Health Canada Santé Canada

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Notice

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Additional Guidance on Transition from the Second to the Third Editions of the IEC 60601 Family of Standards on Health Canada's List of Recognized Standards

Background

Manufacturers applying for a Canadian medical device licence can fulfill elements of the *Medical Devices Regulations'* safety and effectiveness requirements by declaring conformity to standards recognized by Health Canada. Specifically, if an application for a medical device licence contains a Declaration of Conformity to a recognized standard, this can reduce or eliminate the need for the manufacturer to submit the actual test data for those aspects of device safety and performance addressed by the standard. Further information, including the "Guidance Document - *Recognition and Use of Standards under the Medical Devices Regulations*", Health Canada's Declaration of Conformity form and the current List of Recognized Standards can be found on the Health Canada website.

Currently, Health Canada recognizes both the second edition of IEC 60601-1, published in 1988, and the third edition, published in 2005. In October, 2008, Health Canada published a notice indicating that until June 1, 2012, conformity to the second edition of IEC 60601-1 and its related collateral and particular standards would be accepted. After June 1, 2012, conformity to the third edition would be required.

New editions of particular standards (designated as IEC 60601-2-X) harmonized with the third edition of IEC 60601-1 have, in many cases, not yet been published, or have been published only recently, making a full transition to the entire family by the June 1, 2012 deadline unfeasible. Health Canada has received a number of inquiries associated with this transition, particularly concerning how to deal with particular standards. The purpose of this notice is to communicate Health Canada's position on this issue and provide guidance to industry about some specific scenarios surrounding the June 1, 2012 transition date.

Scope

This notice applies to the IEC 60601 family of standards listed on Health Canada's List of Recognized Standards, including those particular standards that were renamed as IEC/ISO 80601-2-XX.

Definitions

IEC 60601-1:1988 refers to IEC 60601-1:1988- Ed.2.0, including Amendment 1:1991, Amendment 2:1995 and Corrigendum 1:1995.

IEC 60601-1:2005 refers to IEC 60601-1:2005-Ed.3.0, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*, and its associated amendments and corrigenda as listed on the current version of Health Canada's List of Recognized Standards.

General standard - designated as IEC 60601-1. This standard is applicable to all devices that fall under the Medical Electrical Equipment (MEE) definition of IEC 60601-1.

Collateral standards - designated as IEC 60601-1-X. These standards specify general requirements applicable to a subgroup of Medical Electrical Equipment (MEE) or a specific characteristic of MEE that is not fully addressed in the general standard.

Particular standards - designated as IEC 60601-2-X. These are standards that are specific to a particular device type. Not all devices will have a particular standard that is applicable to them.

Medical Electrical Equipment (MEE). As defined in IEC 60601-1:2005, MEE is electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and
b) intended by its MANUFACTURER to be used:
    1) in the diagnosis, treatment, or monitoring of a PATIENT; or
    2) for compensation or alleviation of disease, injury or disability.

Health Canada's Approach to Transition for the IEC 60601 Family

The following guidance is provided for manufacturers who submit medical device licence applications for devices that rely on conformity with IEC 60601 to demonstrate safety and effectiveness.

Transition Rules to be applied as of June 1, 2012

- If there is not a particular standard that is directly applicable to the device, it should conform to IEC 60601-1:2005 and its applicable collateral standards.

- If there is a particular standard that is directly applicable to the device and the version that harmonizes with IEC 60601-1:2005 was published by IEC before June 1, 2009, then the device should conform to IEC 60601-1:2005 and its applicable collateral standards in addition to this particular standard.

- If there is a particular standard that is directly applicable to the device and the version that harmonizes with IEC 60601-1: 2005 was published by IEC after June 1, 2009, a three year transition period from the date of publication by IEC will apply. During this transition, Health Canada will accept conformity to both editions and related collateral standards (and both will be listed on Health Canada's List of Recognized Standards).

Additional Guidance Relating to Transition

- If the transition rules above dictate that compliance with the 3rd edition is required for a Declaration of Conformity and you wish to declare conformity to the 2nd edition, applications must be shipped before June 1, 2012.

- We advise against testing a device to some editions within the 60601 family that harmonize with IEC 60601-1:1988 and some editions within the 60601 family that harmonize with IEC 60601-1:2005 (that is, you should not use the old edition of an applicable particular standard and the new edition of the general or collateral standards). However, if this cannot be avoided, the submission should clearly identify this and describe why this does not affect the validity of this testing in demonstrating the device's safety and effectiveness. Furthermore, the same rules with respect to the transition period stated above apply.

- These transition rules will not be applied retroactively. If you currently hold a licence for a device that was tested according to an edition that is no longer recognized, you do not need to submit additional data. This exemption does not apply when an amendment application involves a significant change to characteristics addressed by the IEC 60601 family. In this case, the same rules with respect to the transition period stated above apply.

- A Medical Device Licence is issued by Health Canada when acceptable evidence has been provided to show that the device meets the requirements of the *Medical Devices Regulations*. However, manufacturers are reminded that the Canadian Electrical Code is separate and distinct from the *Medical Devices Regulations* and is mandated by Provincial and Territorial electrical safety authorities, not by Health Canada. Therefore, in addition to having a medical device licence, mains-powered electromedical devices sold in Canada must be "approved" under the Canadian Electrical Code, and must bear a mark of conformity recognised by the Provincial and Territorial electrical safety authorities. For further information regarding these requirements, contact the applicable regulatory authorities. (http://www.csa.ca/cm/ca/en/community/electrical/regulators).

- Other Provincial, Territorial or municipal regulations may also apply to certain types of medical devices.

- The use of standards to meet the requirements of the *Medical Devices Regulations* is voluntary. If the manufacturer has tested the device in accordance with IEC 60601-1:1988 and its associated standards when the Transition Rules prescribe IEC 60601-1:2005 and its

associated standards, manufacturers should provide a summary of the differences in the testing compared to IEC 60601-1:2005 and provide a rationale to demonstrate that these differences do not affect the validity of the testing in demonstrating of the device's safety and effectiveness.

- Although collateral standard IEC 60601-1-9, *Requirements for environmentally conscious design* is a normative reference of IEC 60601-1:2005, the *Medical Devices Regulations* apply only to safety, effectiveness and quality of devices; therefore, Health Canada recommends that manufacturers design their devices in an environmentally conscious manner, but compliance with this collateral standard is not a requirement for licensure.

- Although collateral standard IEC 60601-1-6:2010-Ed.3.0, *General requirements for safety - Collateral standard: Usability* was published less than 3 years ago, the revisions to this standard were editorial in nature and it is considered to fall within the collateral standards associated with IEC 60601-1:2005. Therefore, the transition rules applicable to IEC 60601-1:2005 apply to this collateral standard.

- Health Canada reserves the right to require additional testing deemed necessary to demonstrate safety and effectiveness of any device.

- Consult the Health Canada website for Health Canada's current List of Recognized Standards for the most up-to-date information on IEC standards that are recognized.

Summary

Effective June 1, 2012, if there is no particular standard applicable to the device, then IEC 60601-1:2005 and its applicable collateral standards [that is (i.e.) IEC 60601-1-X] should be used. If there is a particular standard applicable to the device, the most recent edition of that standard and its associated normative reference standards should be used. In this case, a three year transition period is applied from the date of publication of the particular standard.

For further information on the List of Recognized Standards, please contact:

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