrars apply a standard formula when calculating their fees and will normally charge an annual fee plus a per diem rate for audit resources. Registrars contacted indicated that per diem rates for auditors are in the $1400 - $1600 range. Where auditors are required to travel, travel, meal and accommodation costs must also be factored in.

As an example, when asked to provide a quote for a small company with 20 employees located in one site, registrars stated that the cost would be in the $6000 to $7000 range for professional services and annual fees, plus any travel and accommodation costs associated with the service. This includes the cost of annual audits over the 3-year validity period of the certificate.

[12] The issuance of a hard copy quality management certificate could take up to two weeks, but registrars can issue a certificate number that can be quoted in a Medical Device license application within 1 to 2 days.

5. eHealth Infrastructure Projects

5.1. *What about complex eHealth infrastructure projects where many players come together to develop and integrate infrastructure components?*

One of the biggest challenges for vendors will be determining their responsibilities for licensing when they are part of a large eHealth infrastructure project. The complex technical and business arrangements associated with these projects make it difficult to determine who are the manufacturers and who are the distributors of patient management software components, and which components qualify as Class I or Class II medical devices.

The questions and answers below should be considered as general guidelines only. It is recommended that, where there is any doubt about the need for licensing or responsibility for licensing, the vendors and client organizations involved should meet with Health Canada to determine the appropriate course of action.

5.2. *My company has been contracted by a provincial government agency to design and develop clinical registry software that meets the definition of a Class II medical device. The Province is in control of the development project, will own the IP at the end, and will distribute the product to other jurisdictions. Who is responsible for obtaining the Class II medical device license?*

This question has been submitted to Health Canada for their guidance. When received, the response will be published on the ITAC Health Patient Management Software Licensing Working Group blog at www.itachealth.blogspot.com and in future versions of this guide.

It is recommended that you contact Health Canada directly by email at DEVICE_LICENSING@hc-sc.gc.ca if this question applies to your product.

5.3. *My company has been contracted by a provincial government ministry for a Canada Health Infoway funded project to develop patient management software for community-based services. At the end of the project, my company will own the IP and has the right to sell the product to other jurisdictions. Who is responsible for obtaining the Class II medical device license?*

In this situation your company is developing a product for sale and distribution to other provincial jurisdictions. You will own the IP at the end of the project. In this case your company is the "manufacturer" and is responsible for the medical device license.

5.4. *My company configures and integrates commercial off-the-shelf software (COTS) such as database applications, encryption applications, and web portal applications into health information infrastructures operated by provincial and regional health care organizations. Do these COTS applications require medical device licenses?*

The application of the notice to COTS products is not clear at this time. A request for clarification has been sent to Health Canada. When received, the response will be published on the ITAC Health Patient Management Software Licensing Working Group blog at www.itachealth.blogspot.com and in future versions of this FAQ.

It is recommended that you contact Health Canada directly by email at DEVICE_LICENSING@hc-sc.gc.ca if this question applies to your situation.

5.5. *My company has developed a patient management software application that must be customized for each provincial jurisdiction in which it is implemented. The software qualifies as a Class II medical device. Do we apply for a single license, or separate licenses for each jurisdiction in which it is sold?*

If all of the software has the same indications for use with only slight modifications, these software devices would each have their own separate device identifier and could appear on one "family" type license. Please refer to the Guidance for the Interpretation of Sections 28 to 31: License Application Type[13].

If the distinction between the versions of the software is a change in the indications for use (enhanced functionality, etc.) then the software would need to be licensed separately. Please contact Health Canada directly by email at DEVICE_LICENSING@hc-sc.gc.ca to discuss your particular situation if you are not clear on how to structure your licenses.

5.6. *My company is developing a patient management software application under contract with a provincial government agency. We will own the IP for the product at the end, but government employees will play a big role in the design, development, testing and deployment of the application. Does our quality management system have to cover the work undertaken by provincial government employees?*

In this situation your company is the manufacturer and must ensure that the patient management software product is designed, developed and deployed in accordance with your quality management system. Your quality management system documentation must clearly address how you will manage the quality of all contributors, including those

[13] Guidance for the Interpretation of Sections 28 to 31: License Application Type can be found at the following URL: http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/apptype_typedem_main_principal-eng.php

employed by government. If there are any limitations to your ability to manage quality processes, these should be documented as part of your risk management program.

6. References

6.1. *Can you recap the references identified in this FAQ and tell us where to find them?*

The following documents were referenced in this guide.

(Hint: The easiest way to find links for Health Canada documents is to Google them).

Reference	Location
Food and Drug Act	http://laws.justice.gc.ca/en/ShowDoc/cs/f-27/bo-ga:s_1::bo-ga:s_2/20090929/en?page=1&isPrinting=false#codese:2-df:SELL-m1
Medical Devices Regulations (SOR 98/282)	http://laws.justice.gc.ca/eng/sor-98-282/20090929/page-1.html
Notice – Classification of Medical Devices Class I or Class II patient management software	http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/md-im/activit/announce-annonce/md_notice_software_im_avis_logicels-eng.pdf
ISO 13485:2003 Medical devices – Quality management systems – requirements for regulatory purposes	https://www.standardsstore.ca/eSpecs/index.jsp.
ISO 14969:2004 Medical devices -- Quality management systems -- Guidance on the application of ISO 13485: 2003	https://www.standardsstore.ca/eSpecs/index.jsp.
Purchase of Licensed Medical Devices for Use in Health Care Facilities	http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/purchase_md_achat_im_let-eng.php .
Medical Devices Establishment License Application Form	http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/form/frm_mdel-leim_20051216_tc-tm-eng.php
Guidance on Medical Device Establishment Licensing	http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/gui_mdel-doc_aeim_20051117-eng.pdf
List of registrars recognized by Health Canada under section 32.1 of the Medical Devices Regulations	http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php
Class II Medical Device Licence Application Form	http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/licapp_demhom_cla2-eng.php

List of Recognized Standards	http://www.hc-sc.gc.ca/dhp-mps/md-im/standards-normes/md_rec_stand_im_norm_lst_2-eng.php
Guidance Document on Cost Recovery, Fees in respect of Medical Devices Regulations	http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/guidedoc_feesmd_docorient_fraisim-eng.php
Policy on the Canadian Medical Devices Conformity Assessment System (CMDCAS)	http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_syst_pol-eng.php
Guidance for the Interpretation of Sections 28 to 31: Licence Application Type V.1	http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/apptype_typedem_main_principal-eng.php
ITAC Health Patient Management Software Licensing Working Group blog	www.itachealth.blogspot.com
Guidance Document, GD210 - ISO 13485:2003 Quality Management System Audits Performed by Health Canada Recognized Registrars	http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_audit13485_2-eng.php)
GD207 - Guidance On The Content Of ISO 13485 Quality Management System Certificates Issued By Health Canada Recognized Registrars	http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_accep_cert13485_2-eng.php