MEDICAL DEVICES NEWS
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SPECIAL POINTS OF INTEREST:

SGS

NEW EDITION OF EMC STANDARD FOR MEDICAL DEVICES: WHAT HAS CHANGED AND WHEN TO APPLY?

A new fourth edition of the EMC standard IEC EN 60601-1-2 was published in February 2014. It is yet to be fully adopted in the industry and there are many questions on its applicability to different medical devices and changes incorporated. In this article we review the purpose and implications of the change.

WHAT HAS CHANGED AND WHY?

The main reason for publishing this new edition of the EMC standard is the proliferation of mobile phones. People are carrying them around everywhere, including hospitals. When so many people have a mobile radio transmitter in their pocket, the immunity of medical equipment needs to be extended to a level that will allow the unrestricted use of mobile phones in hospitals and near medical devices. Also, compatibility to other wireless systems like WLAN, TETRA and RFID is included in the additional tests and frequency ranges.

In the previous, 3rd edition, of the standard, the requirements were based on the purpose of the equipment. In the current 4th edition, the requirements are based on the intended use environment of the equipment:

- Professional healthcare facilities (hospitals, clinics)
- Home healthcare environments (other locations)
- Special environments (military, industrial, planes/helicopters, cars etc.)

The standard includes some new definitions:

- Intended use (medical purpose only)
- Normal use (including medical use and transport, maintenance, standby)

One of the key issues is risk analysis by the manufacturer. In the Risk Management File (RMF), Essential Performance (EP) and Basic Safety with regard to electromagnetic disturbances of the equipment to be tested shall be defined. The RMF shall also include and define deviations of functionality and performance during EMC phenomenon. Before any tests can be started, careful planning and good communication between the testing laboratory and the manufacturer are essential. This planning has to be documented in a test plan. The EMC laboratory can support the client in making the test plan.

Changes for the emission requirements are minimal. ITE shall now fulfil CISPR 32 and as an informative change, common mode emissions for patient cables are introduced. In addition, a more detailed guide is given in the 4th edition of the standard for selection of emission class A or B, depending on intended use and location.

Changes for the immunity requirements are numerous and substantial, for example:

- IEC EN 61000-4-2 ESD: higher 8/15 kV test levels are required, connector tests modified
- IEC EN 61000-4-3 Radiated RF: Extended frequency range 80-2700 MHz, 3/10 V/m levels, transmitter exclusion band eliminated
- New test for proximity field immunity: 15 discrete frequencies, levels 9-28 V/m, pulse modulations up to 6 GHz
- IEC EN 61000-4-4 Burst/EFT: Repetition rate has been increased from 5 kHz to 100 kHz
- IEC EN 61000-4-6 Conducted RF: 6V/m test level at ISM frequencies and amateur bands
- IEC EN 61000-4-8 Magnetic immunity: Considerably higher test level of 30 A/m instead of 3 A/m
- IEC EN 61000-4-11 Voltage dips: Modified dips / interruptions
- New tests for vehicle equipment, ISO 7637-2 transients (12 VDC) and emissions according to CISPR 25
- New references to RTCA DO-160G for additional requirements concerning intended use in aircraft

Selected pre-compliance tests are strongly recommended during development process to ensure that the new requirements can be fulfilled by the system.

WHEN TO APPLY THE NEW EDITION OF THE STANDARD?

There is no transition period for IEC standards. When a new edition is published, it is valid immediately. In the CB scheme there a no definite rules on when to apply the new edition of a collateral standard. Detailed regulation on transition will be implemented on a national level. However, it is possible to give some guidance, based on IECEE's Operational Document OD-2055 and private communication with CB experts:

1. When a medical device (MD) is tested and certified according to the 2nd edition of the basic standard IEC EN 60601-1, the corresponding EMC standard IEC EN 60601-1-2, ed. 2:2000 + Am.1:2004 is applied
2. 2.When a MD is tested and certified according to the 3rd edition of the basic standard, the corresponding EMC standard is IEC EN 60601-1-2, ed. 3:2007. However, it is possible to test and certify the MD against the EMC requirements separately. In that case the 4th edition can be applied

3. When the MD is tested and certified against requirements of the 3rd edition + Am1:2012 of the basic standard, it is possible to apply both the 3rd and 4th edition of the EMC standard. However, it should be noted that some particular standards include a dated reference to the EMC standard as normative that should be applied. In spite of that, we do recommend applying the most recent edition

4. Within the EU region, presumption of conformity is dictated by the list of harmonised standards that is published in the Official Journal. Unfortunately, there is an ongoing clash between the EU Commission and standardisation organisations that has practically paralysed the list of harmonised standards. Because of that, the manufacturer's Notified Body has to define what represents the state of the art. In most cases, the newest edition of the standard is the safest option

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COMMUNICATE WITH YOUR NOTIFIED BODY

As the legal manufacturer of a medical device, the failure to communicate effectively and within the correct timescale may risk your regulatory approval and ability to sell in a specific market. As a result, the processes and interfaces that contribute to effective communication are more important than ever.

The changing relationships between the stakeholders in the medical device market are directly impacting the nature and type of communications needed for manufacturers to operate successfully. There are relationships and therefore communications between a medical device's legal manufacturer and, the European Competent Authorities, other regulatory authorities, notified bodies, distributors or importers, clinical users, component suppliers, critical sub contractors and OEMs. As some of these relationships move from being a commercial relationship to more of a commercial marriage or partnership, so the communication channels need to change. For example, if manufacturers are to avoid regulatory issues, and in extreme cases loss of certification and inability to trade in the EC or elsewhere, intermittent updates may need to be upgraded to an ongoing dialogue.

RELATIONSHIP WITH YOUR NOTIFIED BODY

The publication of the EU Commission Recommendation on audits and assessments, with the introduction of regular unannounced audits has emphasised the importance of better communications. This article gives advice on the importance of communicating, in particular with your notified body.

Prior to April 2014, the date when most notified bodies started to undertake unannounced audits, many manufacturers relied on being contacted once a year by their notified body to consider what they should have previously communicated to them. For example, this could have been re allocation of activities between sites, change of contact name, changes in important suppliers, changes in critical sub contractors or the commencement of a clinical trial. The notice of a future audit prompted this information to be sent to the notified body, and in some cases this was only explained at the audit's opening meeting. With an unannounced audit it will be too late. It is not acceptable for a notified body to arrive at a site only to discover it no longer manufactures product, or visit an OEM supplier whose contract expired six months ago. This would be an expensive lack of communication because all notified bodies will charge the cost of unannounced audits, even if they are subsequently rearranged at a different location.

EXTERNAL COMMUNICATIONS

The lines of communication which must work effectively are those between the legal manufacturer and their notified body, as well as between the legal manufacturer, their critical suppliers and subcontractors. In very rare cases, when it is anticipated that a notified body may have to take samples from the distribution chain, communications with distributors could also be important, but this is unlikely to be a common scenario.

Many notified bodies, including SGS, have realised that the new obligations imposed by the September 2013 EU Commission documents required changes to client contracts and more detailed obligations on both sides. This presented an opportunity for notified bodies to formalise the notification of information and changes from the manufacturer to the notified body, to cover all the new requirements including unannounced audits. The new

process covers the provision of more detailed information and updates on activities and product ranges at each certified site, plus regulatory actions and clinical trials, critical suppliers and sub contractors, times of factory closure and sometimes production schedules. SGS asks its clients to always use a standard electronic form, to clarify the process.

To initiate the unannounced audit process, SGS, sent a simple questionnaire to all clients requesting confirmation of their activities site by site, the names and address of critical suppliers and sub contractors as well as the dates of any factory closures. Even after reminders, the return rate was only about 25%. This raised the prospect that some manufacturers hoped to avoid or delay unannounced audits. Such evasive action was a short sighted hope, since the audits are a requirement from the Competent Authorities and SGS will schedule them whether this information is confirmed or not. However, in the interests of good client relationships, most notified bodies do not want to arrive at a location only to find that a successful unannounced audit cannot take place. Hence, they are actively trying to confirm the relevant information, either during a scheduled audit or by other means, and it is in the interests of manufacturers to comply.

Having received this initial information, it is then vital that manufacturers update their notified bodies in real time, with changes in their critical suppliers and sub contractors, movement of product related activities and shutdown periods.

The intention has been to ensure that communications between critical sub contractors and the legal manufacturer of devices being own brand labelled, in particular OEM manufacturers, is a dialogue between partners. This would ensure that both sides had all the information required to carry out their respective legal obligations. Much of this communication must now be specified in the contract between the two parties. It must cover aspects such as the provision of technical documentation, the notification of design changes, the feedback of complaints and adverse events from the market.

Having agreed with their notified bodies which suppliers are considered critical, manufacturers must communicate this information to them and ensure that the contract allows the notified body to undertake unannounced audits at their supplier and sub contractor sites. In the same way that the legal manufacturers must keep the notified body informed of changes that could affect the unannounced audit, so these critical suppliers and sub contractors must update their customer, the legal manufacturer, of changes in location, production schedules and so on.

INTERNAL COMMUNICATIONS

Many manufacturers have yet to appreciate the impact the increased responsibilities of their notified body will have on their internal communication and change systems. The major focus of unannounced audits is to check whether the device being manufactured and tested is exactly as described in the technical file, and that manufacturing processes are exactly as described in procedures and work instructions. If internal change control and communication has not ensured that process improvements, changes in critical component suppliers and new production methods have been promptly and correctly translated into changes in the technical file, manufacturers should expect major non conformities to be raised. These internal lines of communication must work better than many did previously.

BEST PRACTICE FOR MANUFACTURERS

It is obvious that change control and the communication of agreed changes to the interested parties (internal and external) is more important than ever. There are two important actions for manufacturers to consider and document. Firstly, to define who in the organisation has the responsibility to inform the appropriate parties and how this should be achieved. For example, a defined person should have the responsibility to inform the notified body of all the relevant changes and they should understand how this is achieved. In the case of SGS, this would be by the mandatory SGS Notification of Changes form.

Secondly, the processes must be operated and documented so that all those with responsibilities to inform other parties, for example, the notified body, the purchasing department and the critical supplier, should be either involved with the change process, or at least be informed immediately the decision is made. This will ensure that vital communications are not forgotten and that regulatory compliance is maintained.

There is very little that is genuinely new with respect to communications, but as with other aspects of manufacturer control unannounced audits focus attention on the negative consequences and costs of poor communication, especially with your notified body.

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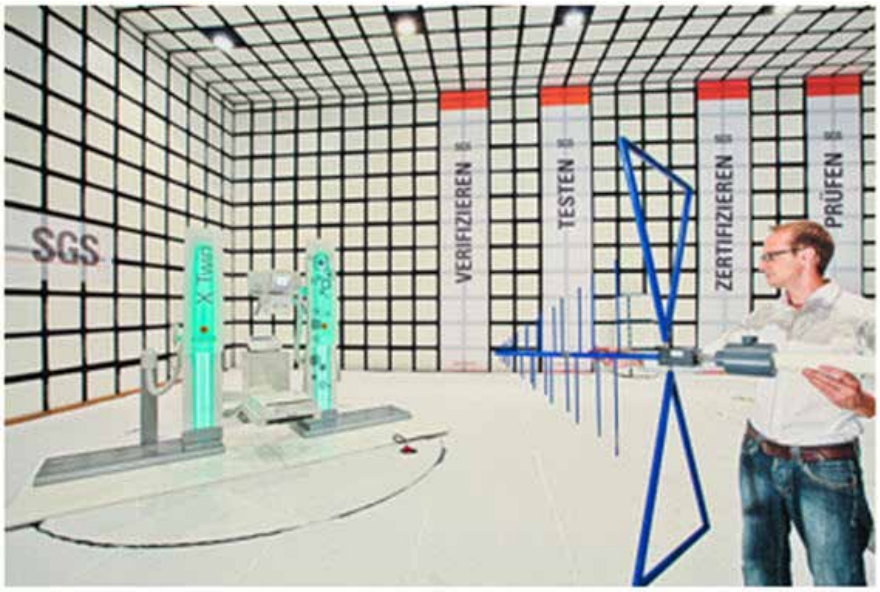
SGS ELECTRO MEDICAL DEVICE SERVICES IN MUNICH

INTRODUCING SGS MUNICH LAB

- Established: 1921
- Employees: 140

The SGS Munich Lab was originally founded as Siemens "Institut für Qualität" in 1921 and became part of SGS Group in 2008. The Munich lab now serves the following key competences for Electro Medical Devices:

- Electromagnetic Compatibility (EMC), Product Safety
- Enviromental Engineering, Qualification of Components
- SGS TÜV Saar GmbH Functional Safety, Homologation
- Battery Testing



EMC Chamber: Radiated Emission Testing of an X-ray System

SGS MUNICH FEATURES

The Munich lab serves as the gateway for services in Germany for Electro Medical Devices. Furthermore, the SGS Munich facility incorporates Test- and Simulation labs, covering an area of over 5,500m^2. Accreditations and approvals received by this facility include:

- DIN EN ISO/IEC EN 17025
- KBA Notification (e/E Mark)
- Notified Body for EMC and R&TTE Directives
- CBTL-Testlab

KEY TYPES OF SERVICES

- EMC Testing e.g. IEC EN 61326, IEC EN 60601-1-2 (10m chamber, 2 x 3m Chamber, 3 x shielded room)
- Product Safety Testing e.g. IEC EN 61010, 60601-x Series, IEC EN 60825-1
- Environmental Simulation Testing
- Functional Safety e.g. IEC EN 61508, ISO 26262, ISO13849/IEC EN 62061, IEC EN 62304
- RoHS & WEEE
- Notified Body and Quality Management System (9001, 13485) CE0120, CE0598
- MTBF Calculation, FIT Rates (IEC EN 61709, SN 29500, MIL-HDBK-217F,..)
- Failure and Damage Analysis
- Biocompatibility Testing (e.g. ISO 10993), Microbiological Tests
- Validation of Cleaning, Reprocessing and Sterilisation
- Virological Testing
- Stability Testing of Packages and Materials

Our technical team has experts in all Electro Medical Device Testing services, such as X-Ray Testing, as well as all other services needed for product safety.

The SGS Munich lab offers a wide range of marks to help you gain access to the global marketplace:

- Europe (CE; EN Standards)
- CB (Global, IEC Standards)
- USA (FDA, UL Standards, FCC)
- Canada (CSA Standards)
- Brazil (INMETRO)
- Japan (JPAL)
- China (CFDA, CCC)
- Customs union Russian (Zollunion Russland), Belarus, Kasachstan (TR EAC)
- SGS Fimko, SGS CEBEC, Russian EAC, SGS US/C

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MEDICAL DEVICES WHITE PAPER

The document summarizes the main aspects of the medical device regulations that currently apply to 13 main global markets (Australia, Brazil, Canada, China, Egypt, Europe, Hong Kong, Japan, Korea, Saudi Arabia, Singapore, Taiwan, USA).

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