

2nd Edition - Autumn 2010



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# MEDICAL :: Talk

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# Dear Readers:

Welcome to the second edition of MEDICAL::Talk, TÜV Product Service's newsletter on the Medical devices industry. This newsletter is designed to keep you informed about regulatory changes within the industry, as well as keep you updated with our latest activities and services.

We trust you will enjoy our first issue. If you have any questions on any of the related topics please contact us, and we will be happy to help.  
Jean-Louis Evans - Managing Director

## The General Safety Standard for medical electrical equipment 60601 1:2005

The 3rd Edition of 60601-1 is here to stay. Since being published in 2005 it has had a rather rocky ride due to its length, complexity and the number of new concepts. The first amendment will appear shortly. This will be a reprint of the whole standard and will deal with some of the difficulties that users and test houses have encountered. It will also reduce somewhat the number of references to the Risk Management file, some of which were not entirely appropriate.

Other than these changes, the new standard will remain in place for designers and manufacturers to follow when producing new models of medical electrical equipment. Whatever the status of your product, you should start preparing for the day when the 2nd Edition is withdrawn. The latest information is that this will be 1 June 2012 (1 June 2013 in the USA).

There are some provisos here. If there is a part 2 which relates to your product and this part 2 has not been updated to relate to the 3rd Edition by the date mentioned, it will be legitimate to continue using the 2nd Edition. If you wish to have testing done according to the requirements of the CB Scheme (an international scheme in which 65 global test laboratories have agreed to accept each others' results), the validity of the 2nd Edition will continue beyond the date mentioned for an as yet undefined time.

It is inescapable that testing to the 3rd Edition will be more expensive than testing to the 2nd Edition. Very roughly, if the product is 'purely electronic', then it will be about 50% more. If the product is electro-mechanical, then the difference will be greater because of the substantial new requirements for mechanical safety. It becomes difficult to put a figure on the percentage increase over the 2nd Ed as it depends in turn on the extent of 'limb trapping' possibilities or other risks of physical damage to the patient and whether or not the patient is supported by the device. A starting figure might be about 70% more than the 2nd Edition.

If you have a new product which has not previously been tested, a cost effective way of getting your product to market (with regard to testing only) is to have your product tested now to the 2nd Edition and earn some revenue from your product being on the market. TÜV is offering testing to the 'deltas' between the 2nd and 3rd Editions and this can be done in a year to 18 months, ensuring continuing compliance with the requirements.

There are ways in which manufacturers can avoid testing fees from creeping up unnecessarily. If you prepare an insulation diagram with the isolation barriers clearly shown and the voltages to which those barriers are subjected, it means that the test house does not have to prepare the diagram as part of the testing.


If you use certified safety components or power supplies, ensure that you have the relevant documentation as evidence of certification. Again, the test house can do this, frequently via the Internet, but it takes time to do so. The same applies to rechargeable batteries and their charging arrangements. These are now covered by the 3rd Edition, but testing them will add considerably and needlessly to the cost. Using previously certified items and providing evidence of certification will help keep costs down.

This article can only draw attention to the introduction of the 3rd Edition and the phasing out of the 2nd Edition, but there is insufficient space for technical details. An overview of the key technical changes was given in a TÜV PS Webinar on 7th July which can be accessed through the following link [www.tuvps.co.uk/webinars](http://www.tuvps.co.uk/webinars).

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# Changes to auditing practice resulting from the revisions of MDD 2007/47/EC

Among the many changes that 2007/47/EC made to the MDD, there is one which will have a noticeable effect on the way in which we audit our clients. The previous versions of the Directive made numerous references to the technical documentation, but said little about how it should be audited.

There are now specific requirements in Annexes II, V and VI regarding the auditing of 'technical files' by Notified Bodies. (Note that the term 'technical files' is not used in the Directive, but it is so widely used and understood that it will be used here and will be abbreviated to TF.)

Manufacturers still have the same leeway regarding the organisation of their TFs and can have a separate file for each product. Or they can group the products together in families having shared characteristics and have a TF for each family. However it is done, the manufacturer must make known to the Notified Body the way his TFs are organised. As the process is new, it is possible that different NBs will ask for this information in different ways.

Only Class IIa and IIb products are affected by the new requirements.

[Here is the commonly agreed interpretation of the directive's statements.](#)

## Class IIa devices

Text introduced into 93/42/EEC by the amending directive 2007/47 EC refers to Class IIa devices as being in 'device subcategories'. The question arose as to what a device subcategory is. Later clarification came from the Notified Bodies Operating Group Best Practice Guide (NBOG BPG) 2009-3. See <http://www.nbog.eu/2.html> for details.

The 'scope expressions' in this guide will be used as device subcategories. (They have another function too.) Non-active devices will be scope expressions MD 0100 to MD 0403. There are 19 scope expressions in this group. Active medical devices will be scope expressions MD 1100 to MD 1404 (also 19 scope expressions).

There are also 'specific scope expressions' for drug/device combinations, animal origin devices and so on.

## Class IIb devices

Text introduced into 93/42/EEC by the amending directive 2007/47 EC refers to Class IIb devices as being in 'generic device groups'.

These are obtained directly from the "preferred terms" within the General Medical Device Nomenclature (GMDN) system. There are thousands of groups of devices and it is highly likely that a manufacturer of a class IIb device will be able to find a group for his product.

Having explained the terminology and its origins, what is the purpose of the new groupings?

Firstly, it is so that manufacturers are able to inform their Notified Body of the number of TFs which fall within each device sub-category (e.g. scope expression) for Class IIa devices and the number of TFs which fall within each generic device group (e.g. GMDN preferred term) for Class IIb devices.

Secondly, it is to enable the Notified Body, having received this information, to plan future audits. This in turn is because these TFs must be audited in a planned, structured and ongoing manner according to the new requirements. (See 2007/47/EC Annex II, 7.2 to 7.5; and Annexes V and VI, 6.2 to 6.4)

According to these requirements, the Notified Body must decide on which TF(s) must be audited in each audit cycle, prepare and retain for future scrutiny by the Competent Authority an internal justification for the choice of file (typical criteria are mentioned in 2007/47) and then carry out the file audit. It is not planned to inform the client which particular TF(s) will be audited in any particular audit cycle.

The file audit may be done either on-site as part of the audit process or off-site. This is to be agreed between the Notified Body and the client. Factors to be taken into account will include time available, location of the TFs, the auditor and the availability of a company person to answer technical questions.

What is not in doubt is that this additional audit task adds to the duration and therefore the cost of any MDD audit by any Notified Body, where technical files are involved. It also adds to the internal administrative tasks that Notified Bodies have to carry out when planning audits.

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Our webinars are presented by TÜV Product Service experts, providing you with up to the minute information that affect you as compliance professionals along with the opportunity to interact from the convenience of your office or home.

## Upcoming Webinar

**Wednesday 13th October at 14:00 - Sterilization of medical devices**

### Overview of presentation

The three main standards for sterilization of medical devices (EN550, EN552 & EN554) were revised in 2006 and 2007 and have either come into force in 2009 or in the case of EtO, completed the transition period in May 2010. These were major changes to the standards and all three were replaced by international versions (ISO11135, ISO11137 and ISO 17665). Requirements for compliance with these have changed – especially with respect to validation and reporting. A high level of competence is required for sterilization validation and it remains one of the most common non-conformities at notified body audits for CE marking.

For more information on these topics and to register for one of our webinars, please visit our website at [www.tuvps.co.uk/webinars](http://www.tuvps.co.uk/webinars).



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If you have any further questions, please contact Simon Middleton at [smiddleton@tuvps.co.uk](mailto:smiddleton@tuvps.co.uk) or Tel: +44 (0)1489 558221.

# Root Cause Analysis of Non-conformities, treatment of other audit findings

The ripples from the recent certification standard ISO 17021:2006 continue to spread. Even though it has been in place for a while, closer examination of the text gives rise to new interpretations.

## Sub-clause 9.1.11 states:

“The certification body shall require the client to analyse the cause and describe the specific corrections and corrective actions taken, or planned to be taken, to eliminate detected non-conformities within a defined time.”

Notified Bodies have long expected the manufacturer (or client) to carry out a root cause analysis (RCA) of any major non-conformity. Looking at the text above, there is no indication of the gravity or extent of the non-conformities that are referred to.

We must therefore extend our requirement for root cause analysis to minor non-conformities.

Whilst it is true that responsible companies did carry out RCAs of all non-conformities, whatever their gravity, TÜV PS did not expect to see the RCA for minor issues. This has now changed.

## Another topic also relates to audit findings.

Closer attention will be paid to the date by which corrections and/or corrective actions will be carried out. Although dates were generally requested in the past, we were content with fairly loose statements of ‘intention to comply’ dates. The client will in future be asked to be specific and to enter the date in a new column in the Corrective Action table.

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