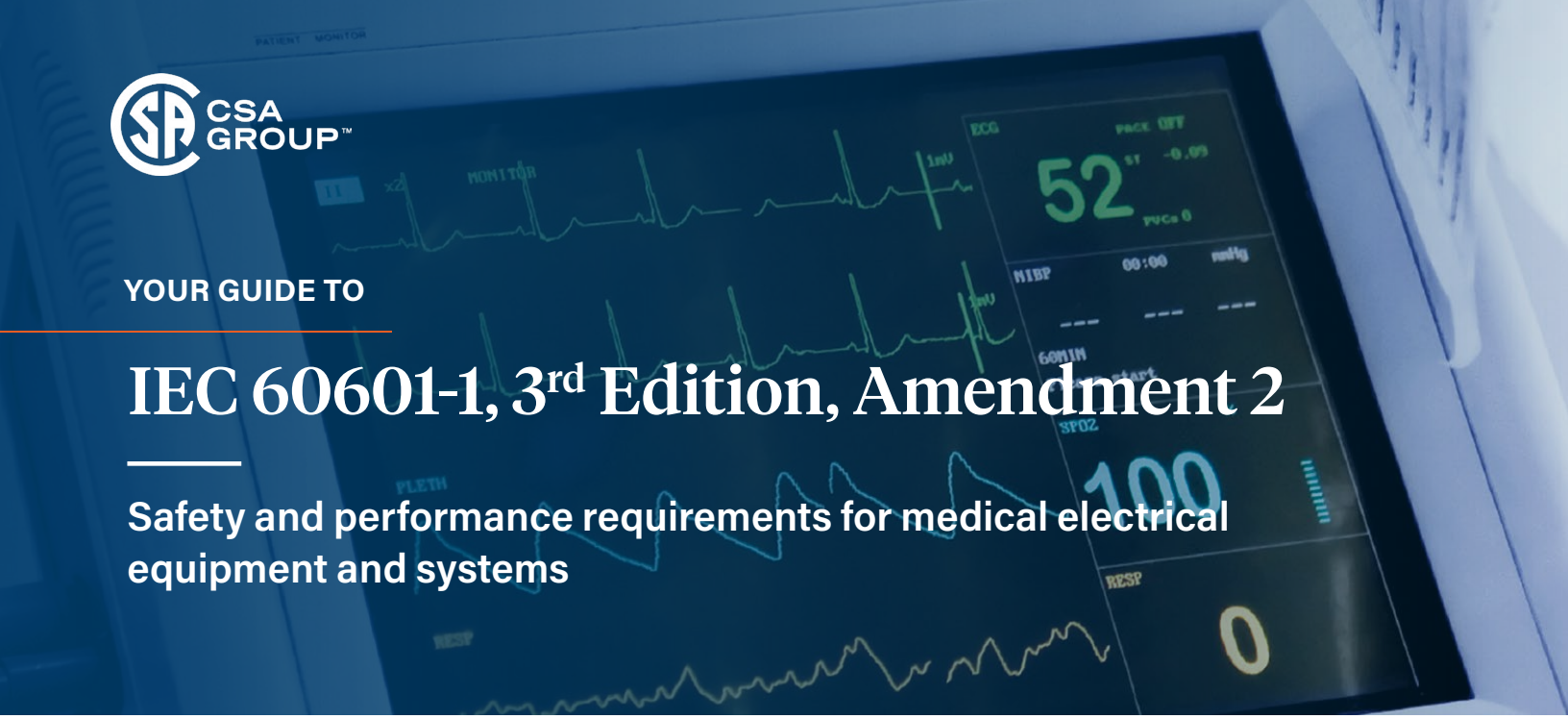


YOUR GUIDE TO

IEC 60601-1, 3rd Edition, Amendment 2

Safety and performance requirements for medical electrical equipment and systems

Implementation Year

Issued: August 2020

No effective date has been established

Understanding IEC 60601-1 and this series of amendments

The IEC 60601-1 is the International Electrotechnical Commission's (IEC's) general standard for medical electrical equipment. Due to advancing technology, and a constant stream of new medical products being developed and entering the medical marketplace, the IEC 60601 series of medical standards exists in an environment of ongoing and rapid change.

This new amendment to the third edition, Amendment 2 (Amd 2) incorporates feedback that the IEC has received from various sources, including the participating National Committees, since the release of Amendment 1 in 2012.

This new amendment also required other Amendment Projects (conducted by IEC Subcommittee 62A), which identified eight standards – the general standard and seven collateral standards – to be updated prior to the release of the fourth edition of the standard, which is not expected before 2025/2026.

Amendment 2 seeks to achieve several key objectives:

- Prioritize **risk management** and **risk mitigation** throughout the entire product design process.
- Address foreseeable hazards and minimize the impact of user error by employing a robust evaluation and **usability engineering** process throughout the design and development of the user interface.
- Ensure that **software** components, common to so many types of medical electrical equipment, meet standards in their **life-cycle development process**.

Overview of important changes

IEC 60601-1 3rd Edition Amendment 2 (IEC 60601-1 Ed. 3.2) introduces changes to the IEC 60601-1 standard, including:

- Changes to the **general standard**
- Major changes to the **alarm** standard (IEC 60601-1-8)
- Updates related to **process standards:**
  - **Risk management** (ISO 14971)
  - **Usability engineering** (IEC 62366-1)
  - **Software development** (IEC 62304)

This guide provides an overview of some of the key changes within these standards.

Changes to the general standard (IEC 60601-1)

Updated references

References to products/components complying with IEC 60950, IEC 60950-1 and IEC 62368-1 and the procedure to accept them in the medical electrical product/system have been updated.

Clause 8 – Separation of parts

This clause has been revised to facilitate acceptance of components and equipment certified to IEC 62368-1 for use in medical equipment and systems.

Major changes to the alarm standard (IEC 60601-1-8)

The definition and prioritization of alarms have been revised. Many of the new changes aim to reduce nuisance alarms and alarm fatigue. Amendment 2 allows for various paths to compliance.

The test methods for alarms have changed significantly. **All medical products with alarms will need to be retested.** The method for measuring an alarm's wave form characteristics has changed, as has the method for determining the sound pressure level. The amendment covers:

- New terms and definitions as well as multiple new definitions and major changes to existing definitions. These revisions will affect how alarms and alarm-condition priority are accessed and evaluated.
- Alarm fatigue and alarm flood
- High-, medium- and low-priority alarms versus operator response/action
- Auditory icons/pointers
- Clinical actionable/non-actionable
- Nuisance alarms signal
- Multiple ways to meet the requirements for audible alarms
- Test method changes that mean **existing products require re-testing to meet the new requirements.**
- DIS and DAS

Changes to the Risk management – Process standard (ISO 14971)

The risk management process must comply with ISO 14971:2019 (3rd edition). The new ISO standard differs significantly from its prior editions. ISO 14971 has been added as the main pillar for risk management under IEC 60601-1.

- Several clauses have been renumbered in the new standard. This will require updating existing RMF documents to comply with the latest edition. This will also have an impact on the collateral standards **1-2, 1-6,** and **1-8.**
- New terms and definitions have also been added as Security Hazards.

Changes to the Usability engineering – Process standard (IEC 60601-1-6)

Amendment 2 introduces a new standard, IEC 62366-1, to address usability requirements in IEC 60601-1. Standard 62366-1 aligns with ISO 14971 and uses the same methods of risk management as 14971 to evaluate user interfaces. It distinguishes itself by using contemporary methods of evaluation, like summative and formative evaluation.

- The usability engineering process must comply with IEC 62366-1:2015
- This standard has been updated to streamline the process and strengthen links to ISO 14971 and related methods of risk management
- Terms and definitions, such as "efficiency", "expected service life", "usability test", "hazard-related use" scenario, "formative evaluation" and "summative evaluation" have been updated
- Clarifying formative versus summative evaluation
- Use of hazard-related scenarios in the usability engineering process
- This will require considerable documentation updates and change in processes to comply

Changes to the Software development – Process standard (IEC 62304:2006)

- The software development process must comply with IEC 62304:2006 and/or IEC 62304:2006/ Amd 1:2015
- Includes updated clarification regarding compliance with IEC 62304 Clauses 4.3, 5, 7, 8 and 9.
- Updated clarification for modification to software, sub-clause 4.3 and 4.4 and Clauses 5, 7, 8 and 9 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015 shall apply.
- Updated clarification for PEMS is intended to be incorporated into an IT-NETWORK

What's the Process?

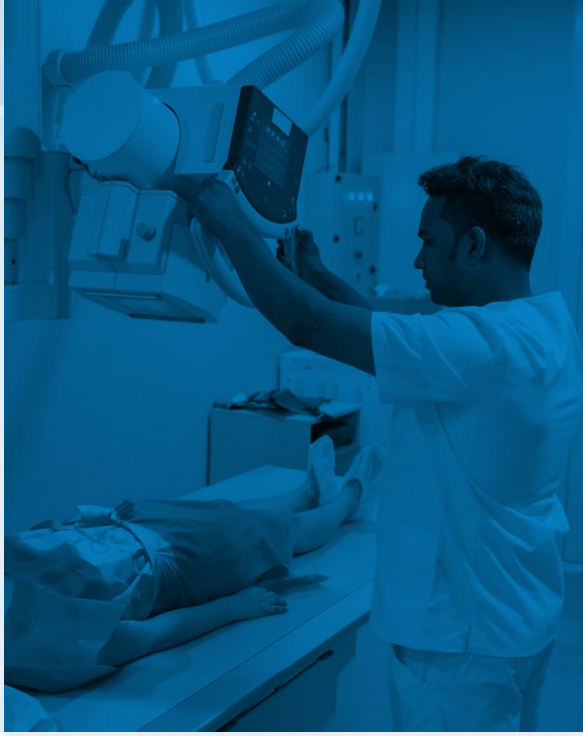
How do I ensure my products are compliant with the updated regulation?

Ensuring that your products meet the updated regulation is a two-step process:

Where the application of IEC 60601-1 Ed. 3.2 for your product does not require any tests to be repeated, we can directly update your certificates and reports to show compliance with IEC 60601-1 Ed. 3.2.

If we determine that testing is required, we'll develop a quote, and conduct the necessary tests. Assuming that the product passes all of the tests, we can then update your certificates and reports to show compliance with IEC 60601-1 Ed. 3.2.

If a product does not pass the required tests/evaluations, we will provide you with a clear list of issues and the corresponding clause references, so you can understand how to apply the requirements of the regulation to your product and reach compliance.



Other Applicable Services

CSA Group offers a range of services to help you with standards compliance:

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- EMD and Radio Testing
- Technical Information Service

The CSA Group Difference

Rely on an internationally recognized company with over 100 years of expertise and knowledge. From our early beginnings developing standards for railway bridges to today's latest sustainable technologies, we're always looking forward and developing innovative standards and testing programs for the most advanced and emerging technologies. Drawing on our industry accreditations, our customer-focused experts can meet your unique testing, inspection, and certification needs. That's how we're committed to your business.

Let's work together

Put CSA Group's industry-leading knowledge and experience to work for you.

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Why CSA Group?

When you work with CSA Group, you'll interact directly with highly qualified technicians and certifiers. Your project will be assigned to a medical certifier. This gives you direct access to a wealth of medical technical expertise related to medical standards that affect your business.

Our direct-contact approach helps your compliance testing run efficiently. In the unfortunate event of a failure or non-compliance, our medical experts will provide detailed reports of the findings to help you understand where the product did not meet the applicable requirements, so you'll have the information you need to make the necessary decisions to get your product back on track.