Working Document for NBRG

Frequently asked Questions related to the Implementation of EN 60601-1:2006 with respect to MDD 93/42/EEC

Clarification of open issues

First NB-MED released version for final commenting by NB's
Version 1.1 (this version includes the first comments of the NB-MED, resolved by the Issues Team, incl FAQ 3.3.3)

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History

During spring 2011, it was realized that the use of EN 60601-1 and its many family members in demonstrating compliance with the relevant and applicable requirements of the European medical device regulatory framework was not too trivial. While relevant guidance on the matter had been published at the CENELEC website as a Q&A document (click here), some Notified Bodies were giving advice that was felt to be not in line with that guidance. On other occasions, questions were raised that were not covered in the guidance.

So, it was concluded that the situation for electrical equipment in medical practice was not totally clear and that additional guidance would be useful. Further contact with the chair of the NB-MED confirmed this desirability, and a small group of experts – the 60601-1 Issues Team – was established. This group developed an enquiry asking for "practical issues in the implementation", that was sent by Cenelec TC 62 to many stakeholders in June 2011(see Annex 1). Also at the international level of IEC the request was distributed as 62A/769/INF in July 2011.

The response to the request was much larger than expected.

End of July 2011, the 60601-1 Issues Team started to work on digesting the issues submitted until then and it took until end of September 2011 until all material had been thoroughly discussed and answers formulated to the questions that were raised. In some cases, the questions were slightly amended to make them a little more general, and a few additional "connecting" questions were developed by the team.

The draft document was submitted to the NB-MED to scrutinize the proposed responses and see if they are also acceptable to all members of NB-MED. Their comments were discussed by the 60601-1 Issues Team and integrated by Jan 2012.

Eventually, the NB-MED approved this document which aims to give guidance on how to address issues around the implementation of EN 60601-1:2005 in Europe. The document is available on www.team-nb.org and the copyright remains with NB-MED and the Issues Team. Usage of this document within the "intended use" is free to everybody. See also chapter 5.

It is believed that the answers, developed in close cooperation with stakeholders, present a well-balanced response to the issues brought forward, and that they will prove to be of use as a reference for all stakeholders.

The 60601-1 Issues Team consisting of:

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expresses a big "THANK YOU" to all those who submitted the issues they saw or had experienced, often together with suggestions on how to address these.

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1. Introduction

This document is intended to clarify some of the many questions that relate to the implementation of EN 60601-1:2006 within the EU under the scope of MDD 93/42/EEC. This document intends to provide guidance on mostly non-technical matter that is relevant for application of the standard series.

This document intends to be reference for manufacturers of electrical equipment in medical practice that wish to use for compliance purposes the EN 60601-1:2006 and its many family members, as well as for **ALL** Notified Bodies dealing with medical electrical equipment, so that the standard will be used in a consistent manner for all electrical equipment in medical practice that are to be placed on the market in the EU.

2. Abbreviations

2nd edition	EN 60601-1:1990 (typically including the two subsequent Amendments)
3rd edition	EN 60601-1:2006 (typically NOT including Amendment 1)
A1	Amendment 1 of EN 60601-1:2006
CD	Committee Draft
CDV	Committee Draft for Vote
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
DKE	Deutsche Kommission Elektrotechnik (German Electrotechnical Committee)
DOCOPOCOSS	Date Of Cessation Of The Presumption Of Conformity Of The Superseded Standard
Edition 2	see 2nd edition
Edition 3	see 3rd edition
EN	European Norm
EU	European Union
ER	Essential Requirement, as set out in Annex I of the MDD
IEC	International Electrotechnical Commission
ISO	International Standardisation Organisation
MDD	Medical Devices Directive (93/42/EEC, in their latest version)
MEE	Medical Electrical Equipment
MES	Medical Electrical System
MNC	Minor Non-Conformity
NANDO	New Approach Notified and Designated Organisations
NB-MED	Notified Bodies accredited for Medical Devices
NC	Non-Conformity
OJEU	Official Journal of the European Union
PoC	Presumption of Conformity
RMF	Risk Management File
SOUP	Software Of Unknown Provenance

3. Questions and Answers

3.1. Process how to place products on the EU market

Question 3.1.1:

What is – briefly – the process for placing medical devices on the market in the EU?

Answer 3.1.1:

For a medical device to be legally placed on the market in the European Union, it must fulfil all the applicable requirements of the MDD, in particular the Essential Requirements specified in Annex I. This obligation holds for each device that is placed on the market (see interpretative document from EC; click here).

The manufacturer must demonstrate that all the applicable requirements are met. For all medical devices that are not class I, a Notified Body competent for medical devices (see the NANDO database for all New Approach Notified Bodies, click here), must verify the evidence and only then the manufacturer has the right to affix the CE-mark on the device and may place this on the market. Also for some class I devices, some aspects require Notified Body evaluation.

The manufacturer may use standards when demonstrating that the applicable MDD requirements have been met. If the manufacturer uses harmonized standards, he may use the concept of "presumption of conformity". This concept means that, if the relevant requirements of the harmonized standard are met, it can be presumed that the Essential Requirements covered by that standard are also met (see for more information the 'Blue Guide'; click here).

It should be recognized that the MDD contains requirements that are not covered by standards and in addition the requirement specification for the product may also add requirements that cannot be covered by testing to the standard. The Annex Z details the relationship between the standard and the essential requirements. The standard does not necessarily cover all applicable MDD requirements.

Question 3.1.2:

When the medical device is not modified, and the regulation does not change, why do I have to provide different evidence with a new harmonized standard?

Answer 3.1.2:

The MDD93/42/EC and AIMDD 90/385/EC require Medical Devices to conform with the essential requirements as given in the Annexes I. Compliance with harmonized standards evokes the presumption of conformity with the essential requirements covered. If such a standard is now no longer harmonized, because it was superseded by a revised version, the manufacturer can no longer rely on the presumption of conformity by using the superseded standard as .

Even if the manufacturer does not use harmonized standards for demonstrating that the medical device meets the legal requirements, the mere fact that a harmonized standard is replaced by another harmonized standard, indicates that the state of the art has changed and that additional effort and evidence will be needed. This state of the art requirement is mentioned in ER 2 of the MDD.

Note that this does not constitute an obligation to use the latest edition of a standard, because the application of harmonized standards is voluntary but the Technical Documentation

shall contain the justification for not using the standard and how the solution used by the manufacturer provide at least the same level of safety and performance as if the harmonised standard would have been used.

Question 3.1.3:

Is a harmonized standard then 'de facto' a mandatory standard?

Answer 3.1.3:

For most parts, standards are voluntary and this is also true for harmonized standards. However, because of the concept of "presumption of conformity", almost all manufacturers use the harmonized standards for practical reasons. The only exception to the voluntary nature of standard is for symbols, for which the use is mandatory if they have been published in a harmonized standard (see MDD ER 13.2: "Any symbol or identification colour used must conform to the harmonized standards.").

Question 3.1.4:

Is it really required to retest medical electrical equipment after the end of the transition period from the 2nd to the 3rd Edition has been reached, even if these products have been marketed for many years?

Answer 3.1.4:

In general: yes, retesting is necessary because of the many differences between 2nd edition and 3rd edition. When a standard is replaced by a successor, the differences between both version will determine whether retesting is sufficient or even redesign is needed. A specific analysis of the differences should be performed and be part of the Technical Documentation to demonstrate whether retesting is sufficient or not.

Question 3.1.5

Why should I bother about the 1 June 2012 date if my EC certificate is valid until 2014? Suppose an MDD class IIb or III electrical medical equipment was placed on the market in the EU in 2009. It has a signed EC Design-Examination Certificate by a NB based on 2nd edition of EN 60601-1 (with no particular standard), valid until 2014-01-01 (five years).

Is this product affected by the DOCOPOCOSS June 1st 2012 related to EN 60601-1:1990 (+ A1 + A2)?

Answer 3.1.5

The certificate validity date is not relevant for the described situation. The manufacturer is responsible that every individual device placed on the market complies with MDD, as described in the interpretative document published by EC (click here). This obligation includes having a process in place to remain compliant with the MDD at all times. Standards change, in that respect EN 60601-1:2006 is nothing special. This process ensures that changes of standards or regulations are captured, evaluated and actions are derived to comply with the state of the art.

That means that the manufacturer has the following options after having completed the new technical evidence:

a) For class III devices the assigned NB must review the updated Design Dossier.

For class IIb devices, the following alternative routes exist

b1) Verification of the updated Technical Documentation initiated by the NB (e.g. sampling, major change reported, additional device added to certificate), or

b2) Verification of the updated Technical Documentation at the first audit after the transition period. This will be easiest if the manufacturer has fully implemented EN 60601-1:2006.

(see also 3.7.2)

Question 3.1.6

If an MEE compliant with the 2nd edition of EN 60601-1 has been shipped before the transition time is over to a distribution centre, does this count as “placed on the market”?

Answer 3.1.6

It depends if that shipping can be seen as placing on the market; see also interpretative document from EC (click here).

a) If the distribution centre is part of the manufacturer: this does not count as "placing on the market"

b) If the distribution centre is not under the control of the manufacturer, then this counts as "placing on market".

Question 3.1.7

Can I replace a 2nd edition compliant device after the transition period? Assume an MEE compliant with 2nd edition of EN 60601-1, placed on the market before the end of the transition time of the 2nd edition, breaks down and needs to be replaced. Can I, based on end user request, send him an identical 2nd edition only compliant MEE?

Answer 3.1.7

No, in principle this is not allowed because its transition time is meanwhile over. That means that the 2nd edition does not anymore give the presumption of conformity with the applicable Essential Requirements of the MDD. The replacement MEE needs to comply with the regulations at the moment of placing on the market. Additional technical evidence –testing, possibly design changes- will be needed to demonstrate that the replacement device is safe and performing according to the harmonized requirements.

Questions 3.1.8

Why does EU require compliance with the 3rd edition for new and legacy products, while other markets require it only for new products?

Answer 3.1.8

As mentioned in answer 3.1.2, devices need to be “state of the art” when placed on the market. This principle holds for Europe, for the benefit of patients. Other jurisdictions have decided on different mechanism and, while we hope that regulatory schemes will converge in future, it is the autonomous decision of each jurisdiction.

Note that other markets often use the concept that no (major) change may occur in the design unless the whole MEE must comply with the new standard. Unlike very simple devices, a typical MEE undergoes multiple component level product changes per year. That makes this legacy concept not really useful in those markets for the longer term.

3.2. Transition process in general

Question 3.2.1:

Would it not have been better if the same end date was chosen for the loss of the presumption of conformity for **all** the standards related to 2nd edition of EN IEC 60601-1? Now it is all very confusing.

Answer 3.2.1:

In theory that could have been done, but it would not have been better. There were many independent working groups involved in writing the various document. Thus, each individual document in the EN 60601-series has been developed at its own pace and was published at its individual date. Additionally, for every kind of product, a different set of documents needs to be applied. As in fact, some documents have not even been finalized, this raises the question, when to set the end of a transition period that allows an appropriate transition period for all particulars.

Transition periods exist for a good reason: all involved that wish to use the standard should be allowed time to prepare for the new situation: compliance with revised standards may require design changes, or substantially altered test equipment or test protocols.

Question 3.2.2:

For a device shown to be in compliance with EN60601-1 2nd edition and the particular standard EN60601-2-34:2000 and for which a valid CE Certificate has been obtained, and for which no material changes have been made or are intended to be made, and which is intended to continue being placed in the market beyond June 1st, 2012, is the device manufacturer required to demonstrate compliance to EN60601-1 3rd Edition, EN60601-1-8:2007, and EN60601-2-34:2011(and make any required material changes to do so) in order to continue distributing product beyond June 1, 2012?

Answer 3.2.2:

In Europe, every single medical device that is placed on the market needs to fulfil the Essential Requirements of the MDD. According to Article 5 of the MDD, Member States shall presume compliance with the Essential Requirements if harmonized standards are applied. If the specific harmonized standard used to demonstrated compliance of a specific product to specific Essential Requirements changes at a given date, then every single medical device placed on the market after that date is supposed to be compliant with the changed or updated standard. This may include the application of Ed.3 even when before that date similar products were already placed on the market in compliance to Ed.2

For the specific situation described, the transition period of EN 60601-2-34:2012 (which is not yet released) will end 09.10.2014 – supersedes the DOCOPOCOSS of the main standard. In the event of more than one applicable particular standard, the latest DOCOPOCOSS takes precedence.

See also sections 3.1.1 and 3.5.

Question 3.2.3:

The end of the transition period of EN 60601-1:2006 at June 1, 2012 will require a large number of medical devices to be tested in the time remaining. The criticality of the situation is further increased, because:

- newly developed medical devices needs to be tested from EN 60601-1:2006, and

- medical devices already marketed in the EU and continued to be placed on the EU market after the product specific transition period is over, needs to be tested.

This conflicts with the bandwidth of the certification agencies and test labs which is limited today and will remain limited until the end of the transition period. Some calculations have led to the conclusion that at most 5% of the medical devices on the market in Europe will have evidence of 3rd edition compliance.

We don´t think a extension of the transition period would solve the problem, as the companies would just wait for the new deadline instead of starting their efforts (as they have done so far). We also don´t see how enforcing the current deadline would be feasible since it would close the European market to a large number of medical devices.

Another practice would be that test institutes and Notified Bodies somehow shortened the testing process what inevitably would lead to sub-standard work. How can it made sure that Notified Bodies will keep their high quality level even when this will result in the above disadvantages for the EU market?

Answer 3.2.3:

The situation is not that critical as described in the question, as June 1, 2012 is the deadline only for those products, for which not a single particular standard exists. There are a few particular standards whose transition time ends earlier, e.g. EN 60601-2-21 for infant radiant warmers (April 1, 2012), EN 60601-2-29 for radiotherapy simulators (Nov 1, 2011), EN 60601-2-37 for ultrasound equipment (Oct 1, 2010) and some others. But for the majority of particulars the transition time ends later. This spread in transition periods will soften the transition to the 3rd edition across the whole range of medical devices.

The Notified Bodies and test labs are fully committed and obliged by their Accreditation Bodies not to compromise their quality level just to make sure all medical devices will get an approval before the June, 1st, 2012.

3.3. Application of EN 60601-1

Question 3.3.1:

Is the EN 60601-1:2006 also applicable to AIMD products?

Answer 3.3.1:

Yes it is. The transition period ends on 1 June 2012; see:

http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/implantable-medical-devices/index_en.htm

Some examples of AIMDD certified products which contain external items, which fall under the scope of EN 60601-1:2006 are listed underneath:

- Programmer (for patients and physicians),
- Speech processor (cochlear implants),
- Power supply for active implantable medical devices
- For some circulatory support systems the pump will be regarded as a TYPE CF APPLIED PART additional to the requirements of the EN 45502-series.

Question 3.3.2:

Are the mechanical requirements of the 3rd edition standard relevant for non-active products?

Answer 3.3.2:

Here we have to give a two-fold answer: the scope of EN 60601-1 states that this standard is applicable to MEDICAL ELECTRICAL EQUIPMENT. That means non-active products are not covered by EN 60601-1.

Mechanical requirements of EN 60601-1 may be used for “non-active-medical-products” if for example:

- the “non-active-product” standards refer to EN 60601-1,
- standards for a specific type of non-active medical products are missing and testing companies create their own test programs, which might refer to EN 60601-1.

Question 3.3.3:

What requirements result from the application of Ed.3 to Power Supplies (PS) with respect to the following situations?

a) Since certification is done on MES level and not on the component level, can I have a MES certified to the 3rd edition even when the external power supply is only compliant to the 2nd edition?

b) What if the PS is a non-EN 60601 compliant product but, for example, approved against EN 60950?

c) And what if the power is supplied not simply by an external PS, but by a complete 2nd edition compliant MEE?

Answer 3.3.3:

These questions address a rather complicated matter and will be answered together. The use of an external 2nd edition power supply (PS) in a 3rd edition MES could be addressed by applying subclause 4.5 Equivalent Safety of EN 60601-1:2006. This requires the following steps which may be rather burdensome in practice:

- Step 1: Check whether the available 2nd edition test report is still valid, i.e. no undocumented changes have been made to the PS since the original testing.
- Step 2: Conduct the delta testing of the PS from the 2nd to the 3rd edition. If the delta test results in failed requirements, then the manufacturer must implement alternative measures which result in a residual risk equal to or less than that of the specific requirement of the 3rd edition.

According to subclause 8.2.1 of the EN 60601-1:2006, a MEE with a separate PS can be regarded as a MES. Such a MES would then consist of at least one Ed.3 approved MEE with one of the power supplies as described in Table 1.

Table 1: Some combinations of an Ed.3 approved MEE with various Power Supplies

Power Supplied by	**Description**	**Acceptable? [1])**
PS, Ed.2 approved	Under condition of clause 4.5 (see above steps 1 - 2)	Yes
PS, Ed.2 approved	After 1 June 2012	No [2])
PS, Ed.3 approved	-	Yes
PS, IEC 60950 approved	Only MOOP is required	Yes
PS, IEC 60950 approved	Also MOPP is required	No [3])
MEE, Ed.2 approved	Until end of transition period (DOCOPOCOSS) for MEE (defined the respective particular standard)	Yes
MEE, Ed.3 approved	-	Yes

[1]) Indicates whether the MES may be 3rd edition certified
[2]) Requires additional full delta-testing to 2nd to 3rd edition of EN 60601-1
[3]) Requires additional full delta-testing from IEC 60950 to 3rd edition of EN 60601-1

Note that the use of a PS in a MES, where the PS is approved only according to the 2nd edition cannot be justified by referring to only clause 16 of EN 60601-1:2006. Therefore, to fulfill the requirements of the 3rd edition, a PS which has fulfilled the 2nd edition must additionally pass delta testing to the 3rd edition or, if only MOOP is required, must pass additionally at least IEC 60950.

As additional technical information, some key technical differences between the 3rd and the 2nd edition are for example:

- Working Voltage and its HV-test, creapage distances, air clearance values
- thickness of insulation
- insulation between layers of PCB-boards
- using triple isolated wires
- using caps bridging the insulation barrier
- thermal cycling tests
- ….others

Question 3.3.4:

My supplier of integrated power supplies is not ready to offer a 3Ed compliant power supply early enough. What options do I have to make my MEE / MES 3 Ed compliant?

Answer 3.3.4:

There are several options, such as:

1. Look for a 3rd edition compliant power supply from a different supplier.
2. If only a Means of Operator Protection (MOOP) is required: it is allowed to use a power supply that complies with EN 60950-1:2005. In addition to the barrier requirements for MOOP according EN 60950, the 3rd edition contains additionally applicable requirements like leakage currents etc.
3. If MOPP is required: If the MEE or MES contains a 2Ed approved power supply, then this power supply needs to undergo a delta testing to 3Ed 60601-1.

Question 3.3.5:

Do we have to make documentation in 2nd edition and 3rd edition if we want to enter, say, the Japanese market?

Answer 3.3.5:

If manufacturers want to market their devices also in other countries than the EU, the local regulations n these other countries will have to be obeyed. If these countries require a different edition of IEC 60601-1 than the one harmonized in the EU as EN 60601-1, there is no way of avoiding application of multiple editions. This aspect includes the MEE documentation.

It needs to be repeated that in most countries the use of (international) standards remains voluntary.

Question 3.3.6:

Given that the rest of the world will not have implemented harmonized standards at the time of DOCOPOCOSS for EN 60601-1:2006, how can device manufacturers reasonably manage the disparity in world-wide standards as a practical business matter?

Answer 3.3.6:

Apply -worst case- both 2nd edition and 3rd edition requirements. See also Answer 3.3.7.

Question 3.3.7:

The EN 60601-1-4 standard for software engineering has been integrated in the 3rd edition but there is also the standard EN 62304 regarding software engineering. When should the EN 62304 be applied? When should the corresponding section of the EN 60601-1:2006 be applied?

Answer 3.3.7:

At the time when EN 60601-1:2006 was published, EN 62304:2006 was not yet available, because IEC 62304 was published only later in 2006. Therefore EN 60601-1:2006 could not refer to EN 62304:2006; this latter standard has become a harmonized standard by now.

For CE conformity: both clause 14 of EN 60601-1:2006 and EN 62304:2006 can be applied. However, EN 60601-1:2006 does not apply to stand alone software.

Question 3.3.8:

Example: A device is shown to be in compliance with EN 60601-1:1990 and this device contains software, which was developed, verified and validated within a design controlled system; however this software development effort cannot demonstrate compliance with EN 60601-1-4. If no software changes are to be made and it is intended to bring the device into compliance with the 3rd edition, is it possible to retrospectively update the software development device history file to capture the software development requirements of 3rd edition? Also, if gaps are identified in this analysis, is it possible to grandfather the gaps with appropriate risk analysis so that software does not have to be redesigned?

Answer 3.3.8:

Such a situation need to be discussed with the NB and the SOUP solution defined in EN 62304 may be used as a base for a solution.

Note: Additionally, state of the art should be considered

Question 3.3.9:

Some technical requirements in the EN 60601-1:2006 lead to a substantial redesign for 3rd edition compliance. For example, meeting the no bottom openings requirement (new in the 3rd edition) is requiring major redesign of existing equipment. Removing the holes has been found to require additional cooling schemes, and that is taking considerable time. Is there a smart way around that?

Answer 3.3.9:

Redesign of bottom openings, to meet the fire enclosure requirements, would probably not be needed. The reason is that the product is already compliant with 2nd edition and thus the risk of fire has already been established to be acceptable based on single fault condition testing, which is still a possible route in 3rd edition.

Question 3.3.10:

Where can the protocol (TRF) version "G" of the 3rd edition of IEC/EN 60601-1 be obtained?

Answer 3.3.10:

This document can be obtained from the IEC webstore at http://www.webstore.iec.ch

Always use the latest version (see also 3.8.6).

Question 3.3.11:

Is there a 3rd edition delta list available for evaluation of already approved (2nd edition) medical products which are already on the market?

Answer 3.3.11:

There is no IECEE delta TRF available, nor will it be created by IECEE. It is strongly recommended to use the official TRF 3rd edition Version “G” from December 2010, which is a full 3rd edition version.

3.4. Role of collateral standards

Question 3.4.1: Status of EN 60601-1-1 and EN 60601-1-4

What happens with current collateral standards like EN 60601-1-1 or EN 60601-1-4 as soon as the 3rd edition is binding (from 1 June 2012 in case of no parts 2)? Are they not relevant as standalone standards any more, or are they incorporated in full into EN 60601-1:2006 ?

Answer 3.4.1:

First of all, the 3rd edition will not become binding, not on 1 June 2012 and not at any other date: all harmonized standards are VOLUNTARY standards. Per 1 June 2012, the 2nd edition will lose its presumption of conformity with the Essential Requirements of the MDD (or AIMD) that it covers, unless there is an applicable part 2 in which case it is called from that part 2 as a normative reference. After 1 June 2012, the 2nd edition of EN 60601-1 will disappear from the OJ list as an independent, harmonized standard.

Note that collateral standards are considered extensions of the basic standard, additional sections if you will. The 3rd edition states clearly in clause 1.3: “Applicable collateral standards … shall apply together with this standard”. Separate listing of collateral standards in the OJ does not mean they can be used as independent, standalone standards.

EN 60601-1-1 and EN 60601-1-4 are collaterals referring to the 2nd edition of EN 60601-1. Their content has essentially been integrated in the 3rd edition. When the 2nd edition of EN 60601-1 no longer gives the presumption of conformity, these collaterals also lose their presumption of conformity.

Question 3.4.2:

What about Collateral standards without an edition relating to the 2nd edition?

For a specific group of MEE and MES a first edition of a collateral standard relates to EN 60601-1:2006 and is work in progress or has recently been published. For these collaterals, there are no editions available relating to the 2nd edition, such as:

- EN 60601-1-10: collateral standard for MEE and MES for the development of physiologic closed-loop controllers (published in the OJ list since 27. November 2008)
- EN 60601-1-11: collateral standard for MEE and MES used in the home healthcare environment (published in the OJ list since 18. January 2011)
- EN 60601-1-12: collateral standard for MEE and MES used in the emergency services environment (IEC work item approved on 18. March 2011)

Is there any guidance beyond the general advice to discuss specific problems related to the application of these new collateral standards with the NB and using Risk Management?

What transition period can be expected for the application of those collaterals?

Answer 3.4.2:

According to subclause 1.3 of Ed.3 collateral standards become normative at the date of their publication and shall apply together with the General Standard. if a totally new collateral standard, a part 1, is published and listed in the OJ, there is no indication of a transition period. However, it is not possible to implement a new standard into an existing product over night. Therefore, if there is no part 2, it is recommended that the NB accommodates an adoption period of 3 years after the date of ratification of the EN. This date of ratification can be found at the CENELEC website (www.cenelec.eu).

If a part 2 exists, and it is compatible to the 2nd edition of EN 60601-1, the new collateral standard does not apply for those products.

If the part 2 is compatible to the 3rd edition, and published prior to the new collateral, also then the new collateral does not apply since the development of the part 2 could not take the new collateral into account.

If a part 2 is revised after publication of the new collateral, then the transition period is determined by the revised part 2.

A typical transition period would be 3 years .

3.5. Role of particular standards (multiple or late particulars)

Question 3.5.1:

Many standards exist for X-ray equipment. Please explain how EN 60601-2-28, EN 60601-2-43, EN 60601-2-44, EN 60601-2-45, EN 60601-2-54, EN 60601-2-63, EN 60601-2-65, and EN 60601-1-3 can be applied.

Answer 3.5.1:

First of all, the contents of EN 60601-2-7 and EN 60601-2-32 have been incorporated into the General Standard or applicable particular standards refering to the 3rd edition of EN 60601-1.

The standards EN 60601-2-43, EN 60601-2-44, EN 60601-2-45, EN 60601-2-54, EN 60601-2-63, and EN 60601-2-65 are comprehensive product standards for assembled X-ray equipment, and exclude each other. The EN 60601-1-3 is referenced from all of these documents and includes general requirements for all diagnostic X-ray equipment. EN 60601-2-28 should be considered as a supplementary standard for equipment, to be used, where the product specific standards are not sufficient. But it is a key standard, when an X-ray tube needs to be CE marked on its own.

For a detailed discussion of what of these particular standards should be applied to what equipment and with what consequences on the transition process, refer to Annex 1.

Question 3.5.2:

If a given X-ray MEE can be used for interventional and non-interventional procedures, is it necessary to apply both EN 60601- 2-43 and EN 60601-2-54?

Answer 3.5.2:

First of all, EN 60601-2-43 applies; this standard references specific clauses out of EN 60601-2-54. Those referenced clauses apply for the non-interventional aspects. The other clauses of -2-54 should be considered for non-interventional aspects based on the outcome of the Risk Mgmt process.

Question 3.5.3:

As of October 2011, there are still a few particular standards referencing 2nd edition for which there is no EN or IEC project approved to adapt them to the 3rd edition. Is there a fixed deadline until when an updated particular must be available? What happens if the work on a particular finishes after June 1, 2012?

Answer 3.5.3:

No, there is no deadline when a part 2 standard must be updated.

A limited number of particulars will not at all be updated to the 3rd edition, or will be late in their process to be updated. As long as the version of the part 2 which references the 2nd edition is listed in the OJ, then this “old” particular can be used to claim the presumption of conformity. If IEC withdraws this “old” particular without replacement, then it will also be withdrawn from the OJ without replacement at some point in time. Immediately after that date, only EN 60601-1:2006 and relevant collaterals can give the presumption of conformity.

Therefore it is recommended that manufacturers should contact standard committees to find out the status of updating the specific part 2 to the structure of the 3rd edition.

Question 3.5.4:
Is compliance with EN 60601-1:2006 required after June 1, 2012 even if the part 2 standard (e.g. EN 60601-2-24) will not be released by the end of the transition period?

Answer 3.5.4:
The part 2 standard defines the transition period. Therefore, the 2nd edition of EN 60601-1, as a normative reference in the part 2, can still be used after 1 June 2012, if the specific transition period for the part 2 standard has not expired for the type of MEE in question. As long as the 2nd edition related part 2 remains listed in the OJ, it can be used to claim presumption of conformity to the ER.

Question 3.5.5:
One of the particular standards to EN 60601-1 2nd edition that have not been revised to comply with the 3rd edition is EN 13544-1:2007 + A1:2009 (Respiratory therapy equipment – Part 1: Nebulising systems and their components). This is a European Standard which "specifies requirements for nebulising systems used for the delivery of drugs in an aerosol from to humans through the respiratory system." It is based on EN 60601-1:1990 and it claims itself to be a particular standard. What standard has priority for products in scope, EN 13544-1:2007 + A1:2009 or EN 60601-1:2006? Do products in scope have to fulfil EN 60601-1:2006 after June 1, 2012?

Answer 3.5.5:

Currently, EN 13544-1:2007 + A1:2009 is on the OJ list of harmonized standards and hence gives presumption of conformity to the MDD Essential Requirements according to the Annex ZA for all products in its scope. It is specifically dedicated to respiratory therapy equipment and makes use by reference of other standards, especially EN 60601-1:1990. Simply the fact that EN 60601-1:1990 as one of the referenced standards will no longer be harmonized has no influence on the evocation of the presumption of conformity when applying EN 13544-1:2007 + A1:2009.

As long as there is no revised version of EN 13544-1 (i.e. Ed.2 of EN 13544-1) available and as long as the DOCOPOCOSS of Ed.2 of EN 13544-1 has not yet been passed, there is no need to apply EN 60601-1:2006. That standard, EN 60601-1:2006, would apply when in the future the next edition of EN 13544-1 will be based on EN 60601-1:2006 and after its DOCOPOCOSS has been passed.

Question 3.5.6:

Can every kind of IEC or ISO standard act as a particular standard and overrule the transition period 1 June 2012 of EN 60601-1:2006?

Answer 3.5.6:

A standard becomes a particular standard to EN 60601-1:2006 in the scope of MDD if

- the EN version of that standard is listed in the OJ, and
- it has a normative reference to EN 60601-1:2006, and
- addresses–normatively- clauses X.Y.Z of EN 60601-1:2006 or of associated collateral standards in such a form that they:
    - apply, or
    - apply with exception of …., or

- do not apply, or
- are replaced by the following requirements: ....)

3.6. Transition period of EN 60601-1:2006

Question 3.6.1:

For an MEE there is no particular standard available related to the 2nd edition of EN 60601-1. However, for this MEE a totally new particular standard related to EN 60601-1:2006 is work in progress. Examples are:

- EN 60601-2-63: for dental extra-oral x-ray equipment,
- EN 60601-2-66: hearing aids and hearing systems.

Can a 3 years transition period for the EN 60601-2-XY be claimed starting from publication of the EN version of the particular standard?

Answer 3.6.1:

If a totally new part 2 is published, and listed in the OJ, there is no indication of a transition period. However, it is recommended that the NB accommodates an adoption period of 3 years after the date of ratification of the EN. This date can be found at the CENELEC website (www.cenelec.eu).

In general, as indicated before, the part 2 is the leading standard. This also applies to the adoption period.

If the new part 2 is harmonized before 1June 2012, then a 3 years adoption period can be agreed after consultation of the Notified Body.

If the part 2 is harmonized after 1 June 2012, then after 1 June 2012 in principle only the EN 60601-1:2006 including applicable collaterals give presumption of conformity to the ER. However the information in the future part 2 may already be used. See also the table provided with answer 3.7.2.

Question 3.6.2:

Is there a current example of a product specific particular standard with an end of its transition period after 1 June 2012?

Answer 3.6.2:

There are several, see OJEU list. One example is EN 60601-2-43 (x-ray equipment for interventional procedures; end of transition period 1 June 2013). Some particular standards, like EN 60601-2-33 (magnetic resonance equipment for medical diagnosis) have already been published as standards relating to the 3rd edition but are not yet listed in the OJEU; it can be assumed that the end of the transition period will be after 1 June 2012.

Question 3.6.3:

Is the transition date already known for EN 60601-2-49?

Answer 3.6.3:

Not known at the moment (2011-09-30). We recommend to subscribe to one of the various internet based services e.g. offered from CENELEC or the EU Commission to be notified of any change of the European status of a specific standard or the list of standards harmonized under the EU MDD.

Question 3.6.4:

My product is in the scope of EN 60601-2-43, which has a transition period ending 1 June 2013. Is the product supposed to be in compliance with EN 60601-1:2006 and its collaterals per 1 June 2012, when their transition period ends?

Answer 3.6.4:

No. Where a part 2 exists, the transition period of that part 2 is leading. Be aware, it is not possible to mix standards referring to different versions of EN 60601-1, if compliance is claimed using the PoC route to CE marking. Therefore, if you use EN 60601-2-43:2000 to claim the PoC after 1 June 2012 (but before 1 June 2013) it includes the 2nd edition of EN 60601-1.

Question 3.6.5

My product is in scope of EN 60601-2-2 (HF generators) and EN 60601-2-10 (nerv and muscle stimulators). While EN 60601-2-2:2009 is already published compliant to 3rd Edition of EN 60601-1, the current version of EN 60601-2-10 is not. Is it possible to apply the “old” -2-10 together with -2-2 which references Ed.3 of EN 60601-1?

Answer 3.6.5

In principle, it is not possible to claim compliance with -2-10 and -2-2 at the same time, because that would mix different editions of the General Standard. However, the manufacturer can use -2-2:2009 based on Ed.3 of EN 60601-1 and use applicable elements of EN 60601-2-10 to demonstrate compliance to the MDD ERs.

3.7. Duties of Notified Bodies

Question 3.7.1:

Is ZLG paper 3.5 A1 legally binding for EU NB's and MEE manufacturers?

The ZLG-paper 3.5 A1 addresses a valid concern in an extremely clear way: "The missing new assessment by the manufacturer after the end of the "doc" or the missing knowledge about the existing of new harmonized standards or scientific knowhow are substantial NON-conformities. If these NON-conformities will not be adequate corrected, the certificates have to be suspended or withdrawn."

Is this paper legally binding? Am I allowed to ignore it? In clear words: If the transition period is over and there is no objective evidence about EN 60601-1:2006 requirements in a point-by-point protocol format, is the NB forced to suspend or withdraw the CE-certificate? No incidents have been reported over 10 years at the 2nd edition EN 60601-1 approved device. For the MDD, compliance with harmonized standards is not mandatory. Why should I fulfil the requirements of EN 60601-1:2006?

Answer 3.7.1:

The ZLG paper 3.5 A1 is an instruction to the Notified Bodies supervised by the ZLG* and needs to be adhered to by those Notified Bodies.

Legally binding is the MDD which contains the ERs in Annex I. Objective evidence of compliance with the ER needs to be demonstrated by the manufacturer.

That no incidents have been reported so far during the last 10 years is not objective evidence for compliance with the applicable ER, i.e. the presumption of conformity is not given. Keep in mind that the 2nd edition requirements reflect the state of the art from 1995 (Amendment 2)

*ZLG : German Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices

See also Answer 3.1.2.

Question 3.7.2:

How shall Notified Bodies act if objective evidence of conformity with the ER by using harmonized standards out of the EN 60601-1:2006 series is not fully given?

Answer 3.7.2:

Due to the Equivalence Principle, objective evidence to meet the Essential Requirements can be demonstrated by other means than taking reference to the General standard. Consequently the manufacturer had to evaluate, verify and validate whether he can ensure an equivalent level of safety compared to fully complying with EN 60601-1, 3rd Ed..

Tab. 1 describes the recommended outcome of an audit performed by the Notified Body when the manufacturer is not fully compliant to Ed.3 depending on the time when the audit will be performed.

Table 1: Recommended responses of NBs on typical situations when auditing manufacturers

Time	No.	Situation	Details	Rating	Required action, comment
Before 2012.06.01 +/- time of part two standards e.g. IEC 60601-2-xx	1	No evidence for complying with future based 3Ed ER of MDD	No procedure how to handle regulatory changes	Observation	QM System not able to handle reg. changes
	2	Plan for implementation of 3Ed is available	Assessment not started or assessment started or purchase order sent to lab.	Observation	This is as well a hint, because to write a plan and to send an order does not necessarily mean, that the manufacturer is in a proper time line for the future 3Ed
	3	Testing of 3Ed has started		Observation	See #2. Note: If the client has several different MEE's and for one the testing is started, that does not mean that for all of his MEE's the transition time could be met.
First audit after transition time is over, e.g. after 2012.06.01, if no part standard deviates the transition period	4	No evidence for complying with ER of MDD, because either the 3Ed TRF is missing or the gap analysis & gap testing (evaluation) between 2Ed & 3Ed is missing	No procedure how to handle regulatory changes or procedure exist but not followed	NC	Req. action: procedure for reg. Changes (1), action plan (2), RM (3), Vigilance system (4).
	5	Like #4, but plan is available	Assessment not started or assessment started or purchase order sent to lab.	NC	Like #4, because objective evidence of meeting the ER is still missing.
	6	Like #5, but testing has started	First results are available	MNC or NC	Depending on risk of product and completeness of implementation first results findings.
Second audit after transition time is over, e.g. after 2013.06.01	7	No evidence for complying with ER of MDD.		NC	Suspension of certificate or reduction of scope
	8	Plan is available		NC	Suspension of certificate or reduction of scope
	9	Plan available, testing not finished		NC	Suspension of certificate or reduction of scope

NOTE: A NC will not be issued if deviation from the harmonized standards is properly substantiated by other objective evidence to meet the relevant ER.

3.8. Application of Risk Management

Question 3.8.1:

Clause 4.2 of EN 60601-1:2006 calls for implementation of risk management according to EN ISO 14971. Compliance is to be checked by inspection of the risk management file.

However, according to MDD, Annex II, clauses 4.1 to 4.3 and Annex III, clause 4.1, the Notified Body is required to examine and assess (i.e. evaluate) the risk management file, what is more than just inspection.

How deep should the RMF inspection / evaluation by the Notified Body go?

Answer:

The MDD is the applicable regulatory framework, and EN 60601-1 is a very useful support tool. The MDD has a mandatory character for NB-MED.

Risk management or, rather, its implementation, is the full responsibility of the manufacturer, but is evaluated by the NB. When the Notified Body evaluates the RMF, a reasonable approach should be adopted.

First, the NB should evaluate whether the overall process implemented by the manufacturer is based on EN ISO 14971, and assess if it covers all the relevant areas of potential hazards.

Second, the NB should evaluate if the risk acceptability is based on:

- relevant international standards, and/or
- regional regulations, and/or
- current values of society / state of the art.

Third, for all clauses where EN 60601-1 requires conducting RM, the Notified Body should check plausibility and technical consistency.

In addition and where deemed necessary, the Notified Body will select a few risks for a more in-depth evaluation. Typically this could include risks:

a) that are estimated as high risks,

b) for which the manufacturer makes use of Clause 4.5 (Equivalent Safety),

c) which have been identified for the first time as they result from innovative technology,

d) which are judged acceptable after a risk/benefit analysis (clause 6.5 of EN ISO 14971:2000),

e) which are judged acceptable according to their probability of occurrence of harm and the severity of that harm, but without applying mitigation measures,

f) for which the Notified Body decides that they require a deeper evaluation, e.g. if there are reasonable doubts that the state of the art is fulfilled.

Question 3.8.2:

What are the *duties of the test house* with respect to the RMF?

Answer 3.8.2:
Checking projects for compliance with EN 60601-1:2006 (incl. applicable collateral and particular standards) requires a 100% verification of all applicable clauses of that standard. This includes all those clauses which refer to RM.

If the manufacturer deviates from any of the verifiable requirements of the standard, he must demonstrate equivalent safety (see clause 4.5), usually the outcome of the risk management process, to be verified by the test house.

For new hazards, e.g. associated with innovative technology, the manufacturer has the duty to include them in his risk management process and also has to work with the test house for proper verification. Clause 4.5 is not applicable for such hazards.

Question 3.8.3:

My risk management process is certified according to EN ISO 14971. Do I need to have my risk management file evaluated for compliance with EN 60601-1:2006, in addition?

Answer 3.8.3:

Yes, if compliance to EN 60601-1:2006 is claimed for every medical device, the risk management file needs to be inspected as it contains device specific technical information. According to MDD, Annex II, clauses 4.1 to 4.3 and Annex III, clause 4.1, the Notified Body is required to examine and assess the risk management file.

Note that certification of the risk management process is not required by EN 60601-1:2006 nor by the MDD, and cannot replace inspection of the RMF or its evaluation, respectively.

Question 3.8.4:

Can I deviate from the requirements in the 3rd edition?

Example: A device is in compliance with the 2nd edition of EN60601-1, and, therefore, does not comply with the latest EN60601-1-8 standard with respect to alarm tones. If this device was made 3rd edition compliant, including with EN60601-1-8:2007, it would have significantly differing alarm tones. If such an updated device is placed in facilities that also have older devices, this could be considered a safety risk due to the reduced usability for clinicians who are used to the previously used alarm tones and now are alarmed by different tones which all have the same meaning? Can the manufacturer reasonably justify **not** changing the alarm tones but still be considered in compliance with 3rd edition?

Answer 3.8.4:

Related to the general question “Can I deviate from requirements of the 3rd edition”, the answer is: YES, this is possible even within EN 60601-1:2006. However the majority of requirements in the 3rd edition is not linked to RM and therefore in case of deviating from that objective evidence of fulfilling clause 4.5 “Equivalent Safety” is needed for compliance to EN 60601-1:2006.

When EN 60601-1:2006 has been used to demonstrate that certain requirements of the MDD have been properly met, as part of the effort to meet all the applicable MDD requirements, the medical equipment can be legally CE-marked and placed on the market in the European Union.

When placing a single device in an environment where it would create a hazardous situation due to the implemented alarm schemes, modifications should be made to mitigate these risks. Strictly speaking, the device may be no longer in compliance with the requirements of EN 60601-1:2006 and if that is the case, just as strictly, the presumption of conformity is not valid for that aspect and, hence, neither is the CE-mark for that individual device. However, provided that the deviation is properly documented by and communicated to both the manufacturer and the customer, this approach is acceptable.

If it can be foreseen that a situation such as described may occur more frequently than once in a lifetime, it should be considered within the regular risk management. A dedicated solu-

tion may be developed and agreed with the Notified Body. Again, this is under the condition of adequate documentation and further arrangement. For example, the Notified Body may require that the equipment can be reprogrammed to provide the new alarm tones for the time all equipment compliant to the 2nd edition has been phased out of the hospital.

Note: the co-convener of the committee that developed EN 60601-1-8:2007 has stated that the 2007 edition, compatible with the EN 60601-1:2006, allows for multiple alarm schemes so that certain adaptations can be made without losing the compliance with EN 60601-1-8:2002.

Question 3.8.5:

What about aligning Risk Management Systems resulting from EN 14971:2001 and 2007?

Answer 3.8.5:

The process to manage risks was introduced with the first publication of EN 14971 in 2001. This version of EN 14971 is referenced by EN 60601-1:2006. However, EN 14971:2007 is the only harmonized version in EU. However, since the differences between both editions of EN 14971 mainly focus on the structure and from a technical point of view are rather negligible, it should be allowed to implement EN 14971:2007 instead of EN 14971:2001.

Question 3.8.6:

While medical device manufacturers implemented Risk Management Systems, many are not based on EN 60601-1:2006. This has proven to be a problem with mapping to the Rev. G of TRF for IEC 60601-1:2005.

Is it required to apply Rev. G of TRF for IEC 60601-1:2005 to comply with EN 60601-1:2006?

Answer 3.8.6:

In their assessment of the Risk Management documentation, relevant for EN 60601-1:2006 compliance, Notified Bodies will verify the content and references of the RMF with a reasonable level of profoundness, regardless of whether Rev. G of the IEC 60601-1 TRF applies. At the moment the IECEE TRF rev G is the latest available TRF. It is recommended to use the latest revision of the IECEE TRF because many NBs involved in the IECEE CB scheme contributed to its continuous improvement. However, this does not mean, that other forms cannot be used to document the Risk Management process with respect to the MDD.

3.9. Amendment 1 related questions

Question 3.9.1:

Is there an amendment of EN 60601-1:2005 on its way?

We have been told that an amendment to EN 60601-1:2006 is in preparation. How will this Amendment 1 fit in the whole EN 60601-1 series of standards, and will the Amendment 1 get a 3 year transition period?

Answer 3.9.1:

It is correct that the first Amendment (A1) of IEC 60601-1:2005, which will result in the first Amendment of EN 60601-1:2006, is under preparation. In fact, the CDV of A1 was approved end of August 2011. Following this approval, it is expected that IEC will publish A1 around September 2012. The EN version, because of the parallel voting, will be published most likely towards the end of 2012. In this case the transition period will likely end at the end of 2015.

Question 3.9.2:

What will be the role of the particulars related to the 3rd edition and also collaterals related to the 3rd edition in the context of A1 with respect to time lines?

Answer 3.9.2:

Particular standards are the leading standards with respect to the transition period from the 2nd to the 3rd edition. Most particular standards have a dated reference to EN 60601-1 and its collaterals. They determine what edition of EN 60601-1 applies. If the particular standard is revised based on A1 of the 3rd edition, and if the transition period of that revised specific particular is over, then the 3rd edition including A1 is fully applicable for the kind of MEE/MES under consideration.

If a particular standard is NOT yet revised, in general, the A1 cannot be applied for such kind of MEE/MES. However, if A1 solves technical issues, manufacturers should contact their Notified Body whether they can apply A1 in total or just the corrected requirements.

Question 3.9.3:

With the A1 to EN 60601-1, 3rd edition, how to demonstrate compliance?

Can compliance with A1 be demonstrated by gap analysis and risk management, or does the MEE have to be retested at an accredited test house?

Answer 3.9.3:

Medical Electrical Equipment (MEE) and Medical Electrical System (MES) that claim compliance to Ed.3 and A1 will have to be (re)tested according to Ed.3 and A1.

A1 will amend EN 60601-1. A new version that consolidates Ed.3 and the A1 will be published as Edition 3.1. With the publication of this amendment, most or even all collateral standards and particular standards will likely need to be amended. As a consequence, A1 will lead to a “new” generation of the EN 60601-1 series of standard that cannot be mixed with Edition 3.0.

Question 3.9.4:

Can I use A1 of EN 60601-1:2006 before its publication in the EU OJ?

Can I use edition 3.1, rather than Edition 3.0 before its publication in the EU OJ, e.g. immediately after its publication by IEC? A1 contains fewer references to the RM and to the tables. Is it possible to move straight from the 2nd edition to A1 of the 3rd edition already before its harmonization?

Answer 3.9.4:

Amendment 1 of EN 60601-1:2006 has not yet been published and is therefore not applicable. Until it will be published in the Official Journal it cannot be used to claim presumption of conformity with the Essential Requirements of the MDD.

However, in consultation with your Notified Body, you may use solutions from A1 as an exception to demonstrate that the requirements of the MDD have been met. Formally, this approach will not give full compliance with Edition 3.0. But as A1 is basically intended to resolve errors and unclear requirements in Edition 3.0, such an exceptional approach may be accepted by your Notified Body.

Question 3.9.5:

Can I use the requirement for Movement over a threshold from A1, as this is easier to comply with?

Clause 9.4.2.4.3 defines requirements for the movement over a threshold. We had a problem to modify castors of our consoles to be able to move over 20 mm threshold without unacceptable risk. Our notified body told us that the A1 will reduce the threshold from 20 to 10 mm. We are in the process of to certify our products for compliance to 3rd edition, but we have not seen this change yet. When can we expect that 20 mm will be changed to 10 mm?

Answer 3.9.5:

The threshold test in the existing standard EN 60601-1:2006 contains a technical error. This error has been corrected in the CDV of A1 which was approved late August 2011. The threshold has been set to 10 mm and it contains a radius of 2 mm at the edge. In addition, the speed of movement has been doubled to 0,8 m/s.

See also answer 3.9.4. The question 3.9.5 relates to one example where the value as given in A1 may be used, yet only after consultation with your Notified Body, as additional conditions have been added in A1. With the publication of A1 in September 2012, the modified test conditions should be accepted.

4. References

IEC document 62A/769/INF

This INF document was published on 2011-07-29 and informed the members of IEC SC 62A on the Request for Issues on the use of the EN 60601-1:2006 for CE-conformity purposes as circulated by Cenelec TC 62. Feedback was requested by 30 September 2011 to the e-mail address 60601Ed3.NBMED.issues@gmail.com.

5. Recommendation for usage

This document is for all stakeholders involved in the process of compliance with the MDD Essential Requirements on the basis of EN 60601-1 and related standards. It aims to give guidance how to address matters resulting from the transition from the 2nd to the 3rd Edition of EN 60601-1 rather than technical issues.

Even when substantial effort has been made to provide clear answers, some may be improved further. Also, additional issues may pop-up as the transition process develops. Any stakeholder is invited to submit comments, suggestions and additional issues to 60601Ed3.NBMED.issues@gmail.com.

It is the goal of the 60601-1 Issues Team and the NB-MED to support the transition process to all stakeholders benefit. Depending on the feedback received in the future, the 60601-1 Issues Team and the NB-MED will decide on the publication of an update.

Annex 1 Applicability of horizontal and role of particular standards (multiple or late particulars) for use in combination with IEC/EN 60601-1, 3rd.ed with respect to X-ray equipment

Note that for many standards, the transition period is still ongoing (see table 2) and therefore, the manufacturer may continue to claim presumption of conformity on the basis of the 2nd edition.

1. General – applicability of standards

EN 60601-1:2006 (ed. 3)

Objective: General requirements for basic safety and essential performance. This is the main standard and applies either by itself or with any part 1 (collateral standard) and any part 2. In fact, all collateral standards (parts 1) are considered to be an integral part of the main standard, and no particular standard (part 2) can be used without the main standard and relevant collaterals.

EN 60601-1-2:2001(ed.3) Electromagnetic compatibility - Requirements and tests,

Object: The object of this collateral standard is to specify general requirements and tests for electromagnetic compatibility of ME equipment and ME Systems. They are in addition to the requirements of the general standard and serve as the basis for particular standards

EN 60601-1-3:2008 (ed.2), DIN EN 60601-1-3:2010

Object: General requirements for protection against X-radiation in X-ray equipment in order that the irradiation of the human patient, the operator, staff and members of the public can be kept as low as reasonably achievable without jeopardizing the benefit of the radiological procedure.

EN 60601-1-6:2004(ed.3), DIN EN 60601-1-6:2010-10

Object: The object of this collateral standard is to specify general requirements (rem.: for usability) that are in addition to those of the general standard and to serve as the basis for particular standards.

EN 60601-1-8:2007 (ed.2), DIN EN 60601-1-8:2008-02

General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Object: The object of this collateral standard is to specify basic safety and essential performance requirements and tests for ALARM SYSTEMS with respect to ME Equipment and ME Systems and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent Alarm signals and consistent control states and their marking for all Alarm Systems

EN 60601-1-10:2008 (Ed.1), DIN EN 60601-1-10:2008-11

Requirements for the development of physiologic closed-loop controllers

Object:

The object of this collateral standard is to specify general requirements for the development of physiologic closed-loop controllers that are in addition to those of the general standard and to serve as the basis for particular standards.

EN 60601-2-28:2010 (ed.2), DIN EN 60601-2-28:2010

Object: The object of this particular standard is to establish particular safety and essential performance requirements for X-ray tube assemblies for medical diagnostics

EN 60601-2-43:2010, DIN EN 60601-2-43:2011

Object: The object of this particular standard is to establish particular basic safety and essential performance requirements for X-ray equipment for interventional procedures and the information to be provided with such equipment.

Note: for a given x-ray MEE which can be used both for interventional and non-interventional procedures, those clauses of EN 60601-2-54 apply which are specifically referenced by EN 60601-2-43.

EN 60601-2-44:2009 (ed.3), DIN EN 60601-2-44:2010

Object: The object of this particular standard is to establish particular basic safety and essential performance requirements for X-ray equipment for computed tomography

EN 60601-2-45:2011 (ed.3), DIN IEC 60601-2-45:2009

Object: The object of this particular standard is to establish particular basic safety and essential performance requirements for mammographic X-ray equipment and mammographic stereotactic devices

EN 60601-2-54:2009 (ed.1), DIN EN 60601-2-54:2010

Object: The object of this particular standard is to establish particular basic safety and essential performance requirements for equipment for radiography and radioscopy

IEC62B/794/CD:2010, EN 60601-2-63:2010

Object: The object of this particular standard is to establish particular basic safety and essential performance requirements for dental extraoral X-ray equipment

IEC62B/795/CD:2010, EN 60601-2-65:2010

Object: The object of this particular standard is to establish particular basic safety and essential performance requirements for dental intraoral X-ray equipment

2. Categorization of X-ray equipment related to its intended use and applicable standards (status 2012-01-20)

Tab. 2 categorizes X-ray equipment depending on its intended use, assigns applicable standards, and lists the resulting DOCOPOCOSS.

Table 2: Standards applicable to X-ray equipment

	Category of X-ray equipment	applicable standard	EU DOCOPO-COSS	Resulting DOCOPO-COSS for category of equipment
0	X-ray tube assemblies for medical diagnosis	IEC60601-2-28:2010 (ed.2),	2013-04-01	2013-04-01
1	X-ray equipment for interventional procedures	IEC60601-2-28:2010 (ed.2), (see explanation below)	2013-04-01	2013-06-01
		IEC60601-2-43:2010,	2013-06-01	
2	X-ray equipment for computed tomography	IEC60601-2-28:2010 (ed.2), (see explanation below)	2013-04-01	2012-05-01
		IEC/EN 60601-2-44:2009 (ed.3),	2012-05-01	
3	Mammographic X-ray equipment and mammographic stereotactic devices	IEC60601-2-28:2010 (ed.2), (see explanation below)	2013-04-01	expected for 2015
		IEC60601-2-45:2011 (ed.3),	not yet published	
4	X-ray equipment for radiography and radioscopy	IEC60601-2-28:2010 (ed.2), (see explanation below)	2013-04-01	2012-08-01
		IEC60601-2-54:2009 (ed.1),	2012-08-01	
5	Dental extraoral X-ray equipment	IEC60601-2-28:2010 (ed.2), (see explanation below)	2013-04-01	
		IEC62B/794/CD:2010, i.e. IEC 60601-2-63 (to be published)	not yet published	expected after 2013
6	Dental intraoral X-ray equipment	IEC60601-2-28:2010 (ed.2), (see explanation below)	2013-04-01	expected after 2013
		IEC62B/795CD:2010, i.e. IEC 60601-2-65 (to be published)	not yet published	

Note: EN 60601-2-28:2010 is a component standard, and contains requirements specific to diagnostic x-ray tube assemblies. If a test of an x-ray tube assembly is performed, EN 60601-2-28 would apply.

The X-ray equipment specific requirements, including requirements for testing, are included in the product specific standards listed above (EN 60601-2-43, EN 60601-2-44, EN 60601-2-45, EN 60601-2-54, EN 60601-2-63, and EN 60601-2-65, respectively). They are compre-

hensive product standards for assembled x-ray equipment, and exclude each other. Hence, if a test is performed on specific X-ray equipment, one of these standards would apply.

If manufacturers and test houses need to address safety aspects of x-ray tube assemblies that are part of the x-ray equipment, then they should use applicable requirements from EN 60601-2-28 in addition to the product specific standards listed above.

If the x-ray tube assembly is already tested according EN 60601-2-28 as a component, then these tests need not to be repeated if overall safety is sufficiently covered by EN 60601-2-43, EN 60601-2-44, EN 60601-2-45, EN 60601-2-54, EN 60601-2-63, or EN 60601-2-65.

3. Summary

Based on the listing in the OJEU the overall compliance of X-ray equipment in regard of IEC 60601-1:2005 and its collateral and particular standards, the DOCOPOCOSS is as described in the fifth column of table 2.

As it is not necessary to apply EN 60601-2-28 in any case, the related DOCOPOCOSS is not of relevance for the above listed equipment.