

Dental Patient Management Software Requires Medical Device Licence

On August 31, 2009, Health Canada issued a notice clarifying the classification of patient management software as a Class I or Class II medical device.¹

Under the Food and Drug Act, Health Canada reviews medical devices to assess their safety, effectiveness and quality before authorizing them for sale in Canada. Since 2003, Health Canada has required manufacturers and distributors of dental products to obtain medical device licenses for their products.

Until the August, 2009 notice, dental patient management software operated in a “grey area” outside of the Health Canada’s medical device licence process. In the absence of specific language regarding patient management software, vendors were not compelled to seek this licensing. The notice issued on August 31, 2009 addressed this issue by clearly classifying patient management software as a medical device subject to medical device licensing requirements.

Under the Act, software that is limited to archiving and viewing patient information, and does not involve the primary acquisition, manipulation and transfer of data, is considered a Class I medical device and subject to Class I licensing. In contrast, Health Canada considers patient management software involved in image acquisition, data manipulation, data analysis, recording of measurements, graphing and flagging of results, or performing calculations to be a Class II device requiring a Class II licence. An ISO 13485:2003 Quality Systems audit is part of the medical device licensing requirements. ISO 13485:2003 certification addresses quality assurance of products, management of customer requirements, and other elements of quality system management.

Most dental software available for sale in Canada today includes some clinical functionality that falls under the Class II definition. For example, functionalities for the capture, import or export of digital images, the rendering and display of numerical data in a graphical format on an Odontogram, perio chart or report, and the compilation and presentation of data demonstrating treatment progress over time, are all covered in the definition of a Class II medical device licence. End users’ use of specific software features that fall under Class II guidelines is not a factor in determining the requirement for licensing. The onus is on the manufacturer to obtain the necessary licence if their product includes Class II functionality.

In a notice issued on May 21, 2010, Health Canada provided guidance to manufacturers of non-compliant patient management software.² The notice recommended that manufacturers determine the classification of their software by June 15, 2010 in order to have sufficient time to meet the licensing requirements. As of February 1, 2011, Health Canada will focus their compliance efforts on non-compliant Class I patient management software medical devices and, as of September 1, 2011, on non-compliant Class II patient management software medical devices. By those dates, all patient management software will be expected to have obtained the necessary licence in order to be eligible for sale in Canada.

The Canadian Dental Association spoke to their membership in a news release dated March 5, 2010.³ The release noted that “patient management software is considered a medical device and is therefore subject to compulsory licensing”. The news release further stated “the costs that vendors may incur as a result of these licensing requirements will likely affect the price or availability of some patient management software in the future. Dentists purchasing patient management software that includes any type of patient data manipulation capacity should ensure that the software product is licensed for sale in Canada and has the appropriate Class I or II classification.”

There is a strong need for quality standards to be upheld by the dental software vendor community, given the increasing use by dentists of software functionality that affects treatment decisions and the move towards a “paperless” or software-based practice. Health Canada’s requirements will ensure that dentists can select products and vendors that are subject to regular testing against a recognizable standard.

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¹ http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_notice_software_im_avis_logicels-eng.php

² http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_suppliers_im_ld_fournisseurs-ghf-eng.php

³ http://www.cda-adc.ca/en/cda/news_events/media/dentistry_news/2010/03_05_10.asp