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Med-Info

International expert information
for the medical device industry

3rd edition of IEC 60601-1:2005+A1:2012

This Med-Info is addressed to

- Manufacturers of medical electrical equipment and systems
- Manufacturers of components of medical electrical equipment

Background

The IEC 60601-1:2005 (3rd edition) was published in December 2005. It is the 3rd edition of the basic standard, replacing the previous version IEC 60601-1:1988+A1:1991+A2:1995.

Amendment 1 (A1:2012) was published in July 2012. The current version of the standard is thus called IEC 60601-1:2005+A1:2012, also known as Edition 3.1.

As basic standard for medical electrical equipment, this standard deals with the general requirements concerning basic safety and the essential performance.

What is the new standard called?

IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. The German version is published as DIN EN 60601-1:2013.

Why did a new edition of the basic standard become necessary and which are the most important changes compared to the second edition?

a) User protection was adjusted to the requirements of IEC 60950-1 for information technology. This has often led to alleviated requirements, and thus allows, under certain conditions, the use of components already approved in IEC 60950-1.

b) Introduction of risk management as an alternative for compliance of individual aspects of the standard and for covering risks not subject to a standard

c) More precise adjustment of the insulation coordination to environmental conditions (e.g. degree of pollution, overvoltage category, etc.)

d) Integration of some collateral standards into the basic standard (e.g. IEC 60601-1-1 Systems)

e) Expansion of the scope of application of the standard beyond basic safety by integration of the essential performance (= Functional Safety)

f) The most national deviations for America (previously in UL 60601-1) have been included in the 3rd edition.

g) Introduction of the term “expected service life”

h) Section 9, “Mechanical hazards”, has been expanded significantly.

i) Key changes in A1:2012:
- Correction of problems that emerged when the standard was applied
- Reduction of references to risk management
- Clarification of the term ”essential performance“

When will the new standard be introduced and what does this imply?

a) MDD conformity assessment procedure, CE marking

Introduction

- Medical devices must comply with the Essential Requirements of the relevant European directives.
- Complying with standards (IEC, ISO, EN, etc., harmonized or non-harmonized) is not mandatory to show compliance with the Essential Requirements.
- Member states* shall presume compliance with the Essential Requirements if harmonized standards are complied with.

  *** Note:** The term "member states" is related to authorities of an EU member state, but does not necessarily include notified bodies and/or manufacturers.
- As there are new international standards that are not yet harmonized, there are some uncertainties whether a medical device complying with the harmonized standards, but not yet with the new internationally recognized standards is still in compliance with the Essential Requirements.
- This discussion also includes questions about the liability of manufacturers placing new products on the market which are not in compliance with new internationally recognized standards – especially if reportable events (incidents) happen.
- EK-Med document 3.5 A1 (title: "Effect of Changed Standards and Scientific Knowledge on Manufacturers and Notified Bodies") describes the common understanding of how manufacturers and notified bodies shall deal with changed standards and new scientific knowledge.

Explanations

- Manufacturers have to take into account the state of the art (SOTA) during the design and construction phase. Essential Requirement No. 2 requires that "the solutions adopted by the manufacturer for the design and construction of the device must conform to the safety principles, taking account of the generally acknowledged state of the art (SOTA)."
- During the following production phase, manufacturers have to take into account all changes in standards and scientific knowledge (SOTA) within the framework of their risk management system until no more new products are placed on the market.
- The risk management approach requires from manufacturers to recognize new international standards as part of new scientific knowledge.
- As a minimum, manufacturers have to conduct a gap analysis if:
  - new (harmonized) standards are issued or
  - new scientific knowledge is available (here: international standard).

  Note: The term "gap analysis" means retesting, reevaluation, and, if necessary, redesign of the medical device. As standards are not mandatory within the EU, a necessary redesign could differ from the standard proposed solution as long as compliance with the Essential Requirements is ensured and the state of the art has been taken into account.
- The current Official Journal (OJ) list (dated November 2017) of harmonized standards (93/42/EEC) contains old part 2 standards of the IEC 60601-2-x series referring to the outdated 2nd edition of IEC 60601-1. New part 2 standards referring to edition 3.0 or 3.1 of IEC 60601-1 are available, but not yet harmonized. These part 2 standards and of course Edition 3.1 of the general standard itself as well as many clauses are reflecting new scientific knowledge and the current state of the art (SOTA).

Conclusion

It is the responsibility of the manufacturer to provide safe medical devices (see 93/42/EEC, Annex I, Chapter 1, Essential Requirement No. 1). If a manufacturer fails to conduct a gap analysis of an applicable new part 2 standard or Edition 3.1 of IEC 60601-1 as defined by the standards during the transition period, products might not be in compliance with the EC directives and their national laws in the member states – at least this manufacturer cannot show evidence that their products comply with Essential Requirement No. 1. This will certainly raise the manufacturer's liability risks in cases of incidents. Notified bodies have to verify the risk management system of certified manufacturers. If a manufacturer is not able to furnish evidence that they have taken into account new standards and new scientific knowledge (e.g. by performing a gap analysis), they cannot prove compliance with Essential Requirement No. 1 described in Annex I, Chapter 1 of the MDD. This case needs to be judged as a minor non-conformity by the audit team.

b) CB procedure: The use of IEC standards is mandatory as part of the CB Scheme. IEC 60601-1:2005 and IEC 60601-1:2005+A1:2012 have been adopted as valid standards by the CB procedure. In addition, the 2nd edition of IEC 60601-1 may also be applied.

c) NRTL approval (**N**ationally **R**ecognized **T**esting **L**aboratory): As part of the NRTL program, TÜV SÜD Product Service is enjoying consistent growth of its testing business and opens up direct access to the American and Canadian market for manufacturers. TÜV SÜD has been accredited as a NRTL by the U.S. Department of Labor: Occupational Safety and Health Administration (OSHA) and by the Standards Council of Canada (SCC). The OSHA has released TÜV SÜD for ANSI/AAMI ES60601-1:2005/(R)2012. The SCC has released TÜV SÜD for CAN/CSA-C22.2 No. 60601-1:2014.

d) Amendment 1 (A1) to IEC 60601-1:2005 includes 496 separate changes and was published in two versions:

- IEC 60601-1 Amendment 1 (2012-07): This 232-page document includes only the wording of Amendment 1.
- IEC 60601-1:2005+A1:2012 (2012-08): This 402-page document is a consolidated version of Amendment 1 integrated into the IEC 60601-1:2005 standard. In this version, the changes introduced by Amendment A1 are highlighted in color. Given this, experts prefer this version in their daily work (ISBN 978-2-8322-0331-6).

e) Outlook: Currently the standardization is working on the IEC 60601-1 Amendment 2 (A2). Final publication as IEC standard Edition 3.2 is planned for December 2019. The A2 project includes the general standard and several collateral standards, which all should be published simultaneously.

Where can I get a test protocol form?

The test protocol has been provided as part of the CB procedure by the IECEE since August 2006. The protocol can be purchased on the Internet. It is available at **www.iec.ch**, under Webstore enter "TRF 60601-1" in the input field "Search".

How can TÜV SÜD Product Service assist you?

Due to our long-standing work in the relevant standards committees we have profound knowledge of the requirements defined by the standard. Our service for you:

- Training sessions on the 3rd edition of IEC 60601-1:2005+A1:2012
- On-site assessment of IEC 60601-1 risk management
- Development-attended testing and customer meetings to ensure correct understanding and application of the standard requirements related to your product
- Product testing and certification for markets worldwide

Your contact partner at TÜV SÜD Product Service can provide further information.

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