

Frequently asked Questions related to Implementation of EN 60601-1:2006

Clarification of open issues

FINAL DRAFT for commenting by NB-MED

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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 was established. This group developed an enquiry asking for “practical issues in the implementation”, that was sent to many stakeholders in June 2011 (see Annex 1). Also at the international level of IEC the request was distributed (62A/769/INF).

The response to the request was beyond expectation and the small team of experts, initially consisting of three, was expanded with Dr. Klaus Neuder of DKE (Frankfurt, Germany).

End of July 2011, the work on digesting the issues submitted until then started 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.

It is believed that the answers, developed in close team cooperation, present a fair response to the issues brought forward and that they can be used as a reference for all stakeholders.

Now it is time for the NB-MED to scrutinize the proposed responses and see if they are also acceptable to all members of NB-MED. The NB-MED comments are kindly awaited by the end of October 2011, at the same e-mail address that was used for the initial submission of the issues: 60601Ed3.NBMED.issues@gmail.com, using the form supplied together with this document.

Happy reading!

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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.

Upon approval and acceptance by NB-MED, this document should serve as a reference for manufacturers of electrical equipment in medical practice (MEE) that wish to use for compliance purposes the EN 60601-1:2006 and its many family members, as well as for **ALL** NB-MED, so that the standard will be used in a consistent manner for all MEE that are to be placed on the market in the EU.

2. Abbreviations

2 nd edition:	EN 60601-1:1990 (typically with the two subsequent amendments)
3 rd edition:	EN 60601-1:2006
CD:	Committee Draft
DKE:	Deutsche Kommission Elektrotechnik (German Electrotechnical Committee)
DOCOPOCOSS:	Date Of Cessation Of The Presumption Of Conformity Of The Superseded Standard
EN:	European Norm
EU:	European Union
IEC:	International Electrotechnical Committee
ISO:	International Standardisation Organisation
MDD:	Medical Devices Directive (93/42/EEC)
MEE:	Medical Electrical Equipment
MES:	Medical Electrical System
NB-MED:	Notified Bodies for Medical Devices
NC:	Nonconformity
OJEU:	Official Journal of the European Union
PoC:	Presumption of Conformity
RMF:	Risk Management File
SOUP:	Software Of Unknown Provenance

<< to be completed >>

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](#)) for the involved device, 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](#)).

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:

If you use a harmonized standard to demonstrate that a medical device meets the applicable ERs, and the standard that was a harmonized standard when the product was first introduced on the European market, but is now no longer harmonized, for example because it was superseded by a revised version, you can no longer rely on the concept of “presumption of conformity” for that superseded standard. This means that for medical devices that are placed on the market after the transition period is over, you are supposed to adhere to the requirements in the new harmonized standard.

Even if you do 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

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, even if these products have been marketed for over 10 years?

Answer 3.1.4:

In general: yes, retesting is necessary because of the many differences between 2nd edition and 3rd edition. As indicated in the answer to 3.1.2, additional effort and evidence will be needed when a standard is being used that loses its status of "harmonized standard", that is: at the end of the transition period. Where a standard is replaced by a successor, the differences between the old and the new version will determine whether redesign is needed or that retesting for the "delta" situation is sufficient. Since the publication of a new standard does not make medical devices that adhere to the old standard unsafe, the manufacturer may in consultation with the Notified Body decide on the extent of the redesign.

Question 3.1.5:

Our Notified Body told us that the 3rd edition of EN 60601-1 consists of 1422 requirements and differs from the 2nd edition in 693 requirements; where can I find these?

Answer 3.1.5:

You can find the 1422 requirements in the 3rd edition of IEC 60601-1:2005 itself. The 693 requirements that are either new or where the 3rd edition is more stringent than 2nd edition can be identified by comparing these editions in detail.

Question 3.1.6:

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 related to EN 60601-1:1990 (+ am1 + am2), June 1st 2012?

Answer 3.1.6:

As mentioned in answer 3.1.2, the manufacturer has to demonstrate that medical devices placed on the EU market comply with the MDD. This holds for all medical devices individually; see interpretative document from EC (click [here](#)). The certificate is issued under the assumption that this condition ("state of the art") is met on an ongoing basis. That means that in this case the DOCOPOCOSS of 1 June 2012 does have an impact on the technical documentation pertaining to that medical electrical equipment.

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

a) Verification by a competent NB of the new design dossier before the transition period is over, or

b) Verification by a competent NB at the first audit after the transition period is over; this will be easiest if the manufacturer has fully implemented EN 60601-1:2006.

Question 3.1.7

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 3.1.7:

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 3.1.8:

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 3.1.8:

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 3.1.9:

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

Answer 3.1.9:

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 around 100 product changes per year (component level). 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 document 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 product were already placed on the market in compliance to Ed.2

For the specific situation described, the transition period of EN 60601-2-34:2011 applies, not the date of the main standard; see also section 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 an 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 be 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.

Therefore, we are convinced that Notified Bodies and test labs will not lower their quality level just to make sure all medical devices will get an approval quite independent of their real quality. This would endanger the well recognized image of the Notified Bodies.

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:

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

b) What if the PS is a non-EN 60601 compliant product but, for example, tested against EN 61950?

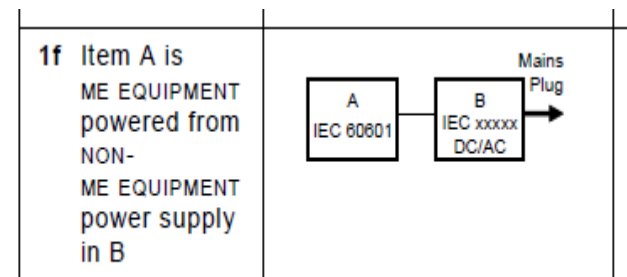
c) And what if the power is supplied not simply by an external PS, but by a complete 2nd edition compliant MEE?

Answer 3.3.3:

a) and b) The external PS can NOT be a solely 2nd edition approved power supply, if the whole MES needs to be approved according clause 16 “ME systems” of the 3rd edition. The PS must either be a 3rd edition approved power supply (or 2nd edition + Delta testing), or an EN 60950 approved power supply. Both options fulfil the system requirements of clause 16.

The reason for this is that, with the suggested approach, a system built of 2nd edition components could become 3rd edition compliant on MES level without explicit testing. Even if an MES is built with only 3rd edition components, the MES is not necessarily 3rd edition compliant: the system needs to be tested for compliance as a whole.

Note: the situation for a non-EN 60601 compliant PS is described in section 1f of table I.1 of EN 60601-1:2006:



c) This describes a situation where a 2nd edition approved MEE supplies power to another MEE, which could be a 3rd edition approved MEE.

This combination may be placed on the market as an MES if the combination fulfils the requirements of clause 16 of EN 60601-1:2006, and the transition periods of both MEE are obeyed. If parts two exist for each of the MEE, their respective transition periods apply; if for one or for both MEE there is no part two, in principle the date of 1 June 2012 applies as end of transition period for one or both MEE.

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 in 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 can be applied.

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:

Because 62304 is meanwhile listed in the OJ, use the SOUP solution out of EN 62304.

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:

It is true that some adaptations following the new standard's requirements may involve more efforts in risk management, design, and testing than other compliance efforts. However, the EN 60601-1:2006 was published in 2006 so this can hardly be used as an excuse for trying to find a workaround that would perhaps not satisfy the requirements in the 3rd edition.

Question 3.3.10:

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

Answer 3.3.10:

www.webstore.iec.ch

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 IEC/EN 60601-1 TRF available, nor will it be created by IEC/EN 60601-1. 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:

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, where 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).

In general, as indicated before, the part 2 –if it exists- is the leading standard. This also applies to the transition period.

If a part 2 exists, and it is a 2nd edition compatible part 2, the new collateral standard does not apply for those products.

If the part 2 is 3rd edition compatible, 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 following the new collateral, then the transition period is determined by the revised part 2.

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:

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.

The EN 60601-2-28 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 are included in 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, respectively, including requirements for testing.

If a test is performed on the X-ray equipment, one of 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 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 they should use applicable requirements from EN 60601-2-28 in addition to 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.

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.

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:

No, EN 60601-2-43 refers to specific clauses out of EN 60601-2-54; those referenced clauses apply.

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 (Ed.2) 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 (Ed.2). 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 available and as long as its DOPOCOSS 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 DOPOCOSS 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
- the standard reflects the structure of EN 60601-1:2006, (e.g. clauses of EN 60601-1:2006 are addressed in the part 2 standards in such a form that –normatively- clause X.Y.Z of EN 60601-1:2006:
 - applies, or
 - applies with exception of, or
 - does not apply, or
 - will be replaced by the following requirements:)

Examples of such standards might be:

- EN 60601-2-XX
- EN 80601-2-XX
- EN ISO XYZXY
- EN IEC XYZXY

3.6. Transition period of EN 60601-1:2006

Question 3.6.1:

For an MEE there is no particular standard available related to 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 1 June 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 (3rd edition) 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. Therefore, if you use EN 60601-2-43: 2000 to claim the PoC after 1 June 2012 (until 1 June 2013) it includes the 2nd Ed of EN 60601-1.

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 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 (latest) 1995!

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:

See table underneath:

Time	No.	Situations	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	Hint	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.	Hint	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		Hint	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 (RMF).

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 shall 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, according to EN 60601-1:2006 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 (i.e. evaluate) 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 EN60601-1, 2nd edition 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 in the 3rd edition”, the answer is: YES, this is possible even within EN 60601-1:2006. However the majority of requirements in 3rd edition are not linked to RM and therefore in case of deviating from that objective evidence of fulfilling clause 4.5 “Equivalent Safety” is needed.

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. This mechanism applies to the type of device, and so for each individual unit, assuming that a quality management system is in place that ensures that all devices of the same make fulfil the same requirements.

When placing a single device in an environment where it would create a hazardous situation that was not foreseen in the design, 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 solution 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 2nd edition compatible equipment has been phased out of the hospital.

Note: the co-convenor 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 the part 1.

Question 3.8.5:

What about aligning Risk Management Systems?

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 3.8.5:

The process to manage risks was introduced with the publication of ISO 14971 in 2000, several years ahead of the EN 60601-1:2006. As a consequence, many manufacturers have implemented a risk management process that is not geared towards EN 60601-1:2006. However, experts that developed EN ISO 14971 have worked very closely with experts who developed the risk management approach in EN 60601-1:2006, so that the optimum alignment has been achieved.

In their assessment of the Risk Management documentation, relevant for EN 60601-1:2006 compliance, Notified Bodies should not be too picky if the format given by Rev. G of the IEC 60601-1 TRF, or an alternative format that provides equivalent level of information has been used. At the moment the IEC TRF rev G is the latest available TRF. But this does not mean, that other formats cannot be used to document test results 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 the amendment was approved end of August 2011. Following this approval, it is expected that A1 will be published by IEC around mid 2012. The EN version, because of the parallel voting, will be published soon thereafter.

On the transition period: this is not clear yet.

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 Ed. Most particular standards have a dated reference to EN 60601-1 and its collaterals. They determine what Ed. 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 errors, 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 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 can 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.

4. References

<< Text to be supplied later >>

5. Recommendation for usage

<< Text to be supplied later >>

Annex 1 – Initial request for issues

Implementation of EN IEC 60601-1 3rd edition

Request for Issues

on the use of the standard for CE-conformity purposes

When the transition period was defined for EN IEC 60601-1:2006 (replacing the 1988 version with its two amendments), several questions arose. These questions were included in a FAQ document that was posted at the CENELEC web site (click [here](#)) to give all users the same interpretation¹: (click [here](#)).

The transition period, after which only the 2006 edition will be giving presumption of conformity with the relevant Essential Requirements of the Medical Device Directive (93/42/EC), is now well underway. As an increasing number of manufacturers are implementing this version of the standard, more questions come up. In particular this is the case in conversations between manufacturers and involved authorities or Notified Bodies considering CE-conformity purposes.

In an attempt to support these discussions, and to harmonize responses, we are looking for specific matters that have arisen and that may have wider relevance. Together with regulatory experts, we will seek answers to those matters that reflect a consensus opinion of the Medical Notified Bodies. Clearly, this is **not** a request for technical matters, e.g., for required test conditions, but rather unclear situation. A few examples of such matters are given in the annex.

If you know of such matters, or even have experienced some yourselves, please share these. If you have reached agreement on these matters or you have proposals for the same, and wish to share: these are also very welcome. As indicated, the matters will be compiled and given to experts for sound advice, followed by scrutiny from NB-MED experts, resulting in the best available recommendations for the matters indicated. This advice will be made publicly available.

Please submit your contributions to: 60601Ed3.NBMED.issues@gmail.com. Note that not all contributions may receive individual responses. We will start work with material submitted by 30 June 2011, yet contributions after that date remain welcome. We expect first results by 30 September.

Thank you for your consideration and valuable contributions.

Martin Schneeberg (TÜV SÜD PRODUCT SERVICE, member of UK 811.1, IEC TC62A, WG14, MT28, A1PMT, IECEE RM TF)

Wolfgang Leetz (Siemens AG, Healthcare Sector, chair of DKE Division 8 (electro medical equipment, electro acoustic, ultrasound, laser), chair of COCIR Standardization Policy Focus Group)

Peter Linders (Philips Healthcare, chair of CENELEC TC 62, chair of COCIR Technical and Regulatory Affairs Committee, member of IEC/TC 62 CAG, A1PMT)

¹ **Collateral standards under the MDD & AIMD**: CLC/TC 62 questions and answers on the EN 60601-series of standards in relation to the MDD and AIMD

Annex – Examples of questions sought

Q1. Valid EC Design-Examination certificate period vs. DOPOCOSS: 2012-06-01:

Example: Suppose an MDD class IIB or III electrical medical equipment was placed on the EEA in 2009. It has a signed EC Design-Examination Certificate by a NB based on 2Ed EN 60601-1, valid until 2014-01-01 (five years).

Question: Is this product affected by the DOPOCOSS related to EN 60601-1:1990 (+ am1 + am2), June 1st 2012? Keep in mind that a valid EC certificate has been issued by a NB which is valid 5 years up to 2014.

Q2. Future totally new particular standards:

For a specific MEE does not exist a specific particular standard related to 2Ed EN 60601-1. However, for this specific MEE a totally new particular standard related to the 3Ed EN 60601-1:2006 is work in progress. This question is relevant at least for:

- 60601-2-63: for dental extra-oral x-ray equipment,
- 60601-2-64: light ion accelerators,
- 60601-2-65: for dental intra-oral x-ray equipment,
- 60601-2-66: hearing aids and hearing systems

Officially such MEE's shall fulfil the complete 3Ed EN 60601-1:2006 plus the relevant particular standard 60601-2-XY at the date 2012-06-01, unless there is a specific transition period for the applicable particular standard. Usually no specific transition period for the totally new particular standards are defined in the OJ, therefore, 2012-06-01 will apply.

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

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

Q3. 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 extremely clear: *"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 "doc" is over and I have not objective evidence about the new 3Ed EN 60601-1:2006 requirements in a point-by-point protocol format, is my NB forced to suspend or withdraw my CE-certificate?