# Everything you needed to know about who's doing what where with IEC 60601-1 – Part 1

The IEC 60601-1 standard on medical electric equipment is a critical tool for many medical technology companies. In this article, the first in a series, ***Leo Eisner*** introduces the standard and shares how it is being used in the US and Canada.

This is the first in a series of articles by the author on IEC 60601-1, 2nd, 3rd & ed. 3.1*, the key international standard covering medical electrical equipment. The series is designed to help companies understand which countries require which versions of the standard at this time and into the future so they can determine a good regulatory strategy for their medical electrical equipment. This first article examines how the standard is being used in the US and Canada. Additional articles will cover the EU, Japan, China, Taiwan, South Korea, Singapore, India, and Brazil.

The IEC 60601-1 standard[1] applies for most medical electrical equipment, but I like to confirm this on a case by case basis before I dive too far into a project and standard(s). First of all, therefore, I review the scope of the standard(s) against the intended use of the medical device to determine whether we have the proper standard(s) to start with.

It is critical to check that the scope (see subclause 1.1**) of the standard does truly apply. For example, not all electrical equipment used in medical practice falls within the definition used in the standard (some in vitro diagnostic equipment does not). Also, while the implantable parts of active implantable medical devices can fall within the definition, they are excluded from the scope of this standard.

Even where a product does not meet the definition of medical electrical equipment, national regulatory bodies (for the purposes of this article the US Food and Drug Administration or Health Canada) still sometimes ask the manufacturer to provide 60601-1 test data. The best advice here is that companies talk to their test houses. If a company requests to meet IEC 60601-1, test houses in most cases can issue some type of test report although they will not be able to issue a CB Scheme*** test report and a CB Scheme test certificate. Also, the test lab will not be able to issue you a Nationally Recognized Test Laboratory certification mark or related test report (the NRTL program is covered in detail in the US section of this article). The CB Scheme system and the NRTL program do not allow certificates to be issued for devices that do not fall under the scope of the standard.

## The US

In the US, there are two different organizations that rely on the US national version of the IEC 60601-1 standard, plus an additional organization that is the issuer of the American national standard.

The Food and Drug Administration, as the US medical device regulator, currently allows for either ANSI/AAMI ES60601-1:2005/(R)2012, C1:2009/(R)2012, A2:2010/(R)2012 or ANSI/AAMI ES60601-1:2005/(R)2012, A1:2012, C1:2009/(R)2012, A2:2010/(R)2012 for regulatory submissions for approval to sell medical devices in the US marketplace.

The former – ANSI/AAMI ES 60601-1 (3rd ed for short) – is an American national standard that is the equivalent of IEC 60601-1, 3rd edition + US national deviations. The latter – ANSI/AAMI ES 60601-1 (ed. 3.1. for short) – is an American national standard that is equivalent to IEC 60601-1, edition 3.1 + US national deviations.

These standards are recognized consensus standards under the FDA. You can use the ANSI/AAMI ES 60601-1, 3rd ed. version of the standard until 1 August 2016, after which only the ANSI/AAMI ES 60601-1, ed. 3.1 version will be the applicable recognized consensus standard. Note, though, if your device falls under the definition of home use as per the FDA final guidance document for devices intended for home use[2], last updated in November 2014, it is highly recommended that you use the most recent version of the standard, ie the ANSI/AAMI ES 60601-1, ed. 3.1 version.

Recognized consensus standards are voluntary so use of them, while helpful, is not mandated. The FDA issued a final guidance document on 17 September 2007 to explain the process for the "Recognition and Use of Consensus Standards"[3]. I have heard from an FDA associate who just recently left the agency that use of recognized consensus standards eases the path through a submission. This means that you will have less resistance from the reviewers than if you use standard(s) that are not recognized consensus standards. On occasion, however, it may make sense to use something other than a recognized consensus standard or standards to prove your device meets the requirements.

The other US agency that is concerned with AAMI ES 60601-1 is the Occupational Safety & Health Administration, under its NRTL program.

OSHA only very recently approved the ANSI/ AAMI ES 60601-1, ed. 3.1 standard for its NRTL program and in the past nine months it has approved eight NRTL labs[4] for this standard.

The reason OSHA has been so slow to get the medical standard updated from UL 60601-1 (2nd edition US national version of IEC 60601-1) to the AAM ES 60601-1 standard is that OSHA never believed that the US national version of IEC 60601-1, 3rd ed. was sufficient to meet the requirements of the OSHA NRTL program requirements. It was only when the Amendment 1 was approved and then adopted as a US national standard that OSHA started the process to add the standard to its list of NRTL approved standards. After this OSHA had to go through the process of the labs applying to OSHA for them to be added to the NRTL program for this standard, which only started getting finalized late in 2014 after a two-announcement process through the *Federal Register*.

It is worth noting that OSHA has not yet withdrawn the UL 60601-1 standard as an American national standard; it will probably not be withdrawn for quite some time as there is no indication that the US national 2nd ed. of IEC 60601-1 (UL 60601-1) will be withdrawn until there is more of an impetus to do so.

When clients come to US test labs, those labs may often by default use the US national version of the standard being requested. Since many countries are still not requiring 3rd ed., the US test lab may opt to use UL 60601-1 if that fits the client's needs. A lot of North American tests labs when doing safety certification projects will issue a US national version and Canadian national version of the test report for the same cost as just one of those; many clients opt for that.

There is not yet much of a push to drop UL 60601-1. Indeed it is unlikely to disappear anytime soon because the UL standard is not being phased out by OSHA and only the FDA so far has phased it out already. Also, Underwriters Laboratories, the developers of UL 60601-1, do not control the 3rd ed. of the US national standard. It seems, therefore, that UL is in no rush to withdraw the 2nd edition.

AAMI now is the standards development organization (SDO) that is in control of drafting the US national version of IEC 60601-1, 3rd ed & edition 3.1. ANSI is the organization that controls what standards become American national standards, and the AAMI US national versions of IEC 60601-1 are ANSI/AAMI standards. ANSI does not publish any standards itself but works with SDOs to accredit those organizations for publication of American national standards.

### Buyer beware

One important point about what national version of the standard is used is that a third-party test house can use whatever national version of the standard or multiple national versions the manufacturer or client asks the test lab to conduct testing to. There is a wide variety of test labs out there, from the better known labs such as UL, CSA (Canadian Standards Association), TÜV SÜD, Nemko, etc, to the lesser known independent labs.

Sometimes the client does not know well enough and so they ask the test lab to tell them what will be best for their product. Some of the better labs will steer you in the proper direction but there are labs that really should not be doing medical device testing. Some, for example, are not fully up to speed on the standard(s) and have caused some of my clients (they became my client after they got a negative report from their notified body or regulator) severe harm. In one case, the client lost more than six months and it took hundreds of hours of my time trying to figure out what part of the testing by the under-par lab was useful and what testing was missing and had to be re-conducted to be able to meet the EU essential requirements checklist and a notified body's review of the client's technical file.

I have seen this multiple times in my 18 years as a consultant so companies need to be very careful over which test lab they choose. They should not skimp on testing for a regulatory submission, as a poor selection can cause more harm than it is worth; having to remedy a poor submission may result in a company not making it to market before it runs out of funding.

## Canada

As with the US, Canada has several different organizations that rely on the Canadian national version of the IEC 60601-1 standard.

The medical device regulator is Health Canada while the Standards Council of Canada is the organization that controls the issuance of the standard itself, like ANSI in the US.

As with the FDA, Health Canada has a guidance document[5] for use with recognized standards. Again as in the US, these standards are voluntary, but Health Canada's guidance states specifically that:

*If a standard is recognized, a manufacturer applying for a licence for a device to which that standard applies must either:*
*a) meet the standard; or*
*b) meet an equivalent or better standard; or*
*c) provide alternative evidence of safety or efficacy*
*In case the manufacturer chooses option (b) or (c), detailed information must be submitted with the device licence application. If the manufacturer does none of the above, a licence will not be issued.*

The latest Health Canada list of recognized standards was issued on 26 September 2014[6] and includes IEC 60601-1, 2nd & 3rd ed. but not yet edition 3.1. It also has the Canadian national version CSA C22.2 No. 60601-1-08, which is the Canadian national version of IEC 60601-1, 3rd ed. + the Canadian national deviations. Also, it is important to be aware of an "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"[7] dated 31 July 2012.

Health Canada has gone back and forth on compliance with the 3rd ed. several times. Officially it wanted all medical device submissions to meet 3rd ed. of IEC 60601-1 or the Canadian equivalent by 1 June 2012. It realized, however, that this would not happen because of the lag with particular standards (IEC 60601-2-XX standards) being aligned with the general standards IEC 60601-1, 3rd edition. It therefore issued the above guidance and in summary said the following:

*Transition Rules to be applied as of June 1, 2012*
1. *If there is not a particular standard that is directly applicable to the device, it should conform to IEC 60601-1:2005 [= 3rd ed. of IEC 60601-1 – Ed] and its applicable collateral standards.*
2. *If there is a particular standard [ie IEC 60601-2-xxx – Ed] 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 [ie IEC 60601-1-xx, like the EMC standards which is IEC 60601-1-2 – Ed] in addition to this particular standard.*
3. *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 [ie either IEC 60601-1, 2nd or 3rd – Ed] and related collateral standards (and both will be listed on Health Canada's List of Recognized Standards).*

### Things you need to know about IEC 60601-1

The general standard is the base of the series of 60601 based standards. There are "collateral" and "particular standards" in the series. A collateral standard is one that may be applicable to some or all medical electrical devices, and so is pretty broad based. The EMC (electromagnetic compatibility) standard (IEC 60601-1-2), for example, applies to all medical electrical equipment but there are other collateral standards that will only apply to a subset of all medical electrical equipment, such as the home use environment medical electrical equipment standard, IEC 60601-1-11. A particular standard in this series applies to a specific type of medical electrical device such as a high frequency surgical device, which is controlled under IEC 60601-2-2. Another example is the endoscopic equipment standard, which is IEC 60601-2-18. There are approximately 70 standards and technical reports (guidance documents) in the 60601 series of standards, and the list continues to grow. This includes the joint ISO IEC projects which are numbered starting with 80601.

The 3rd edition of the standard took over 10 years to get published and still it was rushed out the door near the end of the process. The normal timeline of a typical IEC project is three years; five years is a long time. That is one of the reasons there were so many changes between the 3rd ed. and edition 3.1. Also, 3rd ed. had some major issues that were hard to understand, including the essential performance and risk management file requirements and processes.

It may seem strange but the use of the asterisk in the IEC 60601 series of standards – just after the clause or subclause number – is very helpful indeed. It means that there is "guidance" and "rationale" in the back of the applicable standard; this can be informative and may explain the requirement better than what is in the "normative", ie required, part of the standard.

Under Edition 3.1, the standard has been updated to clarify many issues within 3rd ed. of IEC 60601-1. Amendment 1 included a massive 496 different changes to the standard; only about 70 were considered major to moderate changes and the rest were mostly clarifications. Some of the significant changes included the changes to essential performance, risk management file requirements and processes, humidity preconditioning, and mechanical tests such as instability tests. Readers wishing to see a summary of the major and moderate changes to the standard may want to obtain a copy of IEC/TR 62348:2012, 2nd ed. (this is a technical report or guidance that explains to users the changes and the impact of the changes). IEC 60601-1, 3rd ed. + A1 is much clearer and easier to use than 3rd ed.



 

SCC on the other hand has withdrawn the Canadian national versions of 2nd & 3rd ed. equivalent standards and only the consolidated edition 3.1 is still active under the SCC. That means that CAN/CSA-C22.2 No.601.1-M90 (R2005) (the equivalent of IEC 60601-1, 2nd ed. + Canadian national deviations) and CAN CSA C22.2 No. 60601-1-08 (the equivalent of IEC 60601-1, 3rd ed. + Canadian national deviations) are both withdrawn from the SCC perspective but Health Canada is still considering these standards for regulatory approvals.

The only active standard under SCC for IEC 60601-1 is CAN/CSA C22.2 No. 60601-1-14 (= ed. 3.1). This shows that the publication and release of standards and the regulatory processes are rarely in synch with each other; this can cause even more confusion to those that have to submit products for regulatory approvals. This is especially true of manufacturers that do not have the full regulatory background needed to do such a task. Just as it takes a team of experts to put a 510(k) or any other regulatory submission together, companies need to have a similar perspective when it comes to making sure they have the proper team together to identify the proper standards that will get them to the goal line and also to look at their long-term strategy so they can control their test costs too.

**This article is based on the standard IEC 60601-1, 3rd ed. and on IEC 60601-1, 3rd ed. + Amendment 1 (= A1 or also called the consolidated edition 3.1). The title of the 3rd edition is "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance". The title of the standard changed from 2nd ed. to 3rd ed. with the addition of ESSENTIAL PERFORMANCE to the title in 3rd edition as the concept of ESSENTIAL PERFORMANCE was added to the document.*

***This clause references to both IEC 60601-1, 3rd ed. or ed. 3.1.*

**** The CB Scheme run by the IECEE (IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components) is the world's first truly international system for mutual acceptance of test reports and certificates dealing with the safety of electrical and electronic components, equipment and products. It is a multilateral agreement among participating countries and certification organizations. A manufacturer utilizing a CB test certificate issued by one of the accepted national certification bodies (NCBs) can obtain certification marks of the latter, within their scope of adherence, in the countries where the accepted NCBs are located.*

*The scheme is essentially based on the use of international (IEC) standards. If some members' national standards are not yet completely harmonized with IEC standards, national differences, special national conditions (SNCs) and regulatory requirements are permitted subject to formally declaring and detailing them to the IECEE secretariat for further publication. The CB scheme utilizes CB test certificates to attest that product samples have successfully passed the test conditions and are in compliance with the requirements of the relevant IEC standard(s). When applicable, the CB test certificate and its associated test report can also include declared national differences, SNCs and regulatory requirements of various member countries.*

*The main objective of the scheme is to facilitate trade by promoting harmonization of the national standards with international standards and co-operation among accepted NCBs worldwide in order to bring product manufacturers a step closer to the ideal concept of 'one product, one test, one mark, where applicable'. Source: http://www.iecee.org/cbscheme/cbfunct.pdf.*

*I do not recommend in many cases that my clients pay the additional money for the CB scheme certificate. I do ask them to get a CB scheme formatted report because the regulatory agencies and the majority of test houses are used to reading reports in the CB scheme style format.*

**References**


1. *See https://webstore.iec.ch/preview/info_iec60601-1%7Bed3.0%7Den_d.pdf & https://webstore.iec.ch/publication/2612*
2. *FDA final guidance, Design Considerations for Devices Intended for Home Use, updated 24 November 2014*
3. *FDA final guidance, Recognition and Use of Consensus Standards, 17 September 2007. See also the newer FDA draft guidance, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, 13 May 2014*
4. *Current OSHA NRTL Labs, https://www.osha.gov/dts/otpca/nrtl/nrtllist.html*
5. *Health Canada guidance, Recognition and Use of Standards under the Medical Devices Regulations, Revised date: 11 September 2006; Effective date: 11 September 2006*
6. *Health Canada List of Recognized Standards for Medical Devices, 26 September 2014*
7. *Notice – 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, 31 July 2012*


**Leonard (Leo) Eisner** is principal consultant at Eisner Safety Consultants, a network of consultants headquartered in Portland, Oregon (US) that provides support to medical device companies on US, Canadian, European and other international regulations, and provides support for product safety, risk management, quality systems, and regulatory submissions. He is heavily involved in the development of IEC standards as a member of several of the US National Committees for Medical Electrical Equipment and Home Use Medical Devices. Email: Leo@EisnerSafety.com.