What is ISO 13485?

ISO 13485:2003 is based on the ISO 9000 family of "quality" standards; it is a subset of this broader standard specifically focused on the design, development and manufacturing of medical devices. The actual full title of the standard is: *Medical devices – Quality management systems – Requirements for regulatory purposes*.

As this name implies, 13485 provides a description of what must be included in the Quality Management System (QMS) of a medical device manufacturer. In the case of patient management software publishers, the 13485 standard would apply to the software development processes which these companies undertake to create their products.

How do I know if I need ISO 13485 certification?

In August, 2009, Health Canada ruled that patient management software that does any manner of data manipulation or processing is to be considered a Class II Medical Device and, therefore, will be subject to the requirements for such devices. One of these requirements is that the manufacturer of the device (in this case, the publisher of the patient management software) must employ a QMS that has been audited and certified as compliant with ISO 13485.

At present, there is some ambiguity regarding what software is and is not subject to the Health Canada ruling. As it is currently drafted, the ruling indicates that any software which manipulates data is considered a Class II device. This would exclude software which simply stores/retrieves information or images, for instance; such software would be considered a Class I device. Software which provides even rudimentary support for "imaging or monitoring physiological processes", however, would be a Class II device.

It is also important to note that the entity that "sells" the software in Canada is considered the manufacturer, and so is subject to the ISO 13485 audit requirements, even if the software is provided at zero cost. This means that free and open source software is subject to the Health Canada regulation. It also means that the Canadian distributor of a software product may be considered, for purposes of the Health Canada regulation, to be the manufacturer. Furthermore, there is no exemption for public sector entities who provide patient management software; the Health Canada regulation is motivated by a desire to protect public safety and so applies equally to private and public sector software providers.

What is the process for achieving ISO 13485 certification?

To achieve ISO 13485 certification, there are four main phases:

1. Determine the gaps between your current operating procedures and those necessary to pass the ISO 13485 audit.
2. Close the gaps; make the changes necessary to bring your operating procedures in line with what is needed. Typically, this will involve creating documentation for procedures where there are not, today, formal (auditable) workflows. It is also required, as part of the audit, that the organization is able to demonstrate that team members: (a) are aware that there are standardized operating procedures; (b) know what they are; and (c) know where to find the appropriate (or updated) documentation. Often, this means there will be a need for education and/or training.

3. After your change management process is done, do a pre-audit to insure that you will be successful when the auditor comes. Repeat step 2 to address any gaps that still exist.
4. Be formally audited by a Health Canada recognized auditor.

How long will this process take? How much will it cost?

The answer, of course, is "it depends". Software development shops that, today, follow rigorous *software engineering* principles will find that there are relatively few gaps that will need to be addressed before they undertake a formal ISO 13485 compliance audit. Organizations that do not presently follow any sort of formal procedures will find that they have a lot of documentation to prepare and training to do before they will be successfully able to pass a 13485 audit.

If you're running a tight ship now, the preparations for an audit may be completed in a matter of a couple of months with minimal (if any) outside help required. Organizations that are already CMM Level 5 or ISO 9000 certified, for instance, will have very few preparations to do. On the other hand, if your development practices are largely ad hoc (you have software "artists", not software "engineers"), it could take a half year or more to re-engineer your processes and be ready for an audit. If software engineering is not already a core competency within the organization, you may also need help from external advisors to develop the consistent procedures and practices that will lead to a successful 13485 audit.

If you are in the "tight ship" category, your out-of-pocket costs over the 3-year lifetime of your compliance certificate could be less than $15K. If you're in the other category, and/or if you have a large, geographically dispersed operation, these costs could be 5-10 times that much or more. If you have multiple facilities, the QMS in each will need to be audited for compliance to ISO 13485.

Where can I find more information?

You can download a PDF copy of the ISO 13485 standard from the ISO web site (http://www.iso.org/iso/catalogue_detail?csnumber=36786); the cost is about $150 CAD. There are helpful implementation kits available which include things like templates and "gap analysis" spreadsheets. These typically cost around $1000 (see for example: http://www.13485store.com/). A list of Health Canada accredited registrars (auditors) can be found at: http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php. Many of these organizations also provide training.

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