Despite being on the scene for many years, a crucial standard dealing with the safety and effectiveness of medical electrical equipment continues to raise questions. Nearly 10 years after the release of the third edition of International Electrotechnical Commission (IEC) 60601-1 and three years after the release of the amendment to IEC 60601-1, the issues raised in the standard still challenge many industry users.

Charles Sidebottom, a managing partner of PPO Standards LLC, a consulting firm that focuses on medical device standards, put it this way: “The introduction of a formal risk assessment process within a risk management structure is the biggest change from the second to the third edition of 60601-1. That’s still the area people struggle with the most.”

To confront that confusion and help device manufacturers, AAMI and the FDA hosted a forum this past spring, focusing on the 60601 series of standards. The event brought together:

• Industry professionals who design, develop, test, and market medical equipment
• IEC leaders who helped write the third edition of IEC 60601-1 and its amendment
• U.S. Food and Drug Administration (FDA) regulators who use the series of standards to evaluate the safety of medical electrical equipment

The lively two-day forum, which drew 118 participants, explained the key aspects of the standards and provided unprecedented access to experts, who answered specific questions and offered targeted advice to industry.

“Think of the standards as a tool for ensuring safety.”
—Al Taylor, FDA CDRH

What Is IEC 60601?
A series of technical standards for the safety and effectiveness of medical electrical equipment, currently in its third edition

What’s Included in IEC 60601?
The “general standard,” casually known as the “bible,” includes:
• Part 1: General requirements for basic safety and essential performance
• Amendment 1, known as Edition 3.1
• Collateral standards specifying general requirements for a subgroup or a specific characteristic of equipment. Eight collateral standards have been published:
  – IEC 60601-1-2 ed4.0 Electromagnetic disturbances
  – IEC 60601-1-3 ed2.1 Diagnostic X-ray equipment
  – IEC 60601-1-6 ed3.1 Usability
  – IEC 60601-1-8 ed2.1 Alarm systems
  – IEC 60601-1-9 ed1.1 Environmentally conscious design
  – IEC 60601-1-10 ed1.1 Closed-loop controllers
  – IEC 60601-1-11 ed2.0 Home healthcare environment
  – IEC 60601-1-12 ed1.0 Emergency medical services

“Particular standards,” also known as “the Part 2s,” modify or extend the general standard, or both, to address the needs of a particular group, class, or application of medical equipment or a medical electrical system. Notably, requirements in Part 2 standards supersede requirements in the general standards, which means that Part 2 rules if there are differences from the general standards. More than 70 Part 2 standards have been published, with more in the works, either in the IEC 60601 or IEC/ISO 80601 series for medical electrical equipment.
"Many think of risk management as an ‘add-on’ to the third edition. The third edition has simply made the relationship among identifying hazards, hazardous situations, and risk controls explicit. The rationale of the new standard now provides extensive information allowing us to use the requirements to control risks to acceptable levels, rather than just ‘checking boxes.’ If you do nothing but check boxes, checking boxes is all you will achieve. You will not achieve safety.

"60601-1 remains an invaluable tool for identifying hazards and the ‘trigger events’ that could allow them to cause harm. The standards point out risks we may not have thought of. If we had thought of them, we would have taken care of them."

—Mike Schmidt, principal consultant and owner, Strategic Device Compliance Services, and Secretary, IEC Subcommittee 62D

The FDA recognizes the complete AAMI/ANSI 2012 version of 60601-1, with and without Amendment 1 (2012).

What’s the Big Deal with 60601?
Conformance to the 60601 series of standards holds enormous import for industry. Here’s why, according to S³ Challenge presenter Alex Grob, chief biomedical engineer and quality manager, Medical Equipment Compliance Associates (MECA):
• The 60601 series is a key piece of U.S. and international regulatory compliance—and many regulatory bodies are transitioning to the revised standards.
• Rigorous risk management and risk mitigation requirements in the revised third edition of 60601 increase the level of assurance that a medical device is safe. Compliance with particular standards can help demonstrate effectiveness.
• Conformance to the globally harmonized standards eases entry into most major markets and helps industry meet customer and user expectations.

The FDA recognizes the complete AAMI/ANSI 2012 version of 60601-1, with and without Amendment 1 (2012). After Aug. 1, 2016, the FDA will no longer recognize AAMI/ANSI 60601-1 without Amendment 1. The agency also recognizes several of the collateral and particular standards.

In the European Union (EU), conformance to the revised third edition of 60601 is an important tool for achieving CE marking, a legal requirement to market devices in the EU.

Although complying with the standards is voluntary, compliance does grant a presumption of conformity with the Medical Device Directive (MDD), which is the most common method of satisfying the EU legal requirement. The MDD covers topics that are broader in scope than 60601, but compliance with 60601 satisfies some of the requirements to legally market in the EU.

The shift to the standards also is under way in other markets. Compliance and certification are mandatory in Brazil; compliance is mandatory in Japan and South Korea. Canada, Singapore, and Taiwan are transitioning to the standards as well. Countries differ in the edition of the standards that is adopted, in designating the standards as required or optional, and in their transition periods, thereby complicating the decision to comply with the second edition, third edition, or both. China has not adopted the third edition but is in the process of translating the standards.

Global adoption and transitions to edition 3.1 of 60601 make it clear that industry needs to get a better handle on the differences between its second and third editions.

Cutting to the Chase: What’s New in the Revised Third Edition of 60601?

A More Enlightened Approach to Risk Management. “IEC 60601 has always been about managing risk,” said Sidebottom, secretary, IEC Subcommittee 62A, which is
responsible for the development of the general and collateral standards in the series. As knowledge, science, and experience about the safety of medical electrical equipment have expanded, approaches to risk management and risk mitigation have become more rigorous as well.

The first and second editions focused on basic safety—freedom from unacceptable risk directly cause by physical hazards—by specifying tried-and-true risk control measures or test methods to verify the effectiveness of risk control measures designed and implemented by manufacturers, Sidebottom said. The standards applied the “brick model” of risk management: Any medical electrical equipment or system that became an inanimate object (i.e., a “brick”) when it failed was safe as long as it didn’t shock, burn, or fall on a patient or clinician, for example.

In the run-up to the third edition, the IEC committee began to understand that focusing only on basic safety was not sufficient to achieve the level of safety that stakeholders were beginning to demand of medical electrical equipment and systems. In Sidebottom’s brick analogy, the failed “brick” may have met basic safety requirements, but “if an external defibrillator doesn’t deliver enough energy to the patient, then the patient is at risk,” he explained. In 1994, the committee moved toward a functional safety model—a systematic approach to risks arising if medical electrical equipment or a system should fail to perform its intended function.

The 2005 version of the third edition of 60601 introduced the concept of essential performance—performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by a manufacturer results in “unacceptable risk.” Because both basic safety and essential performance depend on understanding what constitutes unacceptable risk, the third edition introduced a formal risk assessment process within a risk management structure.

"If you are halfway through a product design using the older version of 60601 during the transition period, you don’t have to switch to the new one. However, if you haven’t started design, apply the new version as soon as you can. If a company plans to use an older version of a standard after the transition period, it should document that choice in premarket submissions and documentation and explain how it has addressed all appropriate risks.”

—Jianchao Zeng, senior standards advisor, FDA CDRH
**Risk Management Questions and Answers**

**S3 Challenge presenter Marco Fedeli, medical engineering team leader with Intertek Testing Services, walked through common questions and areas of confusion about topics in the revised third edition of 60601. Here’s a sampling:**

**QUESTION:** My device has been sold for 20 years without issue. Why do I now need a risk management file?
**ANSWER:** A manufacturer must have:
- An established risk management process that complies with ISO 14971.
- Followed this process and established an acceptable level of risk for the device.
- A documented risk management file that demonstrates that the residual risks for this device are acceptable according to this level.

**QUESTION:** My device has rounded corners, and so why it is required that I analyze the risks of sharp edges in the device risk management file?
**ANSWER:** The rounded-corner design is actually a risk control that was implemented to mitigate against the hazard of a patient or operator being cut.

**QUESTION:** What is the essential performance of my device? Is "not burning someone" essential performance?
**ANSWER:** Essential performance in IEC 60601-1:2005 was “performance necessary to achieve freedom from unacceptable RISK.”

Essential performance in IEC 60601-1:2005 and A1:2012 is now: “performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK.”

**Try This** (from IEC 60601-1:2005 and A1:2012)

**Step 1.** IDENTIFY the performance of the clinical function(s).
1. Draw a slight amount of vacuum over a wound.
2. Warm a patient during surgery.
4. Deliver a specific power intensity of ultrasonic vibration to the patient.

**Step 2.** SPECIFY performance limits between fully functional and total loss of the identified performance.
1. A vacuum of –2 to –2.5 psi increases the rate of healing.
2. A warming pad that maintains normothermia of an unconscious patient helps with recovery from anesthesia.
3. A proper surgical table must not flex more than ±0.05° along any axis.
4. The delivery of 2 W/cm² of ultrasonic energy helps with joint pain.

**Step 3.** EVALUATE the RISK from the loss or degradation of the identified performance beyond the limits specified.
1. A vacuum greater than –3 psi may cause permanent harm, while a vacuum of less than –1 psi will not cause harm but will render the device useless.
2. A warming pad that exceeds 40°C may burn an unconscious patient.
3. Unwanted movement of a table of greater than ±0.05° during surgery could lead to harm.
4. The delivery of more than 3 W/cm² may cause harm.

**Result.** If the resulting RISK is unacceptable, then the identified performance constitutes an ESSENTIAL PERFORMANCE.
1. The device must shut down or sound a medium-priority alarm signal when a vacuum of greater than –3 psi is detected.
2. The value of the warming pad shall not differ from the value of the temperature indicated by the temperature control setting by more than ±1°C but not exceeding 41°C (IEC 80601-2-35).
3. No unwanted movement shall result during any SINGLE-FAULT CONDITION and any combined-fault conditions (IEC 60601-2-46).
4. The maximum EFFECTIVE INTENSITY shall not exceed 3 W/cm² with any TREATMENT HEAD or ATTACHMENT HEAD provided by the manufacturer. This requirement shall apply in NORMAL CONDITION and in any SINGLE-FAULT CONDITION (IEC 80601-2-5).
Now, the requirements of 60601 are applied as follows when evaluating risk:

- Satisfying the objective requirements in the general standard or relevant particular standards is presumed to result in a residual risk that is acceptable.
- Where the general standard or relevant particular standards specify requirements but do not provide objective acceptance criteria, the manufacturer provides criteria according to its risk management plan.
- Where the general standard or a particular standard identifies hazards that have to be investigated without providing technical requirements, the manufacturer has to determine if such hazards exist and then control the associated risks so that they are acceptable.
- Finally, the manufacturer has to consider whether hazards exist that are not covered by the standard and deal with them appropriately according to its risk management plan.

In addition, the revised 60601 standards make explicit reference to the use of ISO 14971, *Medical devices—Application of risk management to medical devices*.

The IEC will decide (after a review period that closed on May 8) which, if any, parts of the general and collateral standards need to be revised. In cases where a revision is considered necessary, the target publication date for those revisions in a fourth edition of the standards is 2019.

**Recognition that Patients Are More Vulnerable to Safety Hazards than Operators of Medical Electrical Equipment.** This is “the most profound change” in electrical safety requirements of the revised third edition of 60601, according to presenter Mike Schmidt, principal consultant and owner, Strategic Device Compliance Services, and secretary of IEC Subcommittee 62D.

**BY THE NUMBERS**

An on-site, interactive poll of $S^2$ Challenge industry participants revealed:

- **74%** are now designing, or planning to design, a new product within the next year that complies with the 60601 series of standards.
- **45%** report significant changes to products or documentation when they’ve updated products to comply with the third edition of 60601.
- **41%** have run into internal delays—involving, for example, redesign or documentation—in getting products evaluated to the third edition of 60601.
- **39%** have experienced minor changes to products or documentation when they’ve updated products to comply with the third edition of 60601.
- **28%** have run into external delays by a testing laboratory, subcontractor, or supplier in getting products evaluated to the third edition of 60601.

“It is imperative to remember that Collateral Standards become normative at the date of their publication and shall be applied together with Part 1.”

—Charles Sidebottom,
PPO Standards LLC
In many clinical situations, the patient’s ability to recognize and respond to hazardous situations may be impaired,” Schmidt said. Because patients are presumed to be more vulnerable, the requirements for means of patient protection (MOPP) are greater than the requirements for means of operator protection (MOOP)—and criteria or performance limits for patient versus operator protection are spelled out more comprehensively than in prior editions of 60601.

Some of the changes are significant, particularly for applied parts of medical devices that include a conductive connection that delivers electrical energy to a patient or that returns an electrophysical signal to the patient. “Most importantly, the third edition identifies controls for risk of electric shock that by consensus convey a presumption of acceptable risk,” Schmidt said.

For equipment intended for use in home healthcare, the standards take into account that patients may operate devices themselves. Even when they don’t, caregivers may not be “classically trained” clinicians working in a professional healthcare facility, according to Dave Osborn, senior manager of Global Regulations and Standards, Philips, who was active in developing the third edition of 60601.

Likewise, medical equipment intended for use by emergency personnel, sometimes responding to disasters resulting in mass casualties, must be able to withstand rough handling and extreme environmental conditions. “These users certainly expect the equipment to work, wherever the patient needs
“Manufacturers are asked to do more with testing and documentation in the third edition of 60601. Be prepared. Involve the right people, which likely include different people from ‘traditional’ conformance testing. Have final, or near-final, documentation—and final, production-equivalent, working units—available for testing. Work with your testing laboratory. Understand what they expect. Know what you are getting—a certification report, informative report, CB [Certification Body] report, letter report? Make traceability easy to follow—tracing risks to 60601-1 clauses and to design inputs and outputs. Expect to work more closely with your testing laboratory than you have in the past.”

—Alex Grob, MECA


“Testing has evolved from fixed testing to testing to the environment of use,” Weininger added. “Testing is now more sophisticated.”

The Bottom Line:
What’s the Real Value of 60601?
Companies that embrace the 60601 standards not just as a conformance exercise but as a powerful tool for product design, development, testing, and improvement can realize real, bottom-line value, according to Denny Treu, vice president and senior member, Technical Staff, NxStage.

The company, which makes dialysis systems, benefits from the consolidation of myriad AAMI, IEC, ISO, and Canadian standards, and FDA and international recognition of those consolidated standards. “It is easier today to design an international dialysis system, due to the consolidation of dialysis standards,” Treu said.

NxStage designs dialysis systems for in-center, critical care, and home environments, including mobile equipment that can travel with patients. The company integrates 60601 risk management requirements in the general, collateral, and particular standards throughout the product development cycle, beginning with design. It uses the mechanical requirements for subsystem design—and designs for the entire product life cycle, including servicing and disposables. Treu cited these benefits that NxStage has seen from using the 60601 series of standards:

• Improves safety and usability of medical electrical equipment
• Provides an internationally accepted road map for product design
• Helps in the approval process with regulatory bodies worldwide
• Renders a faster track to market
• Provides a path for innovation and flexibility to develop new technology
• Reduces development costs

Reference

Get Involved
In Standards Development
Your best bet for staying on top of evolving standards such as 60601 is to get involved in the standards development process, expert presenters at the S3 Challenge said. By serving on standards committees, you can help shape the standards, understand changes that are coming, and avoid surprises.

The AAMI standards program consists of more than 100 technical committees, and AAMI administers international IEC and ISO technical committees. To learn more, visit www.aami.org/standards.
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