Product Service

Add value.
Inspire trust.

Med-Info

International expert information
for the medical device industry

Transition of IEC/EN 60601-1
a) Edition 2.2 to Edition 3.0
b) Edition 3.0 to Edition 3.1

Background

Many customers ask when a new edition of IEC/EN 60601-1 should be applied to reach approvals in different markets worldwide. This is an important question because if a product is designed and tested according to an updated edition of IEC/EN 60601-1 solely and the intended markets have not yet changed over to this updated edition by the time the testing is finished, the product cannot be marketed in this specific market.

On the other hand, if a product is designed and tested according to an older edition of IEC/EN 60601-1 now and the intended markets change over to an updated edition of the general standard in the near future, an additional delta testing (and maybe redesign) will be required once transition periods have expired.

Note

Below you will find an informative guidance which may help you to make a decision about the timing when to apply an updated standard of IEC/EN 60601-1.

The guidance (see table beneath) has been compiled to our best knowledge and belief. However, for a legally binding statement relating to the required standard edition please contact the responsible health ministry of the target market.

Special considerations

TÜV SÜD will apply the following approach:

1. Risk management (RM): TÜV SÜD will evaluate the RM file with regard to plausibility and technical consistency as part of product testing, based on ISO 14971 and the philosophy outlined in the IEC/EN 60601-1 series. The approval systems MDD (CE) and IECEE (CB) both require evaluation of the RM file.
2. In the context of product testing, the evaluation of the RM file cannot be replaced by an ISO 14971 audit as the audit is process-related whereas the evaluation of each relevant hazard in the RM file is product-related.
3. Collateral standards in the CB Scheme:
   IEC System of Conformity Assessment Schemes for Electrotechnical Equipments and Components (IECEE) has defined which collateral standards may be excluded within CB testing projects. The details can be found in OD 2055 in the Rules, Operational Documents & Guides section of the IECEE webpage **iecee.org.**

Situation in selected markets

Region/ country	Required edition	Version to be applied	Transition period
EU	Essential Requirements (ER) must be met; Edition 3.1 recommended	ER must be met. Standard compliance is not mandatory. Edition 3.1 is closer to the ER and the state of the art (SOTA), therefore Edition 3.1 is recommended. Official Journal (OJ) list refers to: Edition 3.1	OJ list for presumption of conformity for EU member states: a) 2nd Edition expired on June 1, 2012 b) Edition 3.0 expired on December 21, 2017 c) Annex ZZ of Edition 3.0 expired on December 31, 2015 **Note:** Does not depend on part 2 standards as ER I.2 requires taking account of the generally acknowledged SOTA. Consequently, a gap analysis related to a mixture of editions needs to be conducted.
USA – FDA	Edition 3.1	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Edition 3.1: No time limitation for new submissions and for approved devices which undergo significant changes
USA – NRTL	Edition 2.2 or Edition 3.1	UL 60601-1:2003 or ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	For Edition 2.2 and UL 60601-1 several years expected
Canada – Health Canada	Edition 3.0 or Edition 3.1	IEC 60601-1:2005 or IEC 60601-1:2012	For new submissions or significant changes
Canada – SCC accreditation body	Edition 3.1	CAN/CSA-C22.2 No. 60601-1:2014	Edition 3.1: No time limitation
China – SFDA	Edition 2.2	GB 9706.1-2007	Edition 3.1 maybe planned for 2019 based on verbal information
Australia	Edition 3.1 or equivalent	Essential Principles of Safety and Performance must be met. SOTA is required.	Over, because TGA expects to meet SOTA to comply with Essential Principles of Safety and Performance (email dated January 25, 2013).
Brazil	Edition 3.1	IEC 60601-1:2012	Transition for Edition 2.2 expired on January 1, 2014
Russia	Edition 3.0	as ГОСТ Р МЭК 60601-1-2010	Unknown
IECEE – CB Scheme	Edition 2.2 or Edition 3.0 or Edition 3.1	IEC 60601-1:1988 and A1:1991 and A2:1995 or IEC 60601-1:2005 or IEC 60601-1:2012	No date for the withdrawal of the 2nd Edition mentioned (several years expected)

EU situation

The EU transition periods are independent from existing, non-existing, or non-updated part 2 standards. In general, newer versions of any IEC/ISO standards need to be regarded as new scientific knowledge and therefore need to be taken into account within the framework of the manufacturer's RM system. Within the transition period, a gap analysis related to the new standard edition is therefore expected. Transition period is usually three years from IEC/ISO publication of the standard, if not explicitly defined otherwise in the OJ list.

As the transition period is over, the following problem arises: Devices approved according to the 2nd Edition will no longer be allowed to be marketed in the EU if there is no objective evidence that the ER are met. Therefore, a gap analysis (= delta testing and assessment related to the newer standard) is required. See also ZLG paper 3.5 A1: **https://www.zlg.de/medizinprodukte/dokumente/antworten-und-beschluesse-ek-med.html**

Note

In reality, the vast majority of manufacturers are conducting testing according to the new standard edition instead of conducting a gap analysis. Background is that the new test reports are anyway needed for other international approvals. Furthermore, the involved effort is usually almost comparable.

Question & answer

Question:

My device approved according to the 2nd Edition has been on the market for several years without any critical incidents or near incidents being reported so far. Could I avoid time- and cost-intensive 3rd Edition delta testing and assessment by claiming that grandfathering (positive market experience) is regarded as my RM?

Answer, related to the EU:

Without delta testing and assessment no clause-by-clause objective evidence exists that it has been systematically checked whether the new and more stringent 3rd Edition requirements will lead to a safety problem with the product concerned. Thus a "general" RM statement even in combination with positive market experience (grandfathering) cannot replace delta testing and assessment.

However, once delta testing and assessment are done, "specific" RM (related to a specific clause/hazard of the 3rd Edition) including objective evidence of taking into account the generally acknowledged state of the art (SOTA) as required in ISO 14971 plus

a) for CE: evidence to comply with the ER of the MDD
b) for CB: alternative risk control (clause 4.5)

may be used to cover a specific hazard without redesign, even in the case that the result of delta testing indicates that it failed a specific 3rd Edition clause/requirement. In such a case, discussion in advance between the manufacturer and the certifier about the acceptability of the alternative safety method chosen by the manufacturer is highly recommended.

Recommendation

Based on the fact that some markets still require the 2nd Edition whilst others already have transferred to Edition 3.0 or even 3.1, both editions (2nd Edition + Edition 3.1) have to be tested for worldwide approval.

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

Martin Schneeberg
Phone: +49 89 5008-4476
Email: martin.schneeberg@tuev-sued.de