



**The use of IEC 60601-1 in supporting approvals
of medical electrical devices and the role of the
new collateral standard IEC 60601-1-9**

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1 Introduction

The International Standard IEC 60601-1 has become the global benchmark for medical electrical equipment. Compliance with the IEC 60601-1 International Standard and/or the relevant national version does not equal medical device approval. However, it is a recognized step towards medical device approval in nearly all markets across the world. As a result, many companies view compliance with IEC 60601-1 as a *de facto* requirement in most markets for: product registration; “CE” “UL” “CSA” marking; contract tenders; defense against claims in the event of problems; etc.

The 3rd edition of IEC 60601-1 was published in 2005 and has already been adopted as a new national standard in the US and as a new European standard in Europe. The biggest upgrade in the 3rd edition is that Clause 4.2 requires a manufacturer to have formal risk management process in place which complies with ISO 14971. The next biggest change is the introduction of essential performance into the scope. Another change is that all collateral standards become a normative part of the parent standard IEC 60601-1 on the date of their publication. This is relevant to the new collateral standard IEC 60601-1-9 Environmentally Conscious Design of Medical Electrical Equipment which was published in July 2007.

This paper discusses:

- the adoption of the 2nd edition IEC 60601-1:1988 in national standards and the use of these standards to support approvals of medical electrical devices in the US, Europe, Canada, Japan, Australia and other countries;
- the need for companies to start using the 3rd edition IEC 60601-1:2005 and transition dates for certification to the new national standards in Europe, the US and other countries;
- the normative role of collateral standards in the 3rd edition IEC 60601-1:2005 with particular reference to the new collateral standard IEC 60601-1-9 Environmentally Conscious Design of Medical Electrical Equipment which was published in July 2007.

2 Adoption of 2nd edition IEC 60601-1:1988 in national standards

The role of the International Standard IEC 60601-1 in supporting approvals of medical electrical devices is underlined by the Global Harmonization Task Force which was established by the United States, Canada, Australia, Japan, and the European Union. The Global Harmonization Task Force recommends using IEC 60601-1 as the model for compliance approval processes for medical electrical equipment.

The 2nd edition International Standard IEC 60601-1 was published in 1988 and has been adopted as a national standard in the US, Canada, Japan and Australia/New Zealand, and as a European Standard in EU Member States, Table 1. IEC 60601-1 2nd edition, either as a national standard (such as JIS T0601-1 in Japan) or as the base standard itself (e.g. in Brazil), is accepted in nearly all markets for supporting regulatory registrations or approvals.

Table 1: Adoption of 2nd edition IEC 60601-1:1988 in national standards

Country	2nd edition IEC 60601-1:1988 adopted as
United States	UL 60601-1:2003 (US national deviations)
Canada	CAN/CSA C22.2 No. 601.1 (Canadian national deviations)
European Union	EN 60601-1:1990 (Identical to IEC 60601-1:1988); in UK, BS EN 60601-1:1990
Japan	JIS T0601-1 (Japanese national deviations)
Australia/New Zealand	AS/NZ 3200.1 (Australian and New Zealand national deviations)

2.1 United States

When the FDA launched its standards recognition program in 1998, the 2nd edition IEC 60601-1:1988 was one of the first standards listed. FDA recognizes IEC 60601-1 as a consensus standard with any amendments and with specific national alterations, such as UL 60601-1:2003 and the new ANSI/AAMI ES 60601-1:2005 standard.

Medical electrical equipment manufacturers in the US have the option either to:

- test to IEC 60601-1 or the US national equivalent by a Nationally Recognised Testing Laboratory, or;
- be subject to “field labeling”.

The FDA published a guidance document on the recognition and use of national and international consensus standards on 20 June 2001. Although the FDA guidance clearly states that compliance to IEC 60601-1 or the US national equivalent is not mandatory, it does highlight that “compliance with either of these standards may simplify the regulatory process”.

The FDA guidance goes on to explain that conformance with recognized consensus standards like IEC 60601-1 can provide a reasonable assurance of safety for many applicable aspects of a medical device and has direct bearing on safety determinations made during FDA's premarket application reviews. The premarket application process may include: premarket notification (510(k)), investigational device exemption (IDE) application, premarket approval (PMA) application, humanitarian device exemption (HDE) application, or product development protocol (PDP). With the use of a consensus standard, a submission can contain a declaration of conformity to that standard and eliminate the need to submit the bulk of test data for those aspects of the device addressed by said consensus standard. As a consensus standard, IEC 60601-1 also allows manufacturers of electromedical products to use the abbreviated 510(k) paradigm where appropriate¹.

2.2 Europe

The EC Medical Devices Directive (MDD; 93/42/EEC) declares EN 60601-1 (which is identical to IEC 60601-1) to be a harmonized standard. For products complying with EN 60601-1, this declaration gives a “presumption of conformity” to a large majority of the essential requirements of the Directive. Meeting the essential requirements is a major step toward receiving a CE mark for a device.

The MDD allow self-certification to the standard under a recognized quality system such as ISO 9001:1994 with ISO 13485:1996 (previously EN 46001). The evaluation is subject to review by a notified body as part of the technical file or design dossier review. A notified body may be required for testing of the manufacturer's medical device(s), certification of the manufacturer's quality system, or review of the technical file or design dossier for the medical device based on the classification of the product.

2.3 Canada

The Therapeutic Product Directorate of Health Canada is the Canadian approval agency and recognizes CAN/CSA C22.2 No. 601.1 as the regulatory compliance standard for electrical medical devices. Canada's approval system is similar to that of the EU. The major differences are the registration process, the classification system, the postmarket surveillance method, and the quality system standards used.

Four classes of medical electrical devices are recognized, and registration is required for Class II, III, and IV devices (Class IV being the highest-risk class). Importers, distributors, and manufacturers of Class I devices must get an establishment license.

The quality system requirements are ISO 13485 for Class III and IV devices, and ISO 13488 for Class II devices. A third-party auditing firm accredited by the TPD conducts the certification of the quality system. Class I devices do not require a quality system.

¹ A Primer for IEC 60601-1, Leonard Eisner, Robert M Brown, Dan Modi, MDDI Archive, September 2003.

2.4 Japan

The Ministry of Health, Labor and Welfare is the regulatory agency in Japan. JIS T0601-1 is recognized as the compliance standard to support registration of electro-medical products. The Japanese Association for the Advancement of Medical Equipment (JAAME) is a designated agency appointed by MHLW under the Pharmaceutical Affairs Law. Evaluation data from JAAME or a foreign equivalent organization (such as Underwriters Laboratories or TUV Product Service) based on the JIS T0601-1 standard are accepted in the medical device approval process. Medical devices requiring clinical studies for approval will also have data collected on the product for three years after the product is released, per the MHLW post-market safety assurance program.

2.5 Australia

The Therapeutic Goods Administration, a part of the Federal Department of Health and Ageing, is the regulatory agency in Australia. Medical devices go through a pre-market assessment and are assigned an AUST R number in the Australian Register of Therapeutic Goods, or ARTG. The ARTG is the computer database for therapeutic products approved for supply in or export from Australia.

Manufacturers of therapeutic goods must be licensed and their processes must be compliant with good manufacturing practices, or GMPs. Post-market surveillance of products includes investigation of failures, laboratory testing, and monitoring for compliance with legislation.

The use of standards to support regulatory approval and registration is voluntary, but the use of IEC 60601-1 or AS/NZ 3200.1 to support the electrical safety portion of an application has been acceptable in Australia for some years. The mutual recognition agreement (MRA) between Australia and the EU is finalized. This allows the TGA to permit some EU-notified bodies to assess products and companies in light of the Australian regulations.

2.6 Other Countries

The regulatory environment is growing in Pan-Asian and South American countries. Countries are adopting regulations for medical devices, or increasing the enforcement of regulations already on the books. Most of the countries are following the model of the GHTF. The GHTF model is similar to that of the EU, and gives importance to the recognized (international) standards for showing compliance to the essential principles of safety and performance/efficacy. Most of the countries that have established regulations (and enforce them), such as Korea, Brazil, and Argentina, recognize the IEC 60601-1 standard for showing compliance of electro-medical products to the general safety requirements of the relevant regulation.

3 Transition dates for adoption of 3rd edition IEC 60601-1:2005 in national standards

The 3rd edition of IEC 60601-1 was published in 2005 and has already been adopted as a new national standard in the US and as a new European standard in Europe. The 3rd edition of IEC 60601-1 will be adopted as a new national standard in Canada later this year, Table 2.

Table 2: Adoption of 3rd edition IEC 60601-1:2005 in national standards

Country	3rd edition IEC 60601-1:2005 adopted as:
United States	ANSI/AAMI ES 60601-1:2006 (US national deviations)
Canada	Update to CSA C22.2 No. 601.1 due imminently (Canadian national deviations)
European Union	EN 60601-1:2006 (Identical to IEC 60601-1:2005); in UK, BS EN 60601-1
Japan	Update to JIS T0601-1 due (Japanese national deviations)

Australia/New Zealand	Update to AS/NZ 3200.1 due (Australian and New Zealand national deviations)
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All national standards based on IEC 60601-1 are voluntary, however verifying that a medical device complies with IEC 60601-1 is the established method for documenting that a product has acceptable risk with respect to the hazards addressed by the standard. This makes the issue of when a company should start adopting the new version of a national standard quite tricky.

The need to start using the new national version of IEC 60601-1 depends on how the company is choosing to use the standard to support its regulatory registrations or approvals processes. Leading companies may choose to adopt the new national version of IEC 60601-1 at the earliest opportunity to gain competitive advantage with customers. Other companies may take the view that the marketing benefits of demonstrating early compliance with the new version are not sufficient to warrant early action.

Some national standards set transition dates after which new products can no longer be certified to the old standard. Transition periods also define how long existing products may continue to claim compliance with the old requirements before they must be re-certified to the new standard.

In Europe, EN 60601-1 (the European version of IEC 60601-1) is declared as a harmonized standard under the European Medical Devices Directive. This means that compliance with EN 60601-1 gives a "presumption of conformity" to the Medical Devices Directive. The significant role that the EN standard plays in Europe has resulted in a defined transition period which is written into the EN standard. The forward to EN 60601-1:2006 provides a transition date of September 2009 by which Medical Electrical Equipment manufacturers in Europe who wish to declare compliance to 60601-1 must have switched to using the new version EN 60601-1:2006. The transition date for equipment that falls under the scope of a Particular Standard is three years after the publication of the applicable Particular Standard.

In the United States the standards development organisation (SDO) that published the standard determines how to transition between revisions. For example, UL has repeatedly extended UL 544 and UL 187 (the old US medical standards before UL 2601-1 and UL 60601-1:2003). In July 2004 UL stated that it has extended the withdraw date for UL 544 and UL 187 to January 2010.

According to Medical Equipment Compliance Associates (<http://60601-1.com>), the transition date for the US and Canada will likely be an additional few years after Europe. This is based on speaking with people at the US Certification Agencies. The US Certification Agencies are still gearing up to be able to evaluate medical equipment compliance against the new AAMI ES 60601-1:2006 standard. The requirement for a risk management system in AAMI ES 60601-1:2006 requires Certification Agencies to establish a process which they can use to evaluate this requirement. This has caused Certification Agencies to move forward carefully (and slowly). In view of this, it is likely that the existing UL 60601-1:2003 and CSA C22.2 No. 601-1 will be around for a while yet.

4 Normative role of Collateral Standards in 3rd edition IEC 60601-1:2005

The relationship between the collateral standards and the parent standard 60601-1 in the IEC 60601 family was debated extensively during the development of the 3rd edition IEC 60601-1:2005. In 1995 Amendment 2 to the 2nd edition IEC 60601-1:1988 added sub clause 1.5, which described the kind of requirements that would be contained in a collateral standard and the relationship of the collaterals to the particular standards. However, it was ambiguous with respect to whether or not equipment must comply with any relevant collateral standard before it could be considered to comply with IEC 60601-1. Opinion on the question seemed fairly evenly divided.

In 2003, Subcommittee 62A formally considered this question and decided that, for the third edition, a collateral standard becomes a normative part of the parent standard on the date of its

publication². Accordingly the following clause 1.3 was included in the 3rd edition IEC 60601-1:2005 (underlining has been added).

1.3 Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for basic safety and essential performance applicable to:

a subgroup of medical electrical equipment (e.g. radiological equipment)

a specific characteristic of all medical electrical equipment not fully addressed in this standard

Applicable collateral standards become normative at the date of their publication and shall apply together with this standard.

NOTE 1 – When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards

NOTE 2 – When declaring compliance with IEC 60601-1, the declarer should specifically list the collateral standards that have been applied. This allows the reader of the declaration to understand which collateral standards were part of the evaluation.

NOTE 3 – Members of IEC maintain a register of valid International Standards. Users of this standard should consult this register to determine with collateral standards have been published.

If a collateral standard applies to medical electrical equipment for which a particular standard exists, then the particular standard takes priority over the collateral standard

Clause 1.3 has been included with no deviations in the European standard EN 60601-1:2006 and the US standard ANSI/AAMI ES 60601-1:2006.

As noted in the Journal of Medical Device Regulation, May 2006³ in effect Clause 1.3 allows for an unlimited number of amendments to add new general requirements to IEC 60601-1 because each new collateral standard becomes a normative part of IEC 60601-1 when published. This applies to the new collateral standard IEC 60601-1-9 Environmentally Conscious Design of Medical Electrical Equipment which was published in July 2007.

The forward to the EN 60601-1:2006 standard states that the transition date in the EU for equipment where there are no Particular Standards is September 2009. Hence a company that manufactures or sells medical electrical equipment in Europe and wishes to maintain its declaration of compliance with the parent standard EN 60601-1 must ensure that it is compliant with the new collateral standard IEC 60601-1-9 by September 2009. Of course, companies that wish to declare compliance with the new version EN 60601-1:2006 in advance of the September 2009 deadline (e.g. to gain competitive advantage by demonstrating early compliance to their customers) must ensure that they are in compliance with the new collateral standard IEC 60601-1-9 earlier than this.

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² Technical Report IEC TR 62296 Considerations of unaddressed safety aspects in the Second Edition of IEC 60601-1 and proposals for new requirements, IEC March 2003.

³ IEC 60601-1 The Third Edition, Charles Sidebottom, Harvey Rudolph, Michael Schmidt and Leo Eisner, Journal of Medical Device Regulation, May 2006