

**Joint Initiative Open Forum Session on Software as Medical Devices**  
***Educational session at CEN/TC251 and ISO/TC215 JWG meeting in Rotterdam***

## **Submission from the Canadian Healthcare IT Industry**

*Submitted by: Michael Nusbaum*

*ISO/TC215 Delegate (Canada)*

*Co-Chair, Interoperability and Standards Committee, ITAC Health*

1. Canada's healthcare Information and Communications Technology (ICT) vendor community, represented in this submission by ITAC Health and MEDEC<sup>1</sup>, strongly supports the licensing of patient management software as medical devices. In the absence of a health software-specific standard and regulatory framework, Industry believes that the application of Canada's Medical Devices Regulations (MDR) and the ISO 13485 quality management standard to health software development will "raise the bar" for patient safety and product effectiveness.
2. Industry believes that the application of the MDR and ISO 13485 is in the best interests of vendors, who stand to gain from increased health care provider and consumer confidence in the safety and effectiveness of their products, and of health care providers and consumers who will have evidence that products have been developed under conditions that promote safety and effectiveness. Adapting the MDR framework for software accelerates improvements in safety, effectiveness and quality.
3. ISO 13485 is based on ISO 9001, and has been adapted to meet unique healthcare requirements. It is believed that any future quality standard for health software would similarly be based on ISO 9001, and would therefore represent a relatively modest enhancement to ISO 13485. Software manufacturers that are certified to ISO 13485 should have little difficulty complying with any future health software quality standard.
4. Industry recognizes that ISO 13485 is not software-specific and may not provide a complete solution to software quality (e.g. it does not address patient safety in the user environment where software products are configured by users and user organizations). We have found that definitions for software as medical devices are not clear, causing some confusion in the vendor and user communities. This suggests an important role for ISO/TC215 in defining appropriate standards for health software and harmonizing such standards internationally. Canadian Industry is prepared to support ISO/TC215 in such endeavors.
5. It is noted that Canada's medical device licensing program permits and encourages the use of other applicable international standards appropriate to the manufacture and installation of software, such as those under development at ISO/TC215 addressing risk management and software development lifecycles. Industry would expect that these standards would be integrated into the licensing and certification processes for patient management software as they are approved as international standards.

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<sup>1</sup> ITAC (Information Technology Association of Canada) Health represents approximately 130 Canadian and multi-national information and communications technology companies providing products and services to the Canadian health sector. MEDEC is Canada's Medical Device Manufacturers' Association and represents almost 150 medical device and health software manufacturers.