Deadline for 3rd Edition of EN 60601-1 Looms

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IEC 60601-1 applies to all electrical and electronic medical devices and its accessories. The 3rd edition is in the process of being adopted by global regulatory authorities. But on a national level, regulatory affectivity dates are not harmonized across global jurisdictions. Parallel use of 2nd and 3rd edition is expected through 2012. Compliance with the standard is not required with products deployed in the field, but applies to new products going through regulatory approvals, as well as existing products that are currently compliant with the 2nd edition. In the EU, compliance with 3rd edition will be required to qualify for the CE mark.

Power accessories such as external power adapters or battery chargers, affiliated with a medical device, and used in a medical environment are classified as an electrical medical device accessory. Examples of medical devices that use adapters or chargers include surgical tools, ventilators, digital imaging plates, or defibrillators. Medical adapters and chargers destined for sale in Europe must be compliant with EN 60601-1 3rd edition by June of 2012. The EN 60601-1 is based on the standard IEC 60601-1: 2005, which is the global safety standard for Medical Electrical Equipment. Part 1 is the General Requirements for Basic Safety and Essential Performance. This standard applies to medical chargers that have embedded power supplies or power adapters that provide AC/DC power conversion.

Open Frame Power Supply Compliant with 3rd Edition EN 60601-1.

There are three regional variants: EN 60601-1 in Europe, ANSI 60601-1 in the US, and CSA 22.2 in Canada. For the EU, EN 60601-1 is a harmonized standard and is accepted for the Medical Device Directive for all device classes. Europe currently accepts 2nd & 3rd edition, but 2nd edition will not be accepted after June 2012, and 3rd edition becomes mandatory.

For medical OEMs that supply adapters or chargers into Europe or Canada, there is a pressing deadline that requires all medical devices - including medical-grade adapters and chargers - be certified to EN 60601-1 and CSA 22.2 by June of 2012, respectively. Note that Europe and Canada will not allow the sale of adapters or chargers that are certified to EN 60601-1 and CSA 22.2 2rd edition after that date. So it is critical that OEMs with chargers or adapters get their systems upgraded to 3rd edition before that deadline.

Relative to the 2nd edition IEC 60601-1: 1988, the 3rd edition: IEC 60601-1: 2005 addresses the general requirements for basic safety and essential performance. The major differences between the 2nd and 3rd edition of IEC 60601-1 could be the topic of a very lengthy article. A summary of the affected areas include 1) Essential Performance, 2) Risk Management Process Risk Analysis, 3) Insulation Coordination, 4) Temperature, 5) Leakage Current, 6) Mechanical Hazards, 7) Fire Prevention Requirements, and 8) Component Requirements.

Many medical adapter and chargers have been qualified for both the 2nd and 3rd edition IEC 60601-1 standard. Applicable skillsets utilized in these developments include electrical engineering, mechanical engineering, risk management processes, and regulatory agency management. With the deadline looming in Europe, medical OEMs may need to upgrade their medical adapters and chargers, from 2nd generation IEC 60601-1 to the 3rd edition of this standard.

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