

Medical Device Testing Newsletter



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Compliance with Amendment 1 to EN 60601-1 after 12/2017










EN 60601-1:2006, Amendment 1 (2013) has been published in the Official Journal of the European Union with a date of December 31, 2017. From this date on, Amendment 1 must be applied.

There is a three year transition period for the 3rd edition standard without Amendment. Please see timeline from the Official Journal below:

Dec. 31, 2015	Annex ZZ to EN 60601-1: 2006 ceases to specify presumption of conformity with Essential Requirements of MDD
Jan. 1, 2016	Only clauses and sub-clauses of EN 60601-1: 2006 corresponding with those referred to in Annex ZZ of EN 60601-1: 2006/A1: 2013 will provide presumption of conformity with Essential Requirements of Directive 93/42/EEC to the extent indicated in Annex ZZ of EN 60601-1: 2006/A1: 2013
Dec. 31, 2017	Amendment 1 is applied

Amendment 1 is addressing more than 100 issues so that practitioners and the industry will have a much better understanding of the regulatory requirements.

These issues include:

 Risk Management	 Essential Performance	 Operator and Patient Protection
 Electrical and Mechanical Safety	 Batteries	 Mobile Equipment
 Radiation	 Temperature	 Markings

Note of caution: It's important to understand your target markets and be aware of the regulatory transition periods worldwide. It is possible that some countries may be using a different transition period due to the effective date of another applicable standard for a device. It's entirely possible that it may be necessary for a product to comply with more than one edition of the standard. Your certification body should be able to help you navigate this issue and clarify which edition to use.

Other Helpful Publications

WEBINAR



[IEC 60601-1 3rd Edition And Risk Management: What You Need To Know](#)

WHITEPAPER



[4th Edition Of IEC 60601-1-2 Tightens EMC Requirements](#)

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New Radio Equipment Directive (RED)

In 2014, the European Union (EU) adopted a new set of rules called Radio Equipment Directive (RED), 2014/53/EU. This directive is required in order to place radio equipment on the European market and put them into service. EU Member States had to adapt their National laws and apply its provision from June 13th, 2016. This was also the date of repeal for the then-current Radio & Telecommunications Terminal Equipment Directive (R&TTE-Directive, 1999/5/EC). Manufacturers who are compliant with the existing legislation (R&TTE-, LV- or EMC-Directive) will have until June 13th 2017 to comply with the RED, which brings the Directive in line with the new legislative framework.

Major Changes

The former R&TTED covered relevant components of radio equipment, excluding broadcast TV & radio receivers.

The new RED applies to the following equipment:

- Equipment that intentionally transmits or receives radio waves for communications or radio-determination, regardless of its primary function, and which is placed on the market
- Radio equipment operating at frequencies below 3000 GHz, including radio equipment operating below 9 kHz that is not covered by the R&TTED or by national frequency regulations
- Radio-determination equipment, which is equipment that uses the propagation qualities of radio waves to determine its position

Broadcast TV & Radio

The R&TTED specifically excluded Broadcast TV & radio receivers from its scope. These are now specifically included in the scope of the RED. For example, a product which uses an embedded radio module for communications or to determine its position has to meet the same radio requirements as 'real' radio equipment.

Wired Telecommunications

'Wired' telecommunications terminal equipment does not have "radio" and are no longer covered by the RED. They are instead covered by the Electromagnetic Compatibility Directive (EMC) and Low-Voltage Directives (LVD). In turn, radio equipment covered by the RED is not subjected to the EMCD or LVD, as the essential requirements of those directives are covered by the essential requirements of RED (with certain modifications).

Safety Assessment

Under the new RED a safety assessment must now take into account reasonably foreseeable usage conditions. This means that a manufacturer must consider a potential misuse of the equipment, not just the intended use as outlined in the equipment's instructions.

Spectrum

The RED puts some weight on the efficient and effective use of the spectrum. Radio equipment needs to demonstrate the performance of its broadcast receiver and transmitter parts, as both are considered to affect the efficient and effective use of the spectrum.

Suppliers

The RED also includes much clearer obligations for the equipment operators to identify who has supplied them with radio equipment and to whom they have supplied radio equipment.

Other changes include:

- The use of proper languages for the Declaration of Conformity (DoC)
- Requiring a full DOC be made available, including all information on DOC or simplified DOC via web address/link where a full version can be obtained
- Instructions for product in an easily understood language
- New responsibilities for importers to perform sample testing of radio products made available on the market.

Whitepaper: The Wireless Medical Device Manufacturer's Guide To Market Conformity

Key Learnings:

- Overview Of Wireless Medical Devices
- Two Regulatory Agencies (FDA And FCC)
- Rules Of Communication
- European Differences
- New Challenges For Wireless Devices



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New Directives: Medical Device & In-Vitro Diagnostic Regulation



The new Medical Device Regulation (MDR) will replace the current Medical Device Directives in Europe - Medical Device Directive 93/42/EEC and Active Implantable Medical Device Directive 90/385/EEC. The Directive on In-Vitro Diagnostic Medical Devices 98/79/EC is also scheduled to be replaced by a new regulation on the same subject (IVDR).

At present, final text translations and being completed in all EU official languages and technical inconsistencies are being corrected. A formal adoption is expected sometime in the first half of 2017, and new rules will apply 3 years after publication for medical devices and 5 years after publication for in-vitro diagnostic devices.

What To Expect with the new MDR

The new MDR will have a product scope expansion to include medical devices that may not have a medical intended purpose and/or which are designed for the purpose of prediction of a disease or other health condition. The new MDR also grants Notified Bodies an increased surveillance authority to help reduce risks from unsafe devices, including unannounced audits, other product sample checks and product re-testing. A medical device manufacturer will be required to identify a person responsible for compliance with the MDR requirements within their organization.

Another important change to mention is that the new MDR will require device manufacturers to conduct clinical performance studies and provide evidence of safety and performance, proportionate with the risk associated with a given device.

For device manufacturers who obtain CE Mark certificates ahead of final MDR implementation in 2020, their CE Mark certificates will remain valid for a maximum of five years. Manufacturers must be aware that all CE Mark certificates issued before final MDR implementation will automatically expire four years after the MDR goes into full effect (roughly in 2024).

What To Expect with the new IVDR

The IVDR will take longer to come into full effect. Following translation and formal publication of the regulation in May 2017, there will be a five year transition period. Under this new regulation, what qualifies as an in-vitro diagnostic device has been greatly expanded. It now includes genetic tests, tests that are used to predict treatment response or reactions, and software. The new IVDR creates a risk-based classification scheme: classification A to D. This will replace the more general IVD categories and will also require assessment of the technical documentation for classification B, C or D by a Notified Body.

The new IVDR will provide identification, traceability, and improved access to information, while also increasing the post-market surveillance and reporting responsibilities for manufacturers in all IVD risk classifications.

Another major change will be the requirements for risk-based clinical evidence and protection of patient safety in clinical performance studies. Similar to the new MDR, the IVDR will also require a designated person responsible for regulatory compliance.

Manufacturers of IVD and medical devices who currently have CE Marked products or are planning to obtain the CE Mark soon, should start with a product and regulatory assessment to identify gaps that need to be addressed. An early pre-compliance assessment will allow for the prioritization of the changes needed for successful implementation, as well as inform you of any cost constraint you have to budget for.



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New US FDA Guidance Regarding Post-Market Cybersecurity Risk Management for Medical Devices

The US FDA has issued final guidance regarding post-market cybersecurity risk management for medical devices. The final guidance comes about a year after the FDA published a draft guidance on managing applicable medical device and software product cybersecurity risks. The new FDA document follows the previously issued draft guidance from early 2016 and includes recommendations for manufacturers to identify and monitor cybersecurity risks associated with their products. The final guidance also outlines a risk framework registrants should utilize to determine whether changes they

make to their devices to address cybersecurity vulnerabilities warrant reporting to the FDA. The new post-market cybersecurity risk management guidance applies to devices already marketed in the US, as well as those used as parts of interoperable systems containing software that qualifies as a medical device. Similar to the draft guidance, the final version still contains non-binding recommendations only.

The full 30-page document can be seen on the FDA's website. [Click Here](#)

Publication of ISO13485:2016 Quality System Standard

Did you know that as of February 28, 2019, the new revision of the ISO 13485:2016 has to be used? This also means that as of the same date, the transition must be complete from ISO 13485:2003 and the associated European Standard EN ISO 13485:2012.

The most important changes between the 2003 and 2016 version of the global standard for medical device quality management systems (QMS) are as follows:

- Incorporation of risk-based approaches beyond product realization. Risk is considered in the context of the safety and performance of the medical device and in meeting regulatory requirements
- Increased linkage with regulatory requirements, particularly for regulatory documentation
- Application to organizations throughout the lifecycle and supply chain for medical devices
- Harmonization of the requirements for software validation for different software applications (QMS software, process control software, software for monitoring and measurement) in different clauses of the standard
- Planning and documenting corrective action and preventive action, and implementing corrective action without undue delay
- Emphasis on:
 - Appropriate infrastructure, particularly for production of sterile medical devices
 - Addition of requirements for validation of sterile barrier properties
 - Complaint handling and reporting to regulatory authorities in accordance with regulatory requirements

- Consideration of post-market surveillance
- Additional requirements in design and development for:
 - Usability
 - Use of standards
 - Verification and validation planning
 - Design transfer and design records

ISO 13485 deals with the whole lifecycle from design and development, through manufacture, transport and end of life. This new standard is also used for the Medical Device Single Audit Program (MDSAP), an international effort to reduce redundant audits of medical device manufacturers.

Whitepaper: 5 Reasons Why Choosing MDSAP Certification For Medical Device Manufacturers Soon Is A Good Idea

Inside this Whitepaper:

- Evolution Of MDSAP
- 5 Reasons To Consider Starting The MDSAP Process Now
 - Get To Market Faster
 - Lower Compliance Costs
 - A Soon-To-Be Canadian Requirement
 - Auditor Familiarity And Economies Of Scale
 - Get While The Getting Is Good, Or Wait In Line



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