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Transition from 2nd Edition to 3rd Edition of IEC/EN 60601-1. Date of revision: August 30, 2012

Background

Currently many customers ask *when* the 3rd Edition of IEC 60601-1:2005 should be applied. This is an important question because if a product was designed and tested according to the 3rd Edition solely and the intended markets had not yet changed over to the 3rd Edition by the time when the testing was finished, the product could not be marketed.

On the other hand, if the product is designed and tested according to the 2nd Edition now and the intended markets change to the 3rd Edition in the near future, an additional delta testing (and maybe redesign) will be required once transition periods have expired.

Note

Below you will find some informative guidance which may help you to make a decision about the timing *when* to apply the 3rd Edition.

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 the product testing, based on ISO 14971 and the philosophy outlined in the IEC 60601-1 series.
   The approval systems MDD (CE) and IECEE (CB) 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:
   IECEE issued the "PAC/1727/PDSH" document which allows to exclude IEC 60601-1-2:2007 (EMC), IEC 60601-1-6:2010 (Usability)*, IEC 60601-1-9:2007 (Environment), and clause 11.7 (Biocompatibility, ISO 10993-X standards) from 2nd and 3rd Edition of IEC 60601-1 CB testing.
   This means that all other applicable collaterals and all other applicable clauses have to be included in the CB testing.

* Note that the exclusion of IEC 60601-1-6 is currently under discussion within IECEE CMC and it is expected that evaluation of this standard become mandatory soon.

Situation in selected markets

Region/ country	Today	Accepting 3rd Edition	Transition period	Remarks
EU	2nd Edition 3rd Edition	Yes, can be used. Note: Applicable part 2 and collateral standards shoud be used along with the ***correct*** Edition of the general standard.	The transition time for medical products without an applicable part 2 standard is June 6, 2012. Applicable part 2 standards could further change the transition period in ***both*** directions!	ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm
USA – FDA	2nd Edition 3rd Edition	Yes.	Until June 30, 2013 ➜ for ***new*** submissions. Maybe as well for safety relevant changes at 2nd Edition approved devices.	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=30270
USA – NRTL	2nd Edition + UL 60601-1:2003	Unknown. (OSHA's main concern is related to RM concept in ANSI/AAMI ES60601-1:2005)	Unknown.	www.osha.gov/dts/otpca/nrtl/allstds.html
Canada – Health Canada	2nd Edition 3rd Edition	Yes, can be used.	For new submissions. June 1, 2012 for products without a part 2 standard. Part 2 standards modify the transition time by +3 years from their publication.	www.hc-sc.gc.ca/dhp-mps/md-im/standards-normes/notice_iec_60601_avis-eng.php
Canada – NRTL	2nd Edition +CAN/CSA-C22.2No.60601.1-M90:2003	Unknown. (as CAN/CSA-C22.2 No. 60601-1-08).	Unknown.	www.ccohs.ca/
China – SFDA	2nd Edition	Unknown.	Unknown.	eng.sfda.gov.cn/WS03/CL0757/62136.html (GB 9706.1-2007 = 2nd Edition + A1 + A2 since 2008-07-01).
Japan	2nd Edition 3rd Edition	Yes, since June 1, 2012 as JIS T 60601-1:2012.	May 31, 2015	www.tuv-sud.jp/infoservice/pdf/20120601_06011_t601.pdf
Brazil	2nd Edition	Yes, can be used.	January 1, 2014	www.brasilsus.com.br/legislacoes/anvisa/108530-3.html
Russia	2nd Edition 3rd Edition	Yes. (as ГОСТ Р МЭК 60601-1-2010)	Unknown.	www.standards.ru/document/4583734.aspx
IECEE – CB scheme	2nd Edition 3rd Edition	Yes, can be used.	No date for the withdrawal of the 2nd Edition mentioned (several years expected).	dom5.iec.ch/iecee/ieceemembers.nsf/IECEEScopeInStandardByCat?ReadForm&PC=MED

Worst case scenario

In the EU, the use of harmonized standards is recommended, but not mandatory to show objective evidence that the essential requirements (ER) are fulfilled. The transition period for EN 60601-1 according to MDD will be:

a) for MEE without an applicable part 2 standard: June 1, 2012;
b) for MEE with an applicable part 2 standard: as defined by the EN part 2 standard (e.g. EN 60601-2-37:2008 defines October 1, 2010). Note that in this context EN ISO 80601-2-XX, EN IEC 80601-2-XX and any EN ISO XXXXX (e.g. EN ISO 15004-1:2009) standards which:
   - are listed in the OJ and
   - are based on the 3rd Edition of EN 60601-1:2006 (i.e. IEC 60601-1:2005)

   are regarded as well as a part 2 standard and their date of cessation applies.

When the transition period is over, the following problems could arise:

- 2nd Edition approved devices will no longer be allowed to be marketed in the EU if there is no objective evidence that the ER are met. The assumption of meeting the ER is based on the *valid* harmonized standards; in this case it would be the 3rd Edition. Therefore a delta testing and assessment (2nd Edition ➜ 3rd Edition) would be required (cf. also ZLG paper 3.5 A1: **www.zlg.de/medizinprodukte/dokumente/antworten-und-beschluesse-ek-med.html**)
- As a significant number of device manufacturers might require delta testing and assessment, test houses might be forced to increase testing lead times.

Question & answer

Question:

My 2nd Edition approved device 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 EU:

Without delta testing and assessment, no objective clause-by-clause 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. So a "general" RM statement even in combination with positive market experience (grandfathering) cannot replace delta testing and assessment.

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

a) for CE: evidence of compliance with the ER of the MDD,
b) for CB: equivalent safety (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 acceptability of the alternative safety method chosen by the manufacturer is highly recommended.

Recommendations

1. Based on the fact that some markets still require the 2nd Edition whilst others start to require the 3rd Edition, both editions have to be tested for worldwide approval.
2. Especially for manufacturers with several different devices to be tested, it is recommended not to wait until any possible transition time has expired, but to start gaining experience by beginning 3rd Edition testing asap.
3. For European CE marking, TÜV SÜD is part of the 3rd Edition expert team and has created a very helpful document about the implementation of the 3rd Edition of EN 60601-1:2006 within the scope of MDD 93/42/EEC. The document is dated February 6, 2012; version 1.1 can be found here: **www.team-nb.org/index.php?option=com_docman&task=cat_view&gid=17&Itemid=38&lang=en**

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

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