Choose certainty.
Add value.

IEC 60601-1 (Edition 3.2)

Make a smooth transition with reduced cost and complexity.

Your challenges

With the publication of IEC 60601-1:2005 + A1:2012 + A2:2020, otherwise known as IEC 60601-1 (Edition 3.2), medical device manufacturers must be aware of the varying regulatory transition periods worldwide. Based on past experience with previous transition periods of international standards worldwide, it can be concluded that, as well for the Amendment 2:2020 of IEC 60601-1, a transition period will be given of 3-4 years minimum in the most countries and regions. However, it is also possible that very few countries will require standard compliance with the predecessor standard (edition 3.1) for longer times.

In the general standard of IEC 60601-1 are 78 issues addressed by the amendment 2:2020. Further 32 issues are addressed by several collateral standards such as IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-10, etc. Beyond that referenced standards are either completely new or significantly updated, e.g. IEC 62133-2, IEC 62366-1:2015+A1:2020, IEC 62368-1:2018, ISO 14971:2019. The particular standards IEC 60601-2-XY are planned to be published within 2 years until August 2022, or if the responsible part 2 standard committee will not keep the date, it will be published by the IEC Central Office in a formal way only (update of referenced standards only).

What is IEC 60601-1 (Edition 3.2)?

IEC 60601 is a series of technical standards that ensure the safety of medical electrical equipment. IEC 60601-1 (Edition 3.2) deals with the basic safety and essential performance requirements of medical electrical equipment and systems, and serves to ensure that in normal condition and in fault conditions, no unacceptable risks for patients and/or operators will arise, e.g. related to electrical, mechanical, thermal and functional hazards.

It is assumed that public health authorities in many countries recognise IEC 60601-1 (Edition 3.2) as a pre-

requisite for the commercialisation of electrical medical equipment, at least after its transition period is over. IEC 60601-1 (Edition 3.2) is the newest published general standard with around 1500 single specific requirements. The requirements are often recognised as State-Of-The-Art (SOTA), and are required to be met in different markets around the globe.

Why is IEC 60601-1 (Edition 3.2) important for your business?

IEC 60601-1 (Edition 3.2) will probably become a widely accepted standard in the U.S., Canada, the EU, Japan, Brazil, Russia and Australia. Some major import countries and regions (e.g. EU and Australia) for such equipment are required to take into account the state-of-the-art (SOTA) requirements why newer IEC/ISO standards cannot be ignored after their typically given transition period of 3-4 years will be expired.

To avoid being denied entry into these and other markets, manufacturers with the goal to go worldwide on the market should ensure that their products comply with both the Edition 3.1 and 3.2 of the standard.

IEC 60601-1 (Edition 3.2) expertise from TÜV SÜD

Our experts actively participate in international advisory bodies and standardisation committees. This industry-leading expertise underpins the wide public awareness and first-class international reputation of the TÜV SÜD brand.

Our IEC 60601-1 (Edition 3.2) services

TÜV SÜD offers a full suite of testing and certification services for this standard that can be provided at our state-of-the-art facilities or on-site at your premises.

- **Product testing**
  We operate some of the world's most sophisticated test laboratories, which are capable of testing products to various electromagnetic compatibility, environmental and electrical safety, performance standards and systematic functional safety testing.

- **Certification**
  TÜV SÜD provides certification to safety standards and international standards (e.g. CB scheme and NRTL certification) to assist you in gaining market access for your products.

Your business benefits

- **Save time and money** – by ensuring your product is compliant to both editions in your first prototype, thereby avoiding costly delays in redesign.
- **Minimise risk** – with redesign development right from the beginning.
- **Benefit from global support** – with engineers in your local markets that speak your language and are capable of conducting tests and audits.
- **Work with a single-source partner** – that is an internationally recognised testing body with a strong presence in all major markets worldwide.

Why choose TÜV SÜD?

With over 700 dedicated medical health and services experts situated in major markets worldwide, TÜV SÜD is one of the largest Notified Bodies in the world and the only one to have its own clinical expert team. We also have a dedicated Regulatory Foreign Affairs & Clinical Department to monitor developments in regulations for medical health services and devices globally.

With the widest range of accreditations, we possess an in-depth understanding of international standards and the medical health services sector. In addition to regulatory and quality assurance expertise, TÜV SÜD's experts are also skilled in advanced medical device assessments for functional and software safety, especially related to essential performance.

Choose certainty. Add value.

TÜV SÜD is a premium quality, safety and sustainability company that specialises in testing, inspection, auditing and certifications.

Represented in over 800 locations worldwide, we hold accreditations in Europe, the Americas, the Middle East, Asia and Africa. By delivering services to our customers, we add tangible value to businesses, consumers and the environment.

Related services

TÜV SÜD provides the following related services:

- Assessments of clinical evaluations
- Expertise in high-risk medical devices
- Functional safety for medical devices – full product testing

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