

A draft White Paper from O'Brien Compliance Management

Feedback and any corrections are welcome

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When Should I Design to IEC 60601-1, 3rd Edition?

1. Introduction

IEC 60601-1 is the international basic safety and essential performance standard for electrical medical equipment. The current 2nd edition is IEC 60601-1: 1988 + A1:1991 + A2:1995. In December 2005 a new 3rd edition was publishedⁱ. Many manufacturers are trying to determine when is the required time, and if not required, the optimal time, to start designing to the new edition. Related to choosing an optimal time, what are the impact of the changes? There's no simple answer but let's look at the basic question from a number of angles.

2. Who requires compliance?

Strictly speaking regulatory requirements (mandatory legal requirements) usually don't explicitly require compliance with a product safety standard, but rather regulations typically require an acceptable level of risk that your product will cause injury or property damage, (acceptably small risk of harm).

In the US, medical device manufacturers are regulated by FDA. Whether your device requires a PMA, a 510(k), or is exempt, you're required to have a quality system in compliance with Quality System Regulation (QSR), 21 CFR Part 820. Your quality system will need to include design controls, including verification that your device is "safe and effective". FDA publishes a list of recognized consensus standards, and states, "conformance with recognized consensus standards can provide a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices"ⁱⁱ. OSHA (Occupational Safety and Health Administration), requires NRTL "Listed" equipment in the work placeⁱⁱⁱ. The NRTL program requires compliance to standards similar to the FDA list. NRTL certification organizations include UL, ETL, MET, TUV, CSA, others. Depending on the State, City, or Country authority there may be similar "Listing" requirements.

In Europe, which is similar to most other global markets, regulators require a medical device to comply with high-level "essential requirements" (or referred to by GHTF (Global Harmonization Task Force) as "essential principals of safety and performance"^{iv}). A list of European standards harmonized to the essential requirements is provided. A manufacturer can presume compliance with essential requirements by complying with applicable harmonized standards. (Similarly, IEC standards can be used to presume compliance with the essential principals of safety and performance). This is written into the

Medical Device Directives^v. Europe also has a voluntary (market driven) 3rd party certification program, whereby test laboratories, such as VDE, TUV, KEMA, SEMKO, DEMKO, NEMKO, BSI, IMQ, etc will certify your product to a CENELEC safety standard, to help with customer acceptance.

With this as background, verifying your medical device complies with IEC 60601-1 is the established method for documenting that your product has acceptable risk with respect to the hazards addressed by the standard.

3. Transition Dates

3.1.DOP, DOW

In the world of standards there are 2 key dates for understanding when a standard is in transition. The date of publication (dop) of the new standard, and the date of withdrawal (dow) of the old standard. The first date establishes the start of the transition, during which compliance with either standards is acceptable. The second date establishes the end date by which time compliance with only the new standard is allowed. These dates are formally established by standards bodies which sometimes do not have direct jurisdictional authority, such as CENELEC (Europe), AAMI (US), UL (US), and CSA (Canada), among many others.

Looking first at these standards bodies, CENELEC has published EN 60601-1 (based on IEC 60601-1, 3rd edition). The dop was 1 Jul 2007. “The dow for use of EN 60601-1:1990 (2nd edition) for appliances not covered by a part 2: 12 September 2009. No dow is fixed as long as other parts in the series have to be read with EN 60601-1:1990”^{vi}. Although no dow has been established, it’s expected that it will be at most another 1 to 2 years before each new collateral (IEC 60601-1-xx), and particular (IEC 60601-2-xx) aligned with 3rd edition will have been published. This work in many cases has already been underway since 2004. Once a medical device particular or collateral standard is published it typically will have a 3 year transition.

The European Commission is responsible for issuing updates to the Harmonized List of Standards, in the Official Journal. When a new standard is listed, transition dates are included. To date, the 3rd edition has not been added.

In the US, AAMI (Association for the Advancement of Medical Instrumentation) published the ANSI version of IEC 60601-1 as ES60601-1:2005^{vii}. However no dow was established. This is fine in that it’s really FDA, OSHA, and other local jurisdictions who would legally establish the dow. The 2nd edition is published in the US by Underwriters Laboratories as UL 60601-1, dop Jun 2003, with an earlier version called UL 2601-1, dop 1997. UL could also establish a dow, but will likely defer this to jurisdictional authorities.

In Canada, CSA has not yet published a standard based on the 3rd edition, to replace their 2nd edition standard, CSA C22.2 No. 601.1-M90 + S94. It’s a similar situation in most other countries.

3.2.Certification Organizations

3rd party certification organizations, such as VDE, TUV, UL, etc, are currently accredited to certify to the 2nd edition. They will now presumably seek accreditation to certify to the new 3rd edition. As accreditation audits can sometimes follow a 3 year cycle, new accreditations could be delayed. As the new 3rd edition has transitioned from a device standard to a process standard, (see Impact below), there will also be a need to establish and implement new evaluation policies, procedures, forms, and training.

3.3.De Facto Effective Date

The closest to an effective date that we'll currently find is CENELEC's date for the 2nd edition of 12 September 2009, for devices without a particular. As it's coming from CENELEC it will likely influence the European Commission who's responsible for issuing the Harmonized List of Standards. CENELEC will likely influence other major markets, such as US, and others.

4. What's the Impact for Manufacturers?

4.1.Risk Management

The biggest upgrade in the 3rd edition is that Clause 4.2 requires a manufacturer to have used a risk management process complying with ISO 14971, (Clause 4.2). Records generated by the risk management process are considered to be part of the Risk Management File (which need not be contiguous).

It's no longer acceptable to treat a new medical device design as a black box and consider it acceptable if it complies the safety standard, as was the case with the 2nd edition.

It's now necessary to identify all hazards during design phases, introduce risk controls to maintain an acceptable risk, and verify that these risk controls perform as intended. After a product reaches the market, customer complaints, other field incidences, and your CAPA process will have you refining your risk assumptions, and considering the need for improved risk controls.

While this is a huge change it's consistent with the process that regulators such as FDA or European Notified Bodies have been requiring and against which they already audit. That said we'd say you can anticipate a ramping up of sophistication to which design controls, complaint, and CAPA processes will be audited in the future, as manufacturers and auditors become better versed with ISO 14971.

4.2.Essential Performance

The next biggest change is the introduction of essential performance into the scope. Essential performance are those functions that are normally associated with the intended purpose of the device, and whose loss would result in an unacceptable risk. It's the manufacturer who identifies which functions of the device are essential performance. Consider an ECG monitor. The display of an accurate cardiac signal is a candidate for essential performance. For some monitors it may be enough to have an error alarm should there be loss of an accurate ECG display (due to power loss, component failure, etc). For other monitors, such as those in a ICU, an ECG signal with enough accuracy to determine if

someone's heart is beating normally or not, may be considered essential performance. For some diagnostic ECG devices, more sophisticated accuracy may be essential performance. For therapeutic devices, such as an RF surgical generator, its loss of function could result in a delay of therapy, however depending on if backup devices are suggested in the instructions for use, or if therapy can be rescheduled without undue risk, such loss may not be considered essential performance. Essential performance, once identified, must function in normal use, after reasonably foreseeable misuse, and after any single fault. See Clauses 3.27, 4.1, 4.3, and 4.7 for details.

For many devices it will be necessary to specify suitable protective measures in the instructions for use should loss of function occur. For some of these devices the timing of detection of loss will be critical enough that an alarm function will be considered essential performance, and may need battery backup should there be loss of power. For other devices, such as life sustaining devices, full redundancy may be needed in order to be single fault safe and maintain essential performance. However, consider a life sustaining ventilator. Ventilators are not now always designed to be fully redundant. Should they fail, it's critical that there be a suitable alarm. Nurses and similar health care providers are then instructed about what backup measures to take to maintain the patient's life.

The 3rd edition is not intending to raise the bar of safety but rather to have this scope expansion for efficacy incorporated into the safety standard, so as to assist regulators and manufacturers. It's expected and intended that the particulars, as they become aligned with the 3rd edition, will provide guidance and requirements for establishing essential performance. While this is a huge scope expansion to the standard, the new requirements are consistent with existing regulatory requirements for efficacy.

In some cases there will be overlap when considering if a function should be associated with basic safety or essential performance. For example, the structural strength of a bed rail is important for maintaining therapeutic rest with acceptable risk. As the safety standard requires the device to have acceptable risk whether the bed rail function is considered basic safety or essential performance, the distinction is not that important. What's important is that the bed rail be strong enough, and lack trapping zones so that there be an acceptable risk of injury to patient or operator.

With EMC immunity, the current collateral standard for EMC, IEC 60601-1-2:2001 + A1:2005, requires a device subjected to (relatively strong) external fields to maintain essential performance, to the extent that acceptable risk is maintained. There are no requirements about maintaining other (non-essential) functions, similar to immunity requirements for other equipment types. [-- this is being verified with EMC expert:> *This will be rectified when current draft EMC requirements become adopted. It's foreseen that there will be 2 thresholds for external field strengths, one for normally high field strengths, and a second for abnormally high field strengths. When a device is subjected to the first level of field strength, all functions must be operational, similar to immunity requirements for other equipment types. While subjected to the first normally high field strength, it's foreseen that a single fault could be introduced, such as a component failure, and essential performance, to the extent risk remains acceptable, would need to be maintained. When a device is subjected to the second higher level of strength, only essential performance is required to function, to the extent that acceptable risk is maintained. The abnormally high field strength would be considered a single fault.* <:end--]

4.3.Changes to Verifiable Requirements

In many cases, the testing requirements have become less stringent. For example the 3rd edition has a number of allowances for the use of non-medical equipment for surfaces that are unlikely to be contacted by a patient requiring the more conservative patient level of protection. When their use is appropriate, these allowance are less stringent than the allowances in the current IEC 60601-1-1:2000, the system standard. For example, when appropriate, IT power supplies complying with IEC 60950-1 can be used in medical equipment, without additional protective measures, such as an isolation transformer. Details are in Clauses 4.6, 8, and 16.

Mechanical tensile safety factors in cases where material strength and loading factors are well understood, can be reduced, for example, from 4x to 2.5x. Requirements to protect against unwanted motion have been modernized to add additional guidance, and cover cases where the operator may not have continuous control, suitable reaction time, or a clear field of view. Details are in Clauses 9.2, 9.8, and 14.

Thermal limits now take into account the duration of contact, and in some cases allow higher enclosure and applied part surface temperatures. Details are in Clause 11.1.

In other cases requirements have been expanded to include new requirements. For example there is now a energy reduction test for defibrillation-proof rated equipment. There are new tests for carts, including more step, door jam, and braking tests. For details see Clauses 8.5.5.2, 9.4, and 15.3.5.

4.4.New Clause Numbering

Not related to content, but an important change none the less is that the new 3rd edition uses a new clause numbering system. The 2nd edition used a Section and Clause system. The 3rd edition uses a hierarchical clause numbering system. At times clauses references get up to 5 levels deep, (i.e. Clause 8.9.1.1.3), which is unfortunate, but overall the result is a better organized document. For example, in the 2nd edition the table for creepage and clearance distances is in Clause 57.10, and the table for dielectric test voltages is in Clause 20. These are closely related insulation parameters, and yet they are greatly separated in the 2nd edition. In the 3rd edition these tables are in Clauses 8.8 and 8.9. The IEC has available a free clause mapping document for both editions, IEC TIR62348^{viii}.

5. Design to Both the 2nd and 3rd Edition

5.1.An Ambiguous Overlap

Based on regulatory effective dates, manufacturers of devices without a particular can expect some regulators to start looking for compliance to only the 3rd edition sometime around September 2009. Manufacturers of devices with a particular will have more time, but depending on how long a new device is intended to stay on the market, it may be prudent to design to meet the new requirements.

However, some markets will likely lag behind others. Worse case, some markets may not recognize compliance with the 3rd edition, and instead accept only compliance with the 2nd edition (although this would seem unlikely). Where you're seeking 3rd party certification marks, some of these certification

organizations may initially lack the experience to perform cost or time effective evaluations to the 3rd edition. For some certification organizations, their 2nd edition services may offer a more prudent choice.

Forgetting the effective dates for a minute, one has to also remember that the use of safety standards is typically a choice made by a manufacturer as a tool to assist designing and verifying a device has acceptable risk. The later is the actual regulatory requirement, and the standard is only one means available to meeting the requirement. As the 3rd edition is now a published consensus standard, it represents the new state of the art for verification testing to demonstrate acceptable risk. It's available now as a guidance, as part of your risk management process. This will allow the use of less stringent requirements, and also offers suggestions for tougher testing, if your risk verification process or field complaint process is looking for additional or alternative verification testing.

Based on the advantages of using the 3rd edition, we would suggest that new designs should start using the 3rd edition now. However because of the uncertainty of effective dates, and possible implementation delays at certification organizations, it would be prudent to also document compliance to the 2nd edition.

5.2. Equivalent Safety Clause

Both the 2nd edition and the 3rd edition have an “equivalent safety” clause. In the 2nd edition it is Clause 3.4, and in the 3rd edition it's Clause 4.5. The idea is that alternative means of addressing risks are acceptable provided that residual risk from applying the alternative means and the verifiable requirements in the standard are equivalent or the alternative means is better (less risk).

5.3. Practical Compliance Documentation

Designing to both the 2nd and 3rd editions would seem to be doubling the regulatory documentation burden for hazards covered by IEC 60601-1, however in practice it need not be that burdensome. As previously mentioned the 2nd edition has an “equivalent safety” clause, Clause 3.4. In documenting compliance with the 2nd edition, Clause 3.4 could be invoked. First your risk assessment process must identify the verifiable requirements of the new 3rd edition as representing an acceptable risk. Second, your risk assessment must conclude that meeting the more applicable and recent state of the art requirements of the 3rd edition, in lieu of those in the 2nd edition, is consistent with the level of risk intended by the 2nd edition, and therefore represents an equivalent level of risk. Your compliance documentation (test report) for the 2nd edition would indicate this in Clause 3.4. The 2nd edition clause which was superseded by a 3rd edition clause would refer to the alternative 3rd edition clauses as providing an alternative verification methodology.

One could imagine a 2nd edition short form for documenting only cases where the 3rd edition superseded the 2nd edition. As the 2nd and 3rd editions have the same requirements in many cases, this would be minimal. In the extreme case, a 2nd edition short form would include only Clauses 3.1 and 3.4. Another strategy would be to have a combined 2nd and 3rd edition test report, with common clauses mapped together. Of course the level of documentation will need to be acceptable to your regulators and any 3rd party certifiers you've chosen.

About the Author



Frank O'Brien has over 27 years experience testing and certifying medical devices. Frank is founder and principal engineer of O'Brien Compliance Management, a firm providing risk management and medical device safety services. He was on the committee which drafted the new 3rd edition of IEC 60601-1, and has therefore been working with the new standard for the last 8 years. He's currently on the committee drafting the new home care medical device collateral standard. He understands the US, European, and Canadian regulatory requirements. He is a frequent speaker at AAMI, and other industry conferences, and has authored articles on medical device safety. Prior to forming OBCM, Frank was a Manager and Senior Staff Engineer at Underwriters Laboratories, where he evaluated literally 1000's of medical devices. He was a senior reviewer for UL, and trained medical device staff internationally. Frank has lived and worked in Long Island, NY, USA; Frankfurt, Germany; San Jose, CA, USA; and presently Boston, MA, USA. Frank has a BS in Electrical Engineering from Clarkson University; an MS in Technology Management from Stony Brook University; and is a Registered Professional Engineer.

End note references are intended to provide web links or suitable key concepts and words so that a Google or similar search engine will produce meaningful results.

ⁱ IEC's website is www.iec.ch. Search locally for IEC 60601-1:2005

ⁱⁱ FDA guidance document on Recognition and Use of Consensus Standards, www.fda.gov/cdrh/ost/guidance/321.html

ⁱⁱⁱ The following OSHA NRTL related documents should be consulted:

- Title 29 Code of Federal Regulations Section 1910.7
- 53 Federal Register 12102, 4/12/88; 60 Federal Register 12980, 3/9/95
- STP 2-1.147A - Safety Testing or Certification of Certain Workplace Equipment and Materials, August 7, 1989

^{iv} Global Harmonization Task Force, www.GHTF.org.

^v Medical directives are available at, http://ec.europa.eu/enterprise/medical_devices/legislation_en.htm. Annex I contains the essential requirements. Article 5 explains that harmonized standards can be used to presume compliance with essential requirements. The same website has links to list of harmonized standards.

^{vi} CENELEC's website, www.cenelec.org. Locally search for IEC 60601-1:2006.

^{vii} AAMI's website, www.aami.org. Locally search for ES60601-1:2005.

^{viii} IEC's website is www.iec.ch. Search locally for IEC TIR62348. It is a free download.