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FDA Recognizes AAMI Version of Electrical Equipment Standard

The U.S. Food and Drug Administration (FDA) has formally recognized the Association for the Advancement of Medical Instrumentation (AAMI) version of an international standard on medical electrical equipment.

FDA's recognition of ANSI/AAMI ES60601-1:2005 — *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance* and other collateral standards — comes as welcome news to the medical technology community.

The standard — which is the U.S. adoption of IEC 60601-1/Ed.3:2006 — contains required national deviations to comply with the National Electrical Safety Code, says Charles Sidebottom, director of corporate standards for Minneapolis-based Medtronic and secretary of IEC/Subcommittee 62A, which developed the IEC standard.

The third edition of IEC 60601-1 has been recognized and harmonized in Europe for several years. The AAMI Electrical Safety Committee, which developed the U.S. adoption, is working to harmonize it with NFPA 99, the standard from the National Fire Protection Association (NFPA) on healthcare facilities that remains under development, says Mike Schmidt, co-chair of the committee.

The ES60601-1 standard offers general requirements for basic safety and essential performance of medical electrical equipment.

Schmidt — a principal consultant with Strategic Device Compliance Services in Cincinnati, — praised Carol Herman, director of standards at FDA's Center for Devices and Radiological Health (CDRH), and FDA for their work.

ANSI/AAMI ES60601-1:2005, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*

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"With regulators around the world accepting standards based on the new IEC 60601-1 — such as ES60601-1, which includes only minor changes to the IEC standard — it was critical for manufacturers to be allowed to use it as the basis of submissions in the U.S. as well," Schmidt says.

During the *AAMI/FDA International Conference on Medical Device Standards and Regulation* in March, Herman said that FDA would recognize a version of 60601-1, and that there would be a three-year transition period to the third edition and related collaterals and particulars. A July notice in the *Federal Register* shows FDA chose to recognize the ES60601-1 U.S. version of the standard.

The shift to the third edition is significant, experts say. "It has more of a risk management philosophy behind it, rather than just being pure testing," Sidebottom says.

Other AAMI Standards Recognized

FDA also recently recognized the following collateral standards that were adopted by AAMI. To obtain any of these standards, visit http://marketplace.aami.org.

- ANSI/AAMI/IEC 60601-1-2:2007, *Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility —Requirements and tests*
- ANSI/AAMI/IEC 60601-2-21: 2009, *Medical electrical equipment—Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers*
- ANSI/AAMI/IEC 60601-2-19: 2009, *Medical electrical equipment—Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators*
- ANSI/AAMI/IEC 60601-2-20: 2009, *Medical electrical equipment—Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators*
- ANSI/AAMI/IEC 60601-2-2:2009, *Medical electrical equipment—Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

Founded in 1967, the Association for the Advancement of Medical Instrumentation (AAMI) is a nonprofit organization representing a unique alliance of nearly 6,000 members from around the world united by one mission — to increase the understanding and beneficial use of medical instrumentation through effective standards and educational programs, and publications.