The New Paradigm for Medical Device Safety

Addressing the Requirements of IEC 60601-1 Edition 3.1

Medical devices play a vital role in the diagnosis and treatment of most health-related conditions, and are an important tool in efforts to improve patient care and treatment outcomes. However, today's advanced medical devices usually consist of unique combinations of mechanical, electrical and electronic components and technologies that are frequently controlled by software or programmable controllers. As a result, international regulations and standards applicable to medical devices are being continuously revised and updated to reflect potential safety issues that can result from increasingly complex device designs.

First published in the 1970s by the International Electrotechnical Commission (IEC), IEC 60601-1, Medical electrical equipment – *Part 1: General requirements for basic safety and essential performance*, is the internationally recognized standard addressing general requirements for medical electrical equipment and devices. IEC 60601-1 has undergone a number of significant revisions over the years in an effort to remain current with new and advanced medical technologies. The latest set of changes was introduced with the 2012 publication of Amendment 1 to IEC 60601-1.

Amendment 1, running more than 100 pages in length, introduces more than 20 new requirements for medical devices and more than 60 modifications to existing requirements. Regulatory authorities around the world are already working to implement the requirements of the amended version of IEC 60601-1 (IEC 60601-1:2005+AMD1:2012 or, more commonly, IEC 60601-1 Edition 3.1) into their regulatory approval schemes, with the U.S. Food and Drug Administration scheduled to require evidence of compliance with the latest requirements for new device submittals or modifications as early as August 2016. Therefore, medical device manufacturers should begin planning now to meet the requirements presented in IEC 60601-1 as amended.

This UL white paper provides an overview of the new and modified requirements presented in IEC 60601-1 Edition 3.1. Beginning with a brief summary of the history of the standard, the paper then offers a detailed review of the significant additions and changes presented in Amendment 1, as well as information on other changes that may affect medical device manufacturers. The white paper then presents a timetable for mandatory compliance with the requirements found in the consolidated version of the standard and concludes with some guidelines and recommendations for manufacturers.

A Brief History of IEC 60601-1

The IEC 60601 series of international standards addresses the safety and performance of medical electrical equipment and systems, and serves as the basis for the regulation of medical devices in most jurisdictions around the world. The series consists of a general standard (IEC 60601-1), approximately 10 collateral standards (numbered IEC 60601-1-xx) and about 60 particular standards (numbered IEC 60601-2-xx and IEC/ISO 80601-2-xx). The IEC 60601 series does not apply to most types of in vitro diagnostic equipment (addressed in the IEC 61010 series of standards), or to implantable parts

of active implantable medical devices (covered by the ISO 14708 series of standards).

The first edition of IEC 60601-1 was originally published in 1977. The standard's technical requirements were largely based on those found in the German National Standard VDE 0750, "Medical Electrical Equipment," and its successor European standard EN 60601-1, "Medical Electrical Equipment—Part 1: General Requirements for Safety." A second edition of IEC 60601-1 was published a decade later in 1988. Throughout the 1990s, however, new technologies including software and advanced electronics were increasingly being incorporated into medical devices. These advances underscored the need for a significant overhaul of IEC 60601-1, one that would not only include new technical requirements but that would also support the evaluation of product characteristics that could not be adequately evaluated through standard pass/fail testing.

Released in 2005, IEC 60601-1 Edition 3.0 added a number of product-related safety requirements related to electrical, mechanical, thermal and fire safety. Most important, the third edition took a more comprehensive approach to the concept of safety by introducing new requirements related to the functional safety of a medical device (referred to in the standard as "essential performance"). Going forward, device manufacturers would be required to apply risk management principles to their product safety evaluation process, consistent with those set forth in ISO 14971, *Medical devices—Application of risk management to medical devices*, to identify and evaluate potential safety risks.

During the deliberation and voting process for IEC 60601-1 Edition 3.0, several National Committee members of IEC Sub Committee (SC) 62A (the group responsible for the revision) raised concerns regarding certain provisions in the revision that were deferred for future consideration. Then, following the release of the final revised standard in 2005, the IEC reportedly began receiving comments from manufacturers and certification bodies, detailing a number of specific challenges in designing and testing medical devices to the revised requirements.[1] By the beginning of 2008, SC 62A had tabulated a total of 109 issues related to Edition 3.0 that required consideration.

In an effort to address these concerns, IEC Technical Committee (TC) 62 approved in April 2008 a four year development plan for the drafting of an amendment to IEC 60601-1 Edition 3.0. The goal of this work was to address the outstanding issues identified during the original deliberation on the third edition, and to clarify the application of risk management and essential performance concepts to medical electrical equipment and systems as presented in the standard. Work on drafting the amendment began in the fall of 2008 and concluded in July 2012 with the publication of Amendment 1 to IEC 60601-1 Edition 3.0.

Amendment 1: Significant Additions and Changes

Amendment 1 incorporates more than 250 changes to the text of the standard. Many of these changes represent minor editorial corrections or clarifications, or simply correct outdated references. However, there are a number of key areas where the changes in Amendment 1 significantly alter the meaning and/or intent of the standard, as follows:

- Risk management (Subclause 4.2)—The description of risk management has been completely rewritten with the intent of clarifying exactly how the requirements of ISO 14971:2007 should be applied to the design and evaluation of medical electrical equipment and systems under the standard. The rewrite makes clear that a full ISO 14971 assessment as well as post-production monitoring and reviews are not required for compliance. In addition, a number of references to risk management throughout the standard have been removed as unnecessary and redundant.
- Essential performance (Subclause 4.3)—Amendment 1 now requires manufacturers to establish specific performance limits for their medical electric equipment, and to evaluate essential performance characteristics under abnormal or fault conditions. In addition to these changes, essential performance is now a test criteria in assessing if a hazard is present after a

[1] See "Amendment 1 to IEC 60601-1:2005 on Safety and Performance Published," Charles Sidebottom, Secretary, IECSC 62A, Medical Electronic Device Solutions, August 2012.

specific tests. Finally, manufacturers must declare specific essential performance criteria in the product's technical description.

- PEMS (Clause 14)—Amendment 1 incorporates by reference many of the specific requirements of IEC 62304:2006, *Medical device software—Software life cycle processes*, which are applicable to medical electrical equipment and systems whose operation depends on software or any programmable element (also known as programmable electrical medical systems, or PEMS). In addition, Amendment 1 adopts the term "IT-networking" in place of "data/network coupling," and incorporates validation requirements for equipment connected to a network that has not previously been validated by the device manufacturer.

Amendment 1: Other Changes

In addition to the significant modifications noted above, Amendment 1 also includes important changes in a number of other areas, as follows:

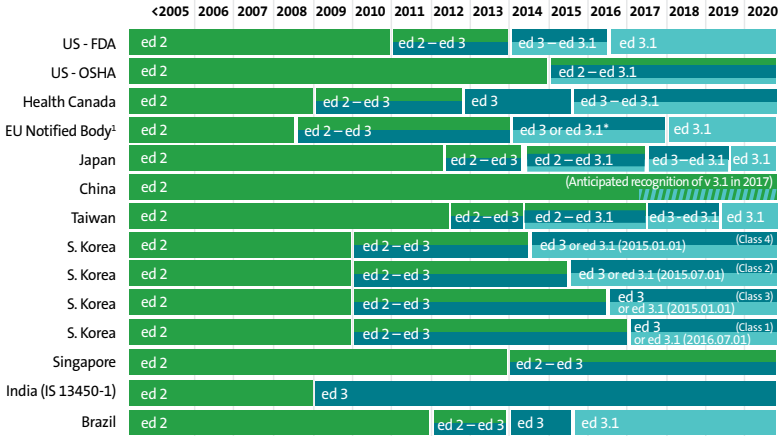
- Humidity (Subclause 5.7)—Requirements for humidity testing originally found in IEC 60601-1 Edition 2.0 have been reinstated.
- Electrical hazards (Clause 8)—There are a number of changes related to protections from potential electrical hazards, including defibrillation protection, protective earth and creepage and clearance distances. There are new limits for leakage current testing for functional earth connections. Protective earth testing with a power supply cord is also required for devices equipped with appliance inlets. Permanently installed equipment must also include a power lockout device if reconnection presents a potential hazard to a user.
- Mechanical hazards (Clause 9)—Testing for mechanical hazards related to instability and mobile equipment has been modified to include functional testing and other changes to the test methods.
- Temperature testing (Clause 11)—For applied parts, temperature limits have been clarified. For overflow, equipment must be designed to ensure that basic safety and essential performance are maintained at all times.
- Construction (Clause 15)—For mechanical strength, the prevailing requirement is now "basic safety and essential performance," replacing "unacceptable risk." Requirements for the construction of transformers have reverted to those found in IEC 60601-1 Edition 2.0. Lithium batteries must comply with the requirements of IEC 60086-4 (for primary cells) and IEC 62133 (for secondary cells).
- Marking and labeling (Subclause 7.2.2)—Equipment and accessory labeling must include a unique serial number or lot batch identifier, date of manufacturer or "use-by" date, and manufacturer contact information.
- Documentation (Clause 7)—A number of new documentation requirements for user manuals and instructions for use (IFU) have been added. In addition, electronic versions of all accompanying documentation must apply the usability engineering process as presented in the collateral standard, IEC 60601-1-6, Usability, in determining what information must be presented.

Regulatory Implementation Timetable for IEC 60601-1 Edition 3.1

The anticipated timeframe for the adoption of the requirements of the IEC 60601-1 Edition 3.1 varies from jurisdiction to jurisdiction. In some jurisdictions, such as South Korea, regulators have only recently adopted the requirements of IEC 60601-1 Edition 3.0 by reference in their applicable regulations. Therefore, manufacturers of medical electrical equipment will likely be required to comply with the requirements of Amendment 1 for access to some priority markets in the near term, even while other jurisdictions continue to regulate the same type equipment according to earlier versions of the standard.

In addition, legislative complexities in certain jurisdictions may create uncertainty as to the prevailing transition dates. A case in point is the situation in the European Union (EU), where EN 60601-1:2006/A1:2013, the EU's equivalent of IEC 60601-1 Edition 3.1, has been published in the *Official Journal of the European Union* as a harmonized standard under the EU's Medical Device Directive (93/42/EEC). Accordingly, as of Dec. 31, 2017, compliance with the provisions of EN 60601-1: 2006 (equivalent to IEC 60601-1 Edition 3.0)

IEC 60601 adoption status for global markets



1. If a particular standard is applicable, the particular standard dictates the transition dates.
* Recommend using Am1 in the EU as of 1/1/2016 due to alignment with Annex ZZ with MDD 93/42/EEC.

will no longer be accepted as evidence of conformity with the essential requirements of the Directive.

This complexity may also play out in other jurisdictions that rely on national versions of international standards as part of their regulatory scheme. For example, in the U.S., both the Food and Drug Administration (FDA) and the U.S. Occupational Safety and Health Administration (OSHA) are slated to adopt ANSI/AAMI ES60601-1: 2005/(R2012) and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012. Both of these national standards are deemed the equivalent of IEC 60601-1 Edition 3.1. But they may also include national deviations that trigger additional requirements for regulatory approval.

Finally, it is important to note that applicable transition dates for medical electrical equipment and systems subject to the requirements of a collateral and/or particular standard in the IEC 60601 series (designated IEC 60601-1-xx and IEC 60601-2-xx) may differ from those applicable to other types of devices, depending on the requirements of the particular standard. These different transition dates may also be reflected in regulations applicable in specific jurisdictions.

Special Considerations for Transitioning to IEC 60601-1 Edition 3.1

Achieving compliance with IEC 60601-1 Edition 3.1 will present considerable complexities for many manufacturers of medical electrical equipment and systems. A particular challenge will be the new requirements applicable to software and other programmable systems that are incorporated in medical electrical equipment. Specifically, the development or modification of software must now also apply formal processes as detailed in IEC 62304:2006. In brief, manufacturers are required to establish a formal software development plan that addresses an expanded set of requirements for:

1. The processes to be used in software development
2. Development deliverables
3. Traceability between system and software requirements
4. Software configuration and change management, including the use of "software of unknown provenance" (SOUP), i.e., off-the-shelf software
5. Practices for addressing problems detected in software products throughout the entire product life cycle.

In addition, the risk management plan required for medical electrical equipment must include a specific reference to the software validation plan where applicable.

For device manufacturers that typically use the IECEE's CB Scheme to obtain acceptance of test reports and certificates by national certification bodies, a further challenge is found in the requirements presented in the IECEE's Operational Document OD-2055. Published in 2014, OD-2055 requires manufacturers seeking certification to IEC 60601-1 as amended to also comply with the usability engineering process that is detailed in

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*. As a result, all CB Scheme test reports for IEC 60601-1 Edition 3.1 must include a technical report demonstrating compliance with the usability engineering requirements principally presented in IEC 62366-1.[2] Compliance with the requirements of other collateral standards may also be required to obtain CB Scheme certification.

Each of these special cases potentially imposes significant additional compliance burdens on manufacturers seeking to demonstrate compliance with the requirements of IEC 60601-1 Edition 3.1. Indeed, these issues may require manufacturers to evaluate their entire product design and validation process and to address specific gaps between existing practices and those prescribed by the amended standard.

Suggested Actions for Achieving Compliance

Clearly, meeting the requirements of IEC 60601-1 Edition 3.1 will require detailed analysis and careful planning by manufacturers of medical electrical equipment and systems, taking into account the standard's new technical requirements as well as the planned transition to the new standard by regulators in target markets. Some suggested actions for achieving compliance include the following:

- Internal audit of product design process—Meeting the added software process and usability engineering requirements in IEC 60601-1 Edition 3.1 may require a complete overhaul of a manufacturer's existing product design and validation processes. Implementing such changes will likely take considerable time and resources. A prompt internal audit of current processes and practices for compliance with the new requirements can help to establish a realistic timetable for making any required changes.
- Proactive design review—For existing products slated to be recertified to the requirements of IEC 60601-1 Edition 3.1, a proactive design review can determine the extent of technical modifications that may be required. For new products or products under development, meeting the requirements of regulations and standards is achieved most effectively when compliance considerations are considered beginning at the earliest stages of the product design process.
- Market intelligence and analysis—Knowledge of the specific technical and regulatory requirements applicable in key target markets is also essential in determining the scope of the overall compliance effort. This is especially important given that the global transition to IEC 60601-1 Edition 3.1 is likely to extend over several years and that many manufacturers may be required to certify their products to multiple versions of the standard.
- Regulatory gap analysis—Based on a market analysis of regulatory requirements, a regulatory gap analysis can help pinpoint markets where existing products can continue to be sold with little or no modification, as well as markets where the new requirements in IEC 60601-1 Edition 3.1 demand the timely redesign and recertification of priority products.
- Contingency planning—Finally, in a regulatory environment in which changes can occur with little advanced notice, advanced planning to identify possible contingencies can minimize the risk associated with unanticipated events or delays.

UL offers a complete range of global testing and certification services for medical electrical equipment, as well as extensive experience in helping manufacturers comply with both the software and usability engineering requirements of IEC 60601-1 Edition 3.1. For additional information, contact Medical.Inquiry@UL.com.

[2] Notably, IEC 62366-1:2015 will be complemented by a Part 2 (publication expected in 2016) that provides tutorial-style guidance on usability engineering (also called human factors engineering) but will not present additional requirements beyond those presented in Part 1.

Summary and Conclusion

For manufacturers of medical electrical equipment and systems, IEC 60601-1 Edition 3.1 represents a significant departure from Edition 3.0 of the standard. While the application of risk management principles has been clarified, the amended standard includes new requirements regarding essential performance, mandates usability engineering evaluations, and requires the adoption of a formal development life cycle process for software. The amended standard also includes a number of new or revised technical specifications for electrical and mechanical hazards, as well as new product labeling and documentation requirements.

The effort to address these changes is further complicated by uncertainty around transition dates. The U.S. FDA has set a transition date of August 2016 for compliance with the requirements of IEC 60601-1 Edition 3.1. But contradictory legislation in the EU could mean that manufacturers will need to demonstrate compliance with the standard's new requirements by the end of 2015. Therefore, manufacturers seeking continued access to key medical device markets should promptly initiate efforts to address the mandated changes.