

Medical Product Compliance

Medical Electrical Products must now meet the 3rd edition of 60601

I. BIG Changes to Medical Product Certification

The move from the 2nd edition to 3rd edition of 60601 is perhaps the most significant standard update ever within the field of Product Safety. There are three reasons for this:

A) Risk Management Added to Certification:

- i. Certifications to the 2nd Edition did not require the use of a Risk Management File (RMF). A medical device manufacturer typically had their Regulatory Group run the Risk Management Process (RMP) per the FDA requirements, while a separate Compliance Team worked with the Safety Agency to obtain UL/CSA/CE certifications. But the 2nd edition is no longer accepted.
- ii. The 3rd edition of the standard includes significant Risk Management File requirements. These requirements are above and beyond what is required by your ISO14971 RMP. An RMF prepared solely using ISO14971 guidelines will not be compliant with 60601-1 third edition. The RMF must also meet the Risk Management requirements within 60601-1 (which go far beyond ISO14971). Consequently, with the 3rd edition, the RMP development team must now work directly with the Safety Certification Team. This is not a simple process.

B) Additional Standards for Compliance:

- i. A 2nd Edition Certification only required compliance with 60601-1 (General Safety), 60601-1-2 (EMC), and any 60601-2-XX Particular Standard that applied to the type of product. Which typically meant one or two safety standards total, plus EMC.
- ii. A 3rd Edition Certification requires all these standards PLUS new collateral standards including 60601-6 Usability (Human Factors), and 60601-1-8 Alarm Safety. In addition, 60601-1 now includes requirements for PEMS (Programmable Electrical Medical Systems) and indicates that software must meet IEC62304. Plus, home healthcare products must also meet 60601-1-11 and emergency medical must meet 60601-1-12, two very environmental test intensive standards. So now you must meet many more standards, especially if you have software and alarms.
- iii. With the 3rd edition, the Certification Labs are required to at least evaluate manufacturer's data for all required Collateral standards. Many of the areas covered by the Collateral Standards anticipate that the manufacturer will be the expert and therefore they are considered "manufacturer's responsibility". Furthermore, the Certification Labs will indicate that if these requirements are applicable, they ask that you provide the TRF (Technical Report File) that documents "how" you comply for every clause in each of the applicable collateral standards.

C) Essential Performance Required:

- i. A new term introduced in the third edition of 60601 that has a significant impact on product compliance. The manufacturer must define the "essential performance" for their product, which is defined as performance of a clinical function where loss or degradation beyond the limits specified results in unacceptable risk (see additional details in step 4 below).

II. Preparing for the 3rd Edition: So with the 3rd edition, there are many more standards to comply with, there is a lot more work needed on the Risk Management File, and you must prepare a TRF to the RMF requirements of 60601-1. This is a lot more work. Therefore, expect your Certification costs to double or more, and the completion time to extend considerably longer (actual lab time may not be that much longer but there is a lot more preparation work before you will be ready to send it to the certification lab). The basic steps to preparation are:

- 1) Product Classifications identified per 60601-1, and -1-11 and -1-12 if applicable,
- 2) Standards Identification: Determine which standards within the 60601 series are applicable including particular standards and, collateral standards such as software, alarms, bio-compatibility, sterilization, PEMS, etc. Several of these standards also reference ISO standards such as ISO62304 and ISO62366.



- 3) Isolation Diagram created showing method of shock hazard compliance to patient and medical practitioner.
- 4) Essential Performance for the product identified and defined - medical products are now required to meet "Essential Performance" as a compliance criteria after many of the tests. Special test samples may be necessary to allow for verifying essential performance after each test.
- 5) Expected Service Life determined including continued use and maintenance. ESL is required input to your Risk Analysis.
- 6) RMF Review and Preparation: If you do not have an RMF yet, training is recommended to teach you how to develop your RMF so that it is compliant with 60601-1 3rd edition. If you already have an RMF, is it 60601-1 compliant? If not, you will need to review your RMF for compliance with the RMF requirements in 60601-1.
 - It is likely that the Certification Lab will ask to see the product's Essential Performance definition in order to provide a firm quote. EP can greatly impact the engineering review time required to verify compliance after each test.
 - The Certification Lab will not spend a lot of time or effort identifying what standards within the 60601 series apply to your product. If you do not specify which collateral and/or particular standards apply, they may not be included in the quote and it will set your project up for failure.
- 7) Product Pre-Compliance Review: At the very least, have the enclosure and all critical components reviewed for compliance to 60601-1 as well as 60601-1-11 and 60601-1-12 if applicable. Ideally, do a clause by clause preliminary review of these standards.
- 8) Collateral Standard TRF's: If Usability, Software & Firmware, PEMS, and/or Alarms is applicable, the product must be reviewed to these standards with TRF's prepared during the review process.
- 9) Test Plan Developed: Summary of all tests, test parameters, and test configurations prepared. Pre-compliance testing should be considered for EMC and any other testing with unpredictable results.
- 10) Markings, Labeling, & Instructions Review: The 3rd edition has a lot more requirements in this area, this is especially the case with -1-11 and -1-12.
- 11) US/CAN/CE Certifications: By properly preparing in steps 1-10, you can help avoid compliance failure.

III. Other 3rd Edition Comments:

- A) Amendment 1: It is in your best interest to use edition 3.1. However, if you are already compliant with edition 3.0, you are good for awhile.
- B) US - UL: The 3rd edition in the USA is not a "UL" standard. The 2nd edition was UL60601-1, but the 3rd edition is managed by AAMI and is known as AAMI ES 60601-1. Consequently, UL Certifications in the US are now done to the AAMI ES 60601-1 standard.
- C) US-CAN-CE-INT: This whitepaper is applicable to all versions of the 3rd edition and edition 3.1 of IEC60601-1 including AAMI ES 60601-1, CSA60601-1, and EN60601-1.

Key 3rd Edition Preparation Questions:

- *Are you really ready for the 3rd edition?*
- *Do you have a complete RMF that is compliant with the RMF requirements of 60601-1?*
- *Have you identified all applicable standards in the 60601 series?*
- *Do you have TRF's for -1-6, PEMS, and -1-8 if they are applicable?*
- *Have you had an expert do a pre-compliance construction review to 60601-1, as well as -1-11 and -1-12 if applicable? It is a lot less expensive to find your problems during pre-compliance.*

**CertifiGroup can assist you with all steps in preparing FDA submittals,
preparing for compliance to the 3rd edition,
and providing US/CAN/CE/International Certification for your products.**