

IEC 60601-1 – THE THIRD EDITION

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IEC 60601-1 was first published in 1977

The third edition of IEC 60601-1 represents a major overhaul of the IEC 60601 family of medical electrical equipment safety standards. First published in 1977, IEC 60601-1 has become the 'bible' of electromedical equipment safety and the parent standard of over 60 particular device standards ranging from diagnostic electrocardiographs to electron accelerators used in radiotherapy.

An Outline of the Changes

Scope of the standard has been amended and enlarged in third edition

The journey toward the third edition began before the last amendment was published in 1995. Formal work on the project began in early 1997 and has taken nearly nine years to complete. During the process of developing the third edition, the scope of IEC 60601-1 was significantly modified and expanded. The first major change came when the long-standing debate within IEC Subcommittee 62A over what some considered an unnecessary limitation in the scope of the standard was resolved, and the Subcommittee removed the phrase 'under medical supervision' from the definition of medical electrical equipment. This change ended the debate over whether or not equipment that met all the other characteristics of medical electrical equipment, but was not intended to be used by or under the close supervision of a trained professional, was within the scope of IEC 60601-1. The automatic external defibrillator (AED) now so common in airports and other public spaces is a good example. While such devices clearly fulfil all the other characteristics of medical electrical equipment, it can be persuasively argued that they are not intended to be used under medical supervision. Under the revised scope of the third edition, there is no question that AEDs are covered by IEC 60601-1.

Definition of medical electrical equipment was amended

The second major change occurred when Subcommittee 62A accepted a proposal from France to add 'or compensation or alleviation of disease, injury or disability' to the definition of medical electrical equipment. Historically, medical electrical equipment was limited to devices intended by their manufacturer to 'diagnose, treat or monitor a patient'. The UK also argued that a strict interpretation of the scope of the second edition of IEC 60601-1 excluded certain patient handling and support equipment. This equipment is not covered in the scope of the ISO Committee dealing with aids for the disabled, except that some models may be intended for both domains of use. Many in the community felt that excluding these devices leaves a large hole in the standard's coverage. A number of other standards, such as ISO 10535 for patient lifting equipment, refer to IEC 60601-1 for electrical safety requirements and so for IEC 60601-1 to exclude this equipment is a contradiction.

Another issue that was extensively debated during the development of the third edition was the relationship of the collateral

standards in the IEC 60601 family. Amendment 2 to the second edition added subclause 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 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 general standard on the date of its publication. In effect, this approach 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.

However, easily the most striking change in the third edition is the requirement for the manufacturer of electromedical equipment and systems to have a formal risk management system in place in order to comply with the third edition of IEC 60601-1.

Manufacturers must now have a formal risk management system in place

In the remainder of this article, three recognised experts in medical electrical equipment safety will provide a high-level overview of this requirement and the impact it will have on manufacturers and certification bodies.

Introduction of a Formal Risk Management Process

Risk management is inextricably woven into the fabric of the third edition. Not only is there a general requirement for manufacturers to establish a risk management process that conforms to ISO 14971 but there are also more than 100 times where the standard directs manufacturers to determine risk acceptability in applying a particular requirement. At each of these decision points, the manufacturer must estimate the risk of its device and take an action dependent upon how that risk compares to its predefined levels of risk acceptability. The third edition still contains objective tests and pass/fail criteria and manufacturers may choose simply to follow such requirements in the design of their device. However, there are still more than 100 decision points where risk acceptability must be assessed in order to select an appropriate option to achieve compliance, define necessary pass/fail criteria, determine testing parameters, add a particular safety feature etc.

Risk management process must comply with ISO 14971

However, the risk management process does much more than this in determining compliance to the third edition. The introduction to the standard states that, 'In all cases, the risk management process will determine whether the requirements of the standard are appropriate and acceptable.' Thus, the risk management process established by the manufacturer allows it a new freedom. Based upon the risk management process, the manufacturer is allowed to tailor the requirements of the standard to the needs of the device (and its intended use), rather than adjusting the device design to

Manufacturers are now free to tailor the standard to the needs of the device

the requirements of the standard. There was precedent for this in the 'alternate construction clause' (subclause 3.4) of the second edition, but the risk management process required by the third edition has much more far-reaching effects.

Risk management process should cover the whole device life cycle not just its design

This newfound freedom does not come without a cost. To claim conformity with the third edition, a manufacturer must establish a risk management process that conforms to ISO 14971. It is important to note that this risk management process must address the entire life cycle of the device, not just the design. Risk management, as described by ISO 14971, is a self-improving process through which the manufacturer must use knowledge gained post-production to improve and refine the safety of the device. Further, this risk management process must be documented, much like a quality management system, and the manufacturer must establish acceptable risks for its device that are based upon regulations, standards, state-of-the-art and other relevant factors.

There are several reasons for the enhanced use of risk management in the third edition. One reason was the recognition that risk management was necessary to allow the third edition to keep pace with changing technology. Standards generally represent state-of-the-art at a moment in time, whereas technology and state-of-the-art advance. Applying a risk management process allows the manufacturer to take advantage of evolving technology, while providing ever-safer devices.

IEC 60601-1 now addresses essential performance as well as basic safety

In addition, IEC 60601-1 had been evolving from a basic safety standard to a standard that addresses both basic safety and essential performance. This is evident from the direction of development of both collateral and particular standards since the establishment of the second edition. Explicit use of risk management is one way to address essential performance safety issues in a meaningful way that would be impossible with a standard that contains only rigid test methods and pass/fail criteria.

Finally, it is recognised that standards (particularly IEC 60601-1) are used for regulatory purposes. Many countries rely on IEC 60601-1 to establish a baseline for the safety and effectiveness of electromedical equipment and systems. Risk management has become an important part of the vocabulary of the regulators. The incorporation of a risk management process into the third edition closely aligns the standard, on which many regulators rely, with other regulatory needs.

Impact on Manufacturers

ISO 14971 and IEC 60601-1 third edition were developed in parallel

It is no accident that ISO 14971 is the model for the risk management process in the third edition. Both standards have been developed in parallel, and members of IEC Subcommittee 62A were key members of the ISO/IEC Joint Working Group 1 on Risk Management, which developed ISO 14971. In part, ISO 14971 was developed to serve the needs of the third edition. Pains were taken to establish consistent definitions and normative language.

As discussed earlier, there are over 100 instances where application of a specific clause, modification of a test protocol, or provision of a particular safety feature depend upon a determination that the risk is acceptable (or that there is no unacceptable risk). Manufacturers must determine risk acceptability using an ISO 14971 compliant risk management process. The third edition states in subclause 4.2 that:

'The requirements of this clause and all requirements of this standard referring to inspection of the RISK MANAGEMENT FILE are considered to be satisfied if the MANUFACTURER has:

- established a RISK MANAGEMENT PROCESS;
- established acceptable levels of RISK; and
- demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK) [emphasis added].'

Subclause 4.2 states that...

Once established, risk acceptability levels are key to application of the third edition. A host of decisions are made based upon comparing residual risks with predefined risk acceptability levels, with some obvious impacts for testing and certification (see the discussion below). Note that there is an implication here that risks will be, in some sense, quantifiable. In 'demonstrating that a residual risk is acceptable', the residual risk must be demonstrated to be less than or equal to an acceptable level of risk. Such a comparison is extremely difficult if risks are not in some way quantifiable or measurable. Many manufacturers are not experienced in this type of quantification and the transition may prove difficult. Further, quantification may be problematic for risks that are intrinsically difficult to quantify, such as the risk of software failure or, for manufacturers of a new device, where there is little or no historical experience to help in estimating risks. Further, if the manufacturer cannot quantify risks, it may prove difficult to demonstrate to a certification body or to a regulator that the residual risk is indeed acceptable.

Residual risk must be less than or equal to a predefined acceptable level of risk

While the requirement to demonstrate that a formal risk management process has been applied is a new requirement, the concept is in fact not entirely new. In the second edition of IEC 60601-1, subclause 3.1 specifies that 'Equipment shall, when transported, stored, installed, operated in normal use, and maintained according to the instructions of the manufacturer, cause no safety hazard which could reasonably be foreseen and which is not connected with its intended application, in normal condition and single fault condition.' This requirement was intended to ensure that new types of medical devices (or simply ones for which there is no device-specific particular standard such as IEC 60601-2-2 for high frequency surgical equipment) would be safe by applying IEC 60601-1 alone. In addition, subclause 3.4 of the second edition states: 'Equipment or parts thereof, using materials or having forms of construction different from those detailed in this standard, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.'

Risk acceptability can be difficult to prove if risks are not quantifiable or measurable

The former of these requirements, while often not addressed by certification bodies, constitutes a *de facto* requirement to analyse the equipment to determine if there are issues of safety associated with its design that are not addressed by specific requirements in the document and address them. In fact, many certification bodies that are also Notified Bodies in Europe have traditionally required that manufacturers provide a risk analysis with the device as evidence that subclause 3.1 has been addressed. Until ISO 14971 was published in 2000, these risk analyses were typically done according to EN 1441.

Manufacturers were reluctant to invoke subclause 3.4 of the second edition

The allowance (contained in subclause 3.4 of the second edition) that manufacturers can address safety hazards through techniques different from those specified in clauses of the standard requires that an analysis be performed to demonstrate that those different techniques yield an equivalent level of safety. The first step in performing such an analysis is to evaluate the level of safety (or residual risk) provided by the requirement in question. Next, the alternative approach to addressing safety must be quantified in terms of the safety it provides and the two are compared to show that the alternative is equivalent in terms of risk.

One of the primary reasons that many certification bodies have avoided applying subclause 3.1 may be that the second edition does not specify a methodology for identifying unaddressed hazards (i.e. there is no italicised compliance criteria). With respect to the allowance to achieve safety through methods other than those specified by the standard (subclause 3.4), manufacturers have been reluctant to invoke it. This is because there is no method specified by the standard for showing that equivalent safety has been achieved and finding out during testing that such an approach is considered unacceptable could be devastating to achieving an on-time product release. Early on in the development of the third edition of IEC 60601-1, those developing the new standard determined that one of the most critical tasks would be to resolve these issues by defining a methodology for identifying, addressing and evaluating risks in the new document.

Third edition defines a methodology for identifying, addressing and evaluating risks

As described above, IEC Subcommittee 62A worked jointly with ISO Committee 210 on the development of a risk management process for medical devices. This new standard offered those writing the new IEC 60601-1 the perfect tool for addressing the shortcomings of subclauses 3.1 and 3.4 in the second edition. Once it was agreed to incorporate a normative reference requiring devices certified to the third edition to demonstrate that ISO 14971 had been applied as well, it became clear that this inclusion could have impacts far beyond subclauses 3.1 and 3.4 of the second edition.

By applying the principles of risk management in the technical requirements of the IEC 60601-1 standard, the writers of the third edition realised that they could produce a device safety standard that would ensure the highest possible level of safety while allowing designers unprecedented flexibility. This resulted in the large number of references to the risk management process, risk control,

unacceptable risk and the risk management file. In order to claim that a device meets the requirements of IEC 60601-1, manufacturers must provide evidence that:

- a risk management process compliant with ISO 14971 is in place;
- the risk management process has been applied to the device being certified;
- analyses or data specified as part of the requirements of IEC 60601-1 have been placed in the risk management file.

To comply with IEC 60601-1, manufacturers must prove that...

While it is not possible to identify all references to applying risk management in the third edition here, a few examples can demonstrate how it is used. The following are intended to provide some insights on how risk management is used in the third edition and the associated documentation required to be placed in the risk management file:

- **Determining which aspects of the device's performance are 'essential performance'**: risk analysis must be applied to identify the performance characteristics that could directly impact the safety of the equipment and those characteristics must be maintained such that no unacceptable risks arise.
- **Determinations regarding classification**: the determination of what level of IP [Ingress Protection] classification (degree of protection from dust and liquids provided by the enclosure) is appropriate must be based on an evaluation of how the equipment is intended to be used and in what environment.
- **Modification of test conditions**: the duration and severity of humidity preconditioning that the equipment is exposed to before tests are performed is determined based on the analysis performed as part of the risk management process.
- **Applicability of requirements**: the third edition requires that parts that can come into contact with the patient be evaluated as part of the risk management process to determine if they should be treated as applied parts (subject to more severe current leakage restrictions) even where they do not meet the definition of applied parts.
- **Determining which compliance limits apply**: the third edition establishes requirements for the maximum temperature of parts that can be contacted based on the material in question (thermal conductivity) and the likely duration of contact. An analysis must be performed to determine the likely duration of contact; the basis of that determination and the analysis must be placed in the risk management file.

Examples are provided to demonstrate how risk management is used in the third edition

In all cases, where the third edition requires application of the risk management process in whole or in part, certification bodies are required to ensure the analyses have been performed and that the data required are in the risk management file. However, it is important to recognise that certification bodies are not to make judgements

Certification bodies must ensure risk analyses have been performed and the required data are filed

Certification bodies are not required to judge the quality of the risk management process and files...

as to whether they agree with the results of applying risk management but only to ensure that the required analyses have been performed and that the data have been incorporated in the risk management file. In an attempt to emphasise these limits on certification bodies, specific compliance text was added to subclause 4.2 as described above.

...but they could refuse to issue certifications if minimum quality levels are not met

This said, it must be remembered that the reputation of certification bodies for performing accurate and responsible evaluations is their most valued commodity. While the standard precludes them from making arbitrary judgements about the quality of a manufacturer's risk management process and files, they will be completely justified in refusing to issue certifications in cases where the risk management process does not meet a minimum level of quality and diligence.

It must also be mentioned that the relationship between the third edition of IEC 60601-1 and ISO 14971 is not unidirectional but reciprocal. Although IEC 60601-1 requires the application of risk management, ISO 14971 also explicitly states that where devices comply with the requirements of device safety standards (such as IEC 60601-1), the risk addressed by those requirements should be considered acceptable. In effect, this means that for electromedical equipment and systems, the use of both standards to ensure safety is inescapable.

Impact on Certification Bodies

At the time of writing this article, certification bodies are still in the process of determining how to certify products to the third edition of IEC 60601-1. As stated previously, to fully comply with IEC 60601-1, the manufacturer must provide the certification body with evidence that it has an ISO 14971-compliant risk management process, the risk management process has been applied to the electromedical equipment or system being certified, and analyses or data specified in IEC 60601-1 are placed in the risk management file. The need to review risk management activities represents a significant philosophical change in the way certification bodies will need to assess devices for certification. How the certification will actually be performed is not clear and some certification bodies may take very different approaches in their assessments. At the very least, certification will likely include a review of the risk management file since this will contain all of the manufacturer's rationale for its decision-making. Additional reviews of the risk management file are also likely when major changes to the product occur. Some type of audit (most likely by the certification body itself) of the risk management system on some type of regular basis may also be necessary to ensure the risk management process stays compliant with ISO 14971 over time.

It is not yet clear how products will be certified to the third edition

Under the first and second editions of IEC 60601-1, certification bodies certified the product was safe by conducting tests as defined in the standard and reviewing the construction of the product (including various marking and labelling requirements) against the

requirements. Now, in many places, the third edition directs the manufacturer to conduct a risk analysis to determine the parameters of a needed test. Certification bodies will need to become expert in risk analysis review and risk management system auditing. Not all certification bodies may have the expertise for these functions or enough resources to conduct the additional work. As noted above, European Notified Bodies generally have some experience with risk analysis review as they are required to review risk management as part of their technical file review for applying the CE mark.

Along with the complication for the certification bodies, manufacturers must realise that their risk management process is likely to be audited as part of the certification process. Such an audit is likely to increase the necessary lead time for certification, as well as its cost. There have been a few discussions recently by some certification bodies over whether issuing an ISO 14971 certificate would be useful (similar to an ISO 13485 certificate). This may now make more sense, especially for some larger manufacturers that design and certify multiple products in a year. The ISO 14971 registration certificate would demonstrate to the certification body that the manufacturer has an ISO 14971-compliant risk management system, relieving them of the burden of having their risk management system reviewed with every product certified. The question naturally arises as to whether one certification body would accept the ISO 14971 certificate of another certification body.

Risk management process audits are likely to increase lead time for certification and costs

In addition to the changes for certification, the inclusion of risk management in the third edition of IEC 60601-1 causes two other difficulties for certification bodies:

Some large companies may benefit from having an ISO 14971 registration certificate

1. In the USA, the Occupational Safety and Health Administration (OSHA) requires certification to the national safety standard for regulating workplace safety. The OSHA recognises a number of Nationally Recognized Testing Laboratories (NRTLs) to do the certification. The NRTLs are audited and accepted by the OSHA based on competence to specific standards. Once recognised, the certification body can issue an NRTL mark that it controls. Currently the OSHA does not have any other standards that deal with risk analysis or risk management that they approve an NRTL to. The OSHA's acceptance of testing laboratories merely relies on the certification bodies' ability to make accurate measurements, not their ability to assess risk management systems. Will the OSHA change their accreditation criteria to accommodate the changes brought by the third edition? If the OSHA does not assess certification bodies for their risk management capability, will the NRTL mark only be an attestation (not a certificate) for the tests conducted? If this happens, what will a manufacturer do when a local jurisdiction requires an NRTL-marked product?
2. The CB [Certification Body] scheme for worldwide acceptability of certification reports has a similar problem. The CB scheme

Two other problems facing certification bodies...

is a system whereby test houses from around the world, who meet the general requirements for the competency of testing and calibration laboratories contained in ISO 17025 and are audited to the CB scheme requirements, are approved as a CB test laboratory. CB test laboratories generate CB certificates and reports that are acceptable in countries that subscribe to the CB scheme. Once the manufacturer has the CB certificate and report from the issuing testing laboratory it can pass these documents onto one or more other testing laboratories (along with some additional information) for issuance of a local certification mark without a full compliment of tests. The CB scheme does not assess a testing laboratory's ability to assess risk management activities. Will the CB scheme accreditation be modified to include risk management assessment capabilities?

Issues still exist that need to be resolved in the near future

After discussing these issues with several certification bodies, it is clear that neither of them have been resolved yet, but they need to be considered and resolved in the near future now that the third edition of IEC 60601-1 has been published.

FDA is developing guidance on the use of the third edition in premarket submissions

If the electromedical equipment or system is a medical device subject to the US *Federal Food, Drug and Cosmetic Act*, the manufacturer may want to submit the results of testing to IEC 60601-1 to the US Food and Drug Administration (FDA) to help demonstrate the product is safe and effective. Recognising the significant changes from the second to the third edition of IEC 60601-1, the Agency is currently developing a guidance document on the use of the third edition in premarket submissions to the Agency. It is not yet clear whether the FDA will recognise the third edition as a Consensus Standard as they did with the second edition of IEC 60601-1. Also, it has not been the FDA's policy to allow transition periods for recognised standards. Once a new edition of a standard is recognised, premarket submissions may no longer reference the previous edition. However, because of the significant changes between the second and the third edition of IEC 60601-1, the FDA is discussing possible changes to their policy to allow a transition period.

From the issues discussed above, it seems obvious that the third party certification approach for the third edition of IEC 60601-1 will need to change significantly. Certification bodies will not be able to merely test and review documentation as they have traditionally done. They will also need to assess the manufacturer's risk management system to ensure that it is compliant with ISO 14971. However, once the risk management process is found to be compliant, the certification body is not allowed to second-guess the risk management decisions made by the manufacturer to comply with the third edition. The certification body can only review the risk management file to see that there is proper rationale for the decision-making.

In the end, the introduction of the ISO 14971 risk management 'process' standard as an element of compliance with the IEC 60601-1 'product' standard is unique within the medical device standards community. This fusion will require that both manufacturers and certification bodies adjust to a more comprehensive view of assuring the safety of devices they design and test.

All parties must adjust to a more comprehensive view of assuring device safety

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