Changes to EN 60601-1
and how to maintain MDD compliance

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Abstract
EN 60601-1 is an "essential safety standard" for any active medical device manufacturer and is harmonised under the Medical Devices Directive (MDD), thereby offering a presumption of conformity with many of the Essential Requirements (ERs). However, on 1 June 2012 the second edition of this standard loses its harmonised status and only the third edition will remain harmonised. Therefore manufacturers need to ensure they maintain compliance with the MDD for new and existing products that are placed on the market after 1 June 2012.

This article provides an introduction to the most significant changes introduced by the third edition of the IEC 60601-1, which is technically equivalent to the European standard, and discusses how the harmonised status of the second and third editions of the standard will affect MDD compliance.

The IEC 60601 family

IEC 60601 is a family of standards and the General (or Part 1) Standard defines the formal structure of the family (chapters, clause numbering, etc). It also defines *basic* safety requirements together with risk management requirements. The General Standard has a number of parallel or collateral standards. Collateral Standards define requirements for specific technologies and/or hazards, such as electromagnetic compatibility, usability and alarms. Building on the basic safety requirements of the General Standard are the Particular Standards, also known as the Part 2 standards. There are presently around 70 Particular Standards. Particular Standards contain requirements for specific equipment types, for example IEC 60601-2-2 for high frequency (HF) surgical equipment. They are top of the hierarchy of the family of standards and usually modify requirements of the General and Collateral Standards and/or add to them. They can also help establish which functions or performances, for a particular device type, are essential to maintain risks within acceptable levels.

Significant changes in the third edition

The first change that you come across when reading the third edition of the General Standard is in the title itself. The words "Basic" and "Essential Performance" have been added.

Basic safety is freedom from unacceptable risk directly caused by *physical hazards* in normal and single fault condition, eg, electric shock, stability, temperatures, etc.

Essential Performance is the *performance* of the equipment that is necessary to achieve freedom from unacceptable risk. The manufacturer will need to identify these during their risk assessment and a test house will look for them in the risk management file. Where a failure to perform would result in unacceptable risk for the patient, operator or others, then those features or functions are considered as Essential Performance.

Some examples include the accuracy of the temperature control of a baby incubator or the flow rate of an infusion pump. If there is an applicable Particular Standard this will help with the identification of Essential Performance by stipulating certain compliance requirements. Where there is no Particular Standard then only the Essential Performance identified by the manufacturer during its risk management process will apply.

Other changes to the General Standard include:

- Larger by around 200 pages, partially due to the extensive rationale in Annex A
- The clause numbering has all changed from the second edition
- Types of requirements, such as electrical safety, are now grouped together in the same clause as far as possible
- Single fault condition is still present in the third edition but in addition the process of risk management has also been introduced to determine acceptable risk levels
- The requirements for medical electrical systems can now be found in clause 16 and those for programmable electrical medical systems (PEMS) within clause 14. The other collateral standards remain separate but clause 2 of the General Standard requires them to be applied where applicable
- Clause 9.6 introduces audible acoustic energy limits, excluding alarms which should comply with the collateral standard IEC 60601-1-8. It also includes limits for hand-transmitted vibrations
- The definition of medical electrical equipment now includes equipment not used under medical supervision, allowing equipment used in the home to fall within the definition. Also, equipment used to compensate for or alleviate a disease or injury or disability has been added to allow devices such as patient hoists to be included within the scope of the standard.

Applied parts

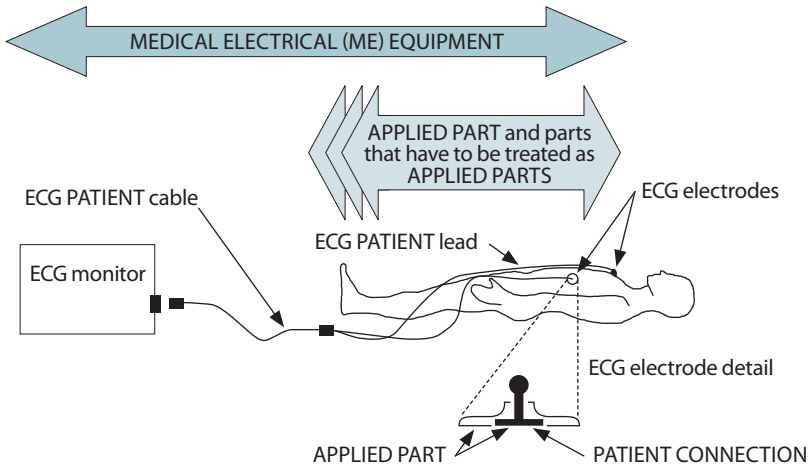
The definition of an "applied part" has also been modified and now only parts that need to come into contact with the patient for it to perform its function are included. Manufacturers are required to use risk assessment to determine which other parts could contact the patient and these parts are then subject to the same requirements, such as leakage, current, etc, but are not labelled as applied parts.

To help clarify the applied part definition, Figure 1 shows Figure A.1 from the third edition. It identifies the medical electrical equipment, applied parts and patient connections for an ECG monitor. The applied parts are the pre-gelled electrodes and the patient connections are the conductive parts of the electrodes. Other parts that are not applied parts but which must meet the same safety requirements (because they are likely to touch the patient) are the ECG patient leads. The ECG patient cable is considered far enough away in this case to not be subject to applied part requirements.

Risk management

Probably the major change in the third edition is the introduction of risk management. This should be nothing new to medical device manufacturers as they should be performing

Figure 1: The "applied part" definition as shown in Figure A.1 in the third edition of the EN 60601-1 standard.



risk management already to meet the MDD requirements. However, it is new to test laboratories and will significantly increase the overall duration of testing a product.

Clause 4.2 is the one that has caused most concern and problems with interpretation. It states that: "A risk management process complying with ISO 14971 shall be performed". Some test houses have interpreted this as meaning that a manufacturer must be certified to ISO 14971. This is not a requirement of the third edition, which is a type test standard, but certainly certification to ISO 14971 would help to show that a manufacturer's risk management process complied with that standard. A test house still needs to inspect the risk management file for the product in order to judge compliance. In addition, other hazards not covered by the third edition need to be covered in the risk management file. So it is important to remember that the risk management file will need to be available when testing is required.

Clause 4.3 requires that the Essential Performance of the equipment be identified, as discussed earlier, and clause 4.4 requires the "expected service life" to be stated in the risk management file.

The expected service life is the maximum period of useful life as defined by the manufacturer. The accompanying documents should provide information to allow the responsible organisation (eg, hospital) to assess when the equipment is approaching the end of its life. This could be given in terms of years of service or number of uses, or tests as part of preventative maintenance to allow the responsible organisation to determine for itself. The need for the information and content should be determined as part of the risk management process.

It is important to remember that it is the manufacturer that decides if a risk is acceptable, considering factors such as:

- Applicable standards and other relevant guidance documents
- Experience with similar devices already in use
- Clinical study data, especially for new technology or new intended uses
- The current state of technology and practice.

A test house will need to review the rationale included in the risk management file and see that the manufacturer has followed its own acceptability criteria. Therefore, a company should look at all clauses that require compliance to be established by inspection of the risk management file. Does your risk management file have answers to all of these? Have a checklist both for you to confirm and for the laboratory to use as a cross-reference. Good laboratories should be able to supply such a checklist.

Some other considerations for risk management include:

- What was an acceptable risk level in the past may no longer be acceptable due to the changing state of the art
- Suitably qualified persons should be used for the risk management process. For example, if the device has software then make sure that a software engineer is part of the team. Similarly someone from clinical affairs should be present, and so on
- It is important to establish and document a risk management plan, including the criteria for risk acceptability, verification activities and the collection and review of production and post-production information
- In addition to the intended use and function of the device, reasonable foreseeable misuse should be included
- Where risk control measures are required these should be verified to show that they have been implemented and that they are effective
- If risk control measures have been added then have they introduced any additional risk?

The risk management report is a management sign-off process and does not need to be a large report. It should, however, at least ensure that the risk management plan has been appropriately implemented, that the residual risk is acceptable and that appropriate methods are in place to obtain relevant production and post-production information.

Electrical safety

Electrical safety has been consolidated into clause 8. Many of the well established concepts of the past are still present. However, sub-clause 8.8, which covers insulation, introduces some new terms to the standard. Means of Protection or MOP is a means for protection from electric shock meeting the requirements of the standard. For example, basic insulation is equal to one MOP and double insulation is equal to two MOPs.

A MOP that relates to a part that is likely to contact the patient is called a Means of Patient Protection or MOPP for short. A MOP that relates to the user or other persons, who do not need the same level of protection as the patient, is called a Means of Operator Protection, also known as MOOP.

These terms were introduced because the creepage and clearance distances in the second edition were considered too stringent in some cases, particularly in power supplies. There were also large jumps in the required values as the reference voltage increased. Since many power supplies are designed to meet IEC 60950 (which is the IT equipment standard) it was decided to harmonise with this standard as much as possible.

So, broadly speaking, MOPPs are effectively the second edition values. MOOP values are from IEC 60950, using overvoltage categories, material groups and pollution degrees. Alternatively, a manufacturer can decide to use MOPP values also for operator protection, ie, use the old second edition values.

The terms "overvoltage category", "material group" and "pollution degree" are new to this standard. Creepage and clearance, together with dielectric strength values, are based on the expected overvoltage transients that could enter the equipment from the supply mains taking account of the normal supply voltage and supply arrangements. IEC 60664-1 (which is the main standard for insulation

coordination) categorises these transients into four groups, called overvoltage categories. For IEC 60601-1 third edition, overvoltage category II is assumed for mains powered equipment and overvoltage category I for secondary circuits.

Material groups are based on the likelihood of electrical tracking of a particular material (see IEC 60112).

Pollution degrees are based on the micro-environment of the circuits in question, eg, whether they are sealed or potted or likely to have conductive dust present.

The extensive rationale in Annex A includes figure A.12, which is a flow diagram to help determine whether the MOP for a part requires MOPP or MOOP values.

Mechanical and thermal safety

Mechanical safety is covered in clauses 9 and 15 and there are now 38 pages of requirements instead of the seven in the second edition. Some of the changes include new verifiable requirements such as dimensions for trap points with moving parts. Again, risk management allows for alternatives based on an equivalent level of risk. Table 20 from the standard provides values for acceptable gap sizes to prevent trap points. For example there are values for head, leg and finger trap points. You will note it includes values for both adults and children, so manufacturers will need to characterise the types of patient their device will be used with during the risk management process. Similarly the intended use environment, eg, hospital or home, will need to be considered.

Clause 11 deals with thermal and fire safety. Temperature limits are given in tables 22 and 23 and these are tested in the worst case ambient as specified by the manufacturer in the technical specification for the equipment. This is a change from the second edition which had a maximum ambient of 40^{0}C.

Surface and applied part temperature limits are now based on the likely duration of contact for that part. The manufacturer determines the contact duration based on a risk assessment and this is documented in the risk management file.

Temperatures of applied parts *not* intended to supply heat often used to cause problems in the second edition. The limit was set at 41^{0}C with a maximum ambient of 40^{0}C allowing for only a one degree rise. In the third edition there is some greater flexibility and temperatures above 41^{0}C may be allowed if these values are given in the instructions for use and the clinical effect of these temperatures are determined in the risk management file.

So, the third edition is a much larger standard which incorporates the systems and PEMS collateral standards. Risk management is the primary change but there are also changes to the definitions of medical electrical equipment and applied part. The electrical safety section has introduced MOPPS and MOOPs and the mechanical requirements have grown considerably. Acoustic and vibration limits have been introduced. Thermal and fire safety requirements are also based a lot more on risk management.

Remember, these are just a selection of key changes and the standard as a whole needs to be studied.

Maintaining MDD compliance

A manufacturer who wishes to place its medical device on the European market needs to comply with the MDD before labelling the device with the CE marking. Demonstrating conformity must include evidence that they comply with the all of the applicable ERs in Annex I of the MDD. Complying with harmonised standards is one of the easiest ways of achieving this since they provide a presumption of conformity with relevant ERs. If harmonised standards are not used then the manufacturer must demonstrate that their alternative solution still meets the ERs.

Where a harmonised standard is not used:

- The manufacturer needs to show that its alternative solution continues to meet the ERs and the current "state of the art" – (see ER2)
- The harmonised standard has to be the gold standard against which an alternative solution is compared since it is a consensus document showing acceptable evidence of ER compliance
- If a notified body has to review an alternative solution then the manufacturer must be able to demonstrate that its alternative provides an equivalent level of safety and essential performance to the harmonised standard and that residual risks are still acceptable
- One means of demonstrating the above is to perform a gap analysis of the alternative solution against the harmonised standard. Where gaps are found, a reasoned technical justification – supported by a risk assessment and, where necessary, testing – should be provided.

Harmonised status of EN 60601-1

It is only EN standards that are harmonised against the MDD, although if an IEC standard is technically equivalent to the EN, then these are also acceptable. EN 60601-1: 2006 was published in the *Official Journal* of the EU in December 2008, making it harmonised against the MDD in addition to the second edition.

The date of cessation of the presumption of conformity with the ERs for the second edition is 1 June 2012. The same applies to the collateral standards if a third edition version exists.

The exception to this is if an applicable Particular Standard exists which is still harmonised. If this is the case then you have to use the second edition General Standard with a second edition Particular Standard. Once the Particular Standard loses its harmonised status then the third editions of the General Standard and Particular Standard should be used. There are many Particular Standards that will still be harmonised after 1 June 2012, so if such a Particular Standard is applicable and applied to a device then there is a longer transition period for the device. So the dates of cessation of the presumption of conformity for the harmonised standards need to be monitored at the EU commission website (http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/).

If a Particular Standard has already lost its harmonised status then the third edition versions of the General and Particular Standards should be used now (eg, EN 60601-2-37 for ultrasound monitoring equipment).

If a Particular Standard does not apply to a device it makes sense to use the third edition of EN 60601-1 for new product designs.

What about products currently on the market?

Although a product may have been on the market for some time and have CE marking, if further units are to be placed on the market in the future then continued compliance will be required with the ERs. This means that the solutions used will still need to meet the state of the art.

A gap analysis can be performed, as discussed earlier, between the requirements of the third and second editions or the equipment can be retested to the third edition.

Conclusion

The 1 June 2012 deadline is now upon us, and after this date manufacturers must be able to demonstrate that all devices they are placing on the European market continue to comply with the ERs of the MDD. The solutions used must comply with the state of the art as required by ER2.

EN 60601-1 third edition can be used or the second edition if an applicable second edition Particular Standard, that remains harmonised, is also applied. If an alternative solution is used then it will be compared with the third edition and an equivalent level or safety and performance would need to be demonstrated.