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Update on National Implementations of IEC 60601-1: 2005

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Update on National Implementations of IEC 60601-1: 2005

European implementation process

On 6 February 2012, the European Notified Body organisation for medical devices (NB-MED) released the first official version (version 1.1) of its frequently-asked-questions document[1] on the implementation of EN 60601-1: 2006 with respect to Directive 93/42/EEC, as amended (the Medical Device Directive, MDD). The NB-MED document is primarily written for the MDD but also applies to Directive 90/385/EEC (the Active Implantable Medical Device Directive, AIMD Directive). The document does not deal with Directive 98/79/EC as clause 1.1 of EN 60601-1: 2006 states that *in vitro* diagnostic equipment that does not fall within the definition of medical electrical equipment is covered by the EN 61010 series.

The NB-MED document is primarily concerned with clarifying the implementation of the third edition of EN 60601-1 and its family of standards. It intends to provide guidance on mostly non-technical issues for the application of the standard.

A previous frequently-asked-questions document on the subject had been published by CENELEC[2]. However, some European Notified Bodies have not been giving advice in line with the CENELEC guidance, and additional questions have been raised that are not covered by this earlier guidance document.

It is expected that the NB-MED document will be revised again but when that will happen is not clear. Once Amendment 1 (A1) to EN/IEC 60601-1: 2006/2005 is published

approximately at the end of 2012/September 2012 respectively it is assumed that there will be more implementation questions that need addressing.

The NB-MED document contains useful information on specific implementation issues and may help the reader understand the intricacies of some of the situations involving the implementation of EN 60601-1 with respect to the MDD and the AIMD Directive. This document may also be of help to many other national medical device regulatory agencies around the world that are transitioning to the third edition of IEC 60601-1: 2005 (or their national version of the standard) in their development of similar guidance documents.

Transition periods

There are only four countries/regions that have officially announced that it is possible to use either the second or third edition of IEC 60601-1, or the national equivalent. They are the European Union (EU), Canada, the USA and Brazil. All other countries currently using the second edition of IEC 60601-1, or their national version, have not provided transition period announcements as yet. It is expected that in the next year or two several Asian countries will announce their transition plans officially; this expectation is based on some countries waiting for Amendment 1 (A1) of IEC 60601-1: 2005 to be published later this year.

For both the EU and Canada, many manufacturers are assuming that the end of the transition period is 1 June 2012 but that is only the case if no Particular standard applies to the product. So, for medical devices that have no Particular standard associated with them, the third edition of EN 60601-1 becomes mandatory on 1 June 2012 to show presumption of conformity with the state-of-the-art. Although manufacturers are not obliged to use a harmonised standard, they would still have to show that their products are state-of-the-art in comparison to EN 60601-1: 2006. This is a high bar and the burden of proof falls on the manufacturer to demonstrate to the Notified Body that the product meets the equivalent requirements of EN 60601-1: 2006 (if the device is Class IIa, IIb, III or Class I with a measuring function if the measuring function is electrically based). All Class I products would still have to meet the requirements covered by the harmonised standards but this equivalency may not need to be demonstrated to a Notified Body as they are not involved in the approval of Class I products, unless the devices are sterile or have a measuring function.

If a Particular harmonised standard of EN 60601 applies to a product, that Particular standard becomes the determining factor for the transition period instead of the general standard EN 60601-1: 2006. If there are multiple Particular standards that apply to the device, one should use the Particular standard with the latest publication date as the determining factor. Some Particular standards' transition periods have already ended (e.g. EN 60601-2-37: 2008, *Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*). Other standards have another year or more to transition. Then there are the more recently-published Particular standards such as EN 80601-2-58: 2009, *Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery* (first edition), which was developed based on the third edition of IEC 60601-1. Section 3.6.1 of the NB-MED

document deals with new standards; these do not have transition periods as there is nothing to transition from/to. It is interesting to note that initially the USA and the EU handled this situation in the same way: the standard became mandatory as soon as it was published in the national regulatory standards' listings. Now, the NB-MED document is *recommending* that Notified Bodies accommodate an adoption period of three years after the date of ratification of the EN (that date is found on the CENELEC website for the specific standard).

As an example, several companies using EN 80601-2-58: 2009 have experienced problems with implementation as the date of ratification for the standard was 1 February 2009 and the actual date of publication was nine months later (i.e. 1 November 2009). This type of time lag impacts manufacturers as many are not aware of new standards as they are being developed. Under the NB-MED document, the transition date for this standard would be recommended as 1 February 2012 but that date is before the NB-MED document was even published and it is before the general standard transition period of 1 June 2012. This is one of the areas where there is likely to be varying interpretations by the Notified Bodies, which may be dictated by the amount of pressure manufacturers put on their Notified Bodies.

It is evident that the use of Particular harmonised standards is causing a lot of confusion among manufacturers, and a large portion of the NB-MED document deals with various scenarios involving Particular standards. One of the confusing points of the EU system to many US device companies is that in the USA and Canada you do not normally have to keep the regulatory submission of a previously-cleared medical device up-to-date (except when the product goes through a significant change, as defined by the US Food and Drug Administration (FDA) and Health Canada), but for the EU that is mandatory according to Essential Requirement 2 of the MDD. This means as new standards or revisions of standards are harmonised under the specific Medical Devices Directives, compliance with them becomes necessary for cleared products that are CE marked under the MDD or AIMD Directive where the presumption of conformity is based on the use of harmonised standards. In reality this tends to be most, if not all, cleared devices as it is hard for a manufacturer to show conformance with the Essential Requirements without using harmonised standards, even though it is not a mandatory requirement.

Table 1 (overleaf) lists the table of contents of the NB-MED document, along with a summary of some of the specific issues covered by each section.

Canadian implementation process

On 22 March 2012, Health Canada issued *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*[3]. On the Health Canada website it is dated 12 April 2012, the date it was posted on the site. This document is much simpler and more straightforward, in some respects, than the European NB-MED document. Currently, Health Canada recognises both the second and third editions of IEC 60601-1. Prior to this notification to manufacturers, after 1 June 2012 Health Canada would only have accepted the third edition of IEC 60601-1, with its related Collateral

Table 1. Table of contents of the NB-MED document

Number	Topic	Specific issues addressed
	History	
	Table of contents	
1.	Introduction	
2.	Abbreviations	
3.	Questions and answers	
3.1.	Process how to place products on the EU market	• Explains 'placing medical device on the market' in the EU. • Is it necessary to retest to third edition of EN 60601-1 when a product has been on the market for years? • Does a transition date of 1 June 2012 apply when an EC certificate has a 2014 expiration date? • Does a product in a distribution centre equal 'placed on the market'? • If a piece of medical electrical equipment, which met the second edition, breaks down after the transition period, what standard applies for the replacement? • Why does the EU require third edition compliance for new and legacy products?
3.2.	Transition process in general	• Is use of the newest harmonised standards required after the transition dates even if the product has not changed? • Would it have been better to have all the standards in the 60601 series have the same transition period? • Are there enough test house resources (e.g. expertise, laboratory space, test equipment) for all the testing that will be required by the EN 60601-1: 2006 deadline of 1 June 2012 (for only third edition without Particular standards)?
3.3.	Application of EN 60601-1	• Does EN 60601-1: 2006 apply to AIMDs? • Are the mechanical requirements of the third edition applicable to non-active products? • Answers a number of specific power supply questions. • How to manage applications in several countries where the other countries require the second edition but the EU requires the third edition.

		• EN 62304 in relation to third edition of EN 60601-1. • Software development issues. • If for some reason a major re-design is needed to meet the third edition, are there smart ways to deal with this? • How to obtain a test protocol Test Report Form (TRF) version G of the third edition. • Is there a third edition delta list available for evaluation of an approved second edition product?
3.4.	Role of Collateral standards	• Are harmonised standards binding? • What happens to Collateral standards (i.e. EN 60601-1-XX) that have been integrated into the third edition of EN 60601-1? • How to deal with Collateral standards that do not have an edition aligned with the second edition of EN 60601-1 (e.g. EN 60601-1-11 and 60601-1-12).
3.5.	Role of Particular standards (multiple or late Particulars)	• A discussion on the multiple standards related to x-ray equipment. • If x-ray equipment has interventional and non-interventional procedures, do both EN 60601-2-43 and 60601-2-54 apply? • Some Particular standards do not reference the third edition of 60601-1, so what happens then? • Is compliance with the third edition required after 1 June 2012 even if a Part 2 standard will not be released until after the transition period? • How to deal with EN 13544-1: 2007 + A1: 2009, which is aligned with the second edition of EN 60601-1 and currently there is no development of a second edition of EN 13544-1. • Can every kind of IEC or ISO standard act as a Particular standard?
3.6.	Transition period of EN 60601-1: 2006	• Particular standards with a transition period ending after 1 June 2012. • Is a transition date known for EN 60601-2-49? • Transition issues with EN 60601-2-43. • How to deal with EN 60601-2-2 and 60601-2-10, which have different transition dates.
3.7.	Duties of Notified Bodies	• Is the ZLG (German Central Authority of the Federal States for Health Protection

		with regard to Medicinal Products and Medical Devices) paper 3.5 A1 legally binding for Notified Bodies and medical electrical equipment manufacturers? • Process for a Notified Body audit of a technical file or design dossier of a product that has not started the process, or where set-up has been planned but testing has not started, or testing has been partially started.
3.8.	Application of risk management	• What are the different roles of the applicable stakeholders in this process, including the manufacturer, the Notified Body, the test house, etc? • Explanation of equivalent safety (clause 4.5 of 60601-1 third edition). • How to deal with the differences between EN 14971: 2001 (equivalent to ISO 14971: 2000) and EN 14971: 2007. • Mapping revision G of TRF for IEC 60601-1: 2005 with risk management documentation that is required for EN 60601-1: 2006.
3.9.	Amendment 1 related questions	
4.	References	
5.	Recommendation for usage	
Annex 1	Applicability of horizontal and role of Particular standards (multiple or late Particulars) for use in combination with IEC/EN 60601-1, third edition with respect to x-ray equipment	
Annex 1, 1.	General – applicability of standards	
Annex 1, 2.	Categorization of x-ray equipment related to its intended use and applicable standards (status 20 January 2012)	
Annex 1, 3.	Summary	

standards (i.e. IEC 60601-1-XX) and related Particular standards (i.e. IEC 60601-2-XX) that are aligned with the third edition. As discussed earlier, this approach would not have worked well as there are some Particular standards that are not aligned with the third edition yet, or that have only recently been published by the IEC (in the last year or so). Therefore, many manufacturers will not have had the time and/or resources to understand the requirements, do any re-design work, update their labelling, update their risk management file, prepare the product for testing (including gathering all appropriate information to support the testing), and then test the product to show (hopefully) that the product complies with all the requirements of the third edition of IEC 60601-1 and the applicable Collateral and Particular standards.

The recent Health Canada guidance document sets out the following transition rules to be applied from 1 June 2012:

- If there is no 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(s) that is directly applicable to the device and the version that aligns with IEC 60601-1: 2005 was published by the International Electrotechnical Commission (IEC) *before* 1 June 2009, then the device should conform to IEC 60601-1: 2005 and its applicable Collateral standards in addition to the Particular standard(s). If there are multiple Particular standards that apply to the device, one should use the Particular standard with the latest publication date to make the necessary applicability determinations.
- If there is a Particular standard(s) that is directly applicable to the device and the version that aligns with IEC 60601-1: 2005 was published by the IEC *after* 1 June 2009, a three-year transition period from the date of publication by the IEC will apply. If there are multiple Particular standards that apply to the device, one should use the Particular standard with the latest publication date to make the necessary applicability determinations. During this transition, Health Canada will accept conformity to both editions and related Collateral standards (and both will be listed in Health Canada's *List of Recognized Standards*).

These transition rules will not be applied retroactively. Therefore, any existing Health Canada Medical Device Licences that use the second edition of IEC 60601-1 will not require testing to the third edition unless there is a significant change to the product as defined in the *Guidance for the Interpretation of Significant Change of a Medical Device*[4]. Health Canada does not require a product to meet the state-of-the-art in the same sense as the European legislation, so a manufacturer need only apply to Health Canada when it has a new medical device that requires a licence or the manufacturer has to amend a device licence because of a significant change to the product.

Before 1 June 2012, it will still be possible to apply for a Medical Device Licence from Health Canada for a product that meets the second edition of IEC 60601-1; however, the licence submission will need to be lodged with Health Canada prior to 1 June 2012.

Standards are voluntary under the Canadian *Medical Devices Regulations*, so any test data obtained to the second edition of IEC 60601-1 and its applicable Particular and Collateral standards can still be submitted to Health Canada after the transition date of 1 June 2012. A manufacturer would have to provide a summary of the differences in the testing compared to IEC 60601-1: 2005, applicable Collateral and Particular standards, and provide a rationale to demonstrate that these differences do not affect the validity of the testing in demonstrating the device's safety and effectiveness. This is no small task because, as mentioned in the previous section, the burden of proof is a high bar.

The Canadian guidance also discusses an important distinction in relation to IEC 60601-1-6: 2010 (third edition). The guidance states:

> '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'.

The guidance document does state that Health Canada reserves the right to require additional testing deemed necessary to demonstrate safety and effectiveness of any device. Another very important note is stated near the end of the document which says:

> 'A Medical Device Licence issued by Health Canada provides authorization to import or sell a medical device in Canada and is evidence that the device meets the requirements of the *Medical Devices Regulations*. Manufacturers are reminded that Provincial or Territorial electrical safety requirements are separate and distinct from the requirements of the Regulations. For further information regarding these requirements, contact the applicable regulatory authorities. A listing of some such authorities is available at: http://www.csa.ca/cm/ca/en/community/electrical/regulators'.

The guidance mentions that the Health Canada website should be consulted for the most current *List of Recognized Standards*[5]. It should be noted that there are standards that have been published by the IEC that are not on this list, such as the fairly new standard IEC 60601-1-11: 2010 on the home-use environment for electromedical devices. Communications with Health Canada about this specific standard have indicated that since this standard is not on the *List of Recognized Standards*, providing a Declaration of Conformity to this standard would not be appropriate. Separate from this Declaration of Conformity you would not want to preclude an applicant from submitting test data for this standard, if it is applicable to supporting the submission.

US implementation process

The US transition period will end on 30 June 2013 and after this date the second edition of IEC 60601-1, with its national deviations, will not be accepted by the FDA for regulatory submissions. No guidance document or notification has been issued to date so the issue of what to do when a third edition aligned Particular standard has not been released, among many other implementation issues, is still to be answered. There has been work on a guidance document related to the risk management process specifically with respect to the third edition of IEC 60601-1, but it has not been released to date. It is unclear when, and if, that document will ever be released.

There have been no third-party test houses approved by the Occupational Safety & Health Administration (OSHA) as a Nationally Recognized Testing Laboratory (NRTL) for medical electrical devices to issue the NRTL safety mark for IEC 60601-1: 2005 or ANSI/AAMI ES 60601-1: 2005 (US national version of IEC 60601-1: 2005). There have been multiple

test houses that have requested this approval but the OSHA has not moved forward on this standard as of yet. The OSHA is still trying to work out how to deal with a standard like ANSI/AAMI ES 60601-1: 2005 where the manufacturer is involved in the test process because a significant portion of the standard compliance is determined by use of the manufacturer's risk management process and risk management file which the manufacturer needs to provide the objective evidence to the test laboratory.

Brazilian implementation process

Brazil has detailed its transition period and which versions of its national standard for 60601-1 will apply in the Annex to Normative Instruction IN No 3 of 21 June 2011[6]. The transition period started on 1 January 2012 and will end on 1 January 2014. During this transition period it is possible to use either ABNT NBR IEC 60601-1: 1997 (Brazilian first edition equivalent to IEC 60601-1, second edition) or ABNT NBR IEC 60601-1: 2010 (Brazilian second edition equivalent to IEC 60601-1, third edition). At the end of this transition period only ABNT NBR IEC 60601-1: 2010 will be valid. If a product has been tested to the third edition of IEC 60601-1: 2005 through a testing laboratory accredited by the International Laboratory Accreditation Cooperation, the InterAmerican Accreditation Cooperation or the European co-operation for Accreditation, and the laboratory fulfils all requirements of Ordinance No 350 from the National Institute of Metrology, Quality and Technology (Inmetro), then this should be acceptable to the National Health Surveillance Agency (Anvisa).

In addition to the general standard 60601-1 (either the ABNT NBR IEC or the IEC versions), the applicable Collateral(s) and Particular(s) to the specific medical device will also need to be met. As with the other countries discussed above, the Collateral and Particular standards that apply to a device will need to be aligned with the appropriate version of the general standard 60601-1. Currently there are talks between Anvisa and industry to make this clear. Until these discussions are completed and hopefully resolved, it is not clear how this information will be communicated.

Summary

It is clear that each country or region has its own way of dealing with the implementation of IEC 60601-1: 2005 (third edition) or the applicable national version. One reason why each country's implementation process is different, for the same basic standard, is because of how standards are dealt with when it comes to obtaining an approval from the national regulatory body. It is therefore necessary to become familiar with each country's implementation process for IEC 60601-1: 2005 to be able to get clearance in the countries where a product will be submitted for regulatory approval.

Over time there will be more countries that will accept the third edition but it could be many years before the third edition is global in nature. So, if a product is certified to the second edition by a third-party test house, it is highly recommended that certification to the second edition is maintained in addition to obtaining certification to the third edition, if applicable to the national scheme of concern.

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