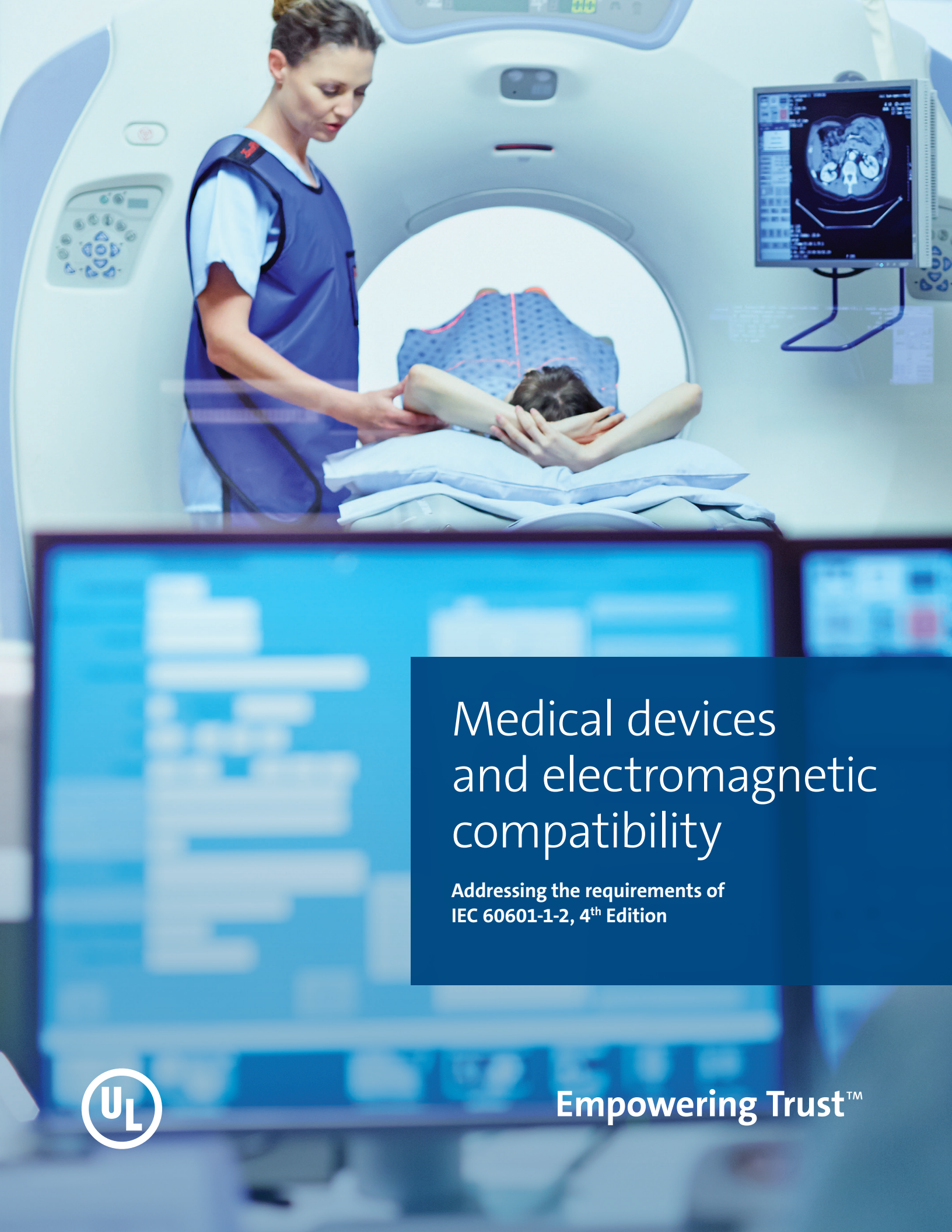


Medical devices and electromagnetic compatibility

Addressing the requirements of IEC 60601-1-2, 4th Edition

Empowering Trust™

Executive Summary

Risk of electromagnetic interference and immunity have long been important in the evaluation of the safety of medical devices by regulatory authorities. But the expanded scope of environments in which medical devices are being used today, along with the growing prevalence of all types of medical and non-medical systems and devices utilizing wireless communications technologies, new challenges have been created for medical devices and increased potential risks to patients.

IEC 60601-1-2, the internationally-recognized medical electrical equipment standard addressing requirements and tests for susceptibility to and immunity from electromagnetic disturbances, has recently undergone an extensive revision to address these new challenges and risks. Originally published in 2014, the fourth edition of IEC 60601-1-2 will come into effect in the U.S., Canada, and the European Union (EU) on Dec. 31, 2018. As of that date, jurisdictions of authorities in the U.S. and Canada will require new medical devices submitted for regulatory review demonstrate compliance with fourth edition requirements. In the EU, the new standard IEC 60601-1-2, 4th Edition will replace IEC 60601-1-2, 3rd Edition as the consensus standard for compliance to the Medical Device Directive. Therefore, devices using IEC 60601-1-2, 3rd Edition as the consensus standard will not be considered acceptable for the Medical Device Directive after Dec. 31, 2018.

This UL white paper provides an overview of the fourth edition of IEC 60601-1-2 and the specific issues device manufacturers need to address ahead of the pending transition date. Beginning with a brief summary of the history of the standard, the paper then offers a detailed review of the significant changes and additions presented in the fourth edition. The white paper also highlights the specific responsibilities that device manufacturers must address before submitting their devices for testing and concludes with other considerations for achieving compliance with the revised standard.

A brief history of IEC 60601 and IEC 60601-1-2

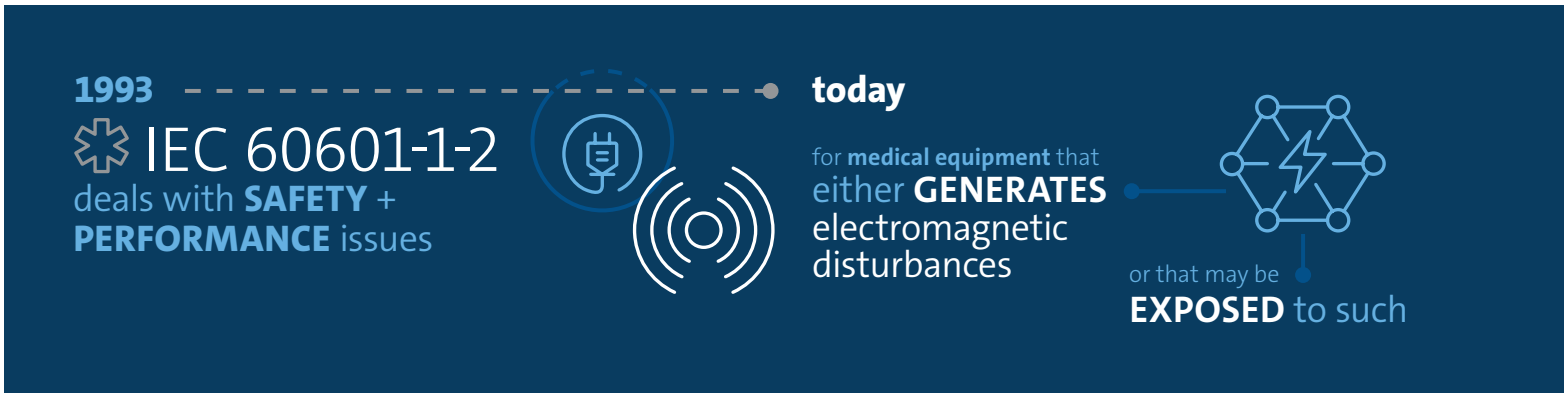
The IEC 60601 series of international standards addresses the safety and essential performance of medical electrical equipment and systems and serves as the basis for the regulation of medical devices in most jurisdictions around the world. The series consists of a general standard (IEC 60601-1), approximately 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).

IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests deals with safety and performance issues for medical equipment that either generates electromagnetic disturbances or that may be exposed to such disturbances from other sources. Specifically, the standard defines immunity thresholds intended to protect medical devices from electromagnetic interference (EMI) generated by co-located powered devices and equipment, as well as emissions thresholds that limit a device's ability to generate its own potentially harmful EMI. Adherence to the electromagnetic compatibility (EMC) requirements of IEC 60601-1-2 helps to minimize the potential for device malfunction that could place patients and healthcare providers at risk.

IEC 60601-1-2 has undergone a number of significant revisions since its initial publication in 1993 in order to remain current with new and advanced medical technologies. The latest set of changes was introduced with the 2014 publication of the fourth edition of IEC 60601-1-2. Prompted in part by the need for more stringent EMC requirements to address the prevalence of wireless connected devices in healthcare technology, the fourth edition also reflects today's use of medical devices in a wide variety of settings from professional healthcare facilities to residential and homecare environments.

Importantly, the fourth edition of IEC 60601-1-2 complements the comprehensive approach to risk

management found in the current edition of IEC 60601-1, the general standard applicable to medical devices. The fourth edition now places an emphasis on an assessment of all EMC-related risks associated with the essential performance and basic safety requirements of a given medical device that is consistent with the specific environments in which the device is intended for use. Rather than attempting to define specific requirements for each and every circumstance, the fourth edition instead requires each manufacturer to develop a test plan for their device that will evaluate compliance with the essential performance and basic safety requirements of the standard.



IEC 60601-1-2, 4th Edition: key changes from the third edition

The fourth edition of IEC 60601-1-2 incorporates a number of significant changes from the third edition of the standard. The most important changes include the following:

- **Defined environments of intended use –** The fourth edition replaces the "life support" and "non-life support" classifications used in the third edition with three intended use environments: 1. professional healthcare facilities, such as hospitals, clinics and other medical facilities; 2. home healthcare settings; and 3. special environments, such as industrial zones and military installations. This change harmonizes the intended use locations of the revised standard with those found in other collateral and particular standards in the IEC 60601 series.
- **The adoption of a risk management approach –** As previously noted, the fourth edition applies the principles of the risk management approach presented in edition 3.1 of IEC 60601-1 (the current edition) to medical device safety issues. Specifically, the standard now requires manufacturers to conduct a risk assessment of the safety issues related to EMC in connection with each medical device, consistent with the requirements of *ISO 14971, Medical devices – Application of risk management to medical devices*. This risk assessment must cover the specific operating conditions and test levels anticipated in the device's intended use environment.
- **The importance of essential performance and basic safety –** The risk management process is also intended to define the essential performance and basic safety requirements of a given device. Pass/fail requirements related to specific emissions and immunity limits are now designed to help ensure that essential performance and basic safety will not be compromised by the "reasonably foreseeable" maximum level of electromagnetic disturbances in the intended use environment.
- **An increase in ESD immunity test levels –** To address an increase in the threats of damage related to device exposure to electrostatic discharge (ESD), ESD immunity levels under IEC 60601-1-2, 4th Edition, have been significantly increased. In addition, the methodology for evaluating connectors for their immunity to ESD has been modified.

- **More stringent requirements for immunity to wireless devices –** As previously noted, an important motivation for the revision of IEC 60601-1-2 was the increased use of wireless technology either integrated into a medical device or in devices and equipment used in close proximity to medical devices. As a result, the fourth edition modifies the specifications of tests and test levels used to determine the effects of radiofrequency (RF) communications on a given device.
- **Port-specific immunity test and test levels –** The fourth edition also includes changes to the specifications of immunity test and test levels according to the available ports of the medical electric equipment or system. For example, for most tests, immunity testing is now conducted at only a single line voltage instead of two, as previously specified.
- **Exclusion of I/O cables shorter than three meters from immunity testing –** The fourth edition now excludes from immunity testing I/O cables that are less than three meters long. However, it is important to note that regulators in some jurisdictions may not recognize this exclusion, and may require all I/O cables to undergo immunity testing regardless of their length.
- **Inclusion of non-medical ITE –** The fourth edition now stipulates that information technology equipment (ITE), such as computers, laptops and tablets that function as an essential component of a medical device or system and which can affect the device's essential performance, must also meet the relevant EMC requirements of the standard.

New requirements for device manufacturers transitioning to the fourth edition

In addition to the previously noted changes, IEC 60601-1-2, 4th Edition places significant additional responsibilities on medical device manufacturers seeking to demonstrate compliance with the standard's requirements. The most important of these new responsibilities requires the device manufacturer to develop a comprehensive test plan prior to actual testing. This test plan is intended to dictate the approach and the specifics to be used by the testing laboratory in its evaluation of the device.

At a minimum, the test plan must address the following issues:

- The intended use of the medical device
- The specific environments in which the medical device will be used
- The essential performance and basic safety risks associated with the device during its intended use and in the intended use environment
- A description of the physical and electrical setup required for testing
- A description of the device configuration(s) and operating modes to be tested
- A description of the plan for monitoring essential performance during testing
- The test levels for each emissions and immunity test to be conducted
- The pass/fail criterial for each emissions and immunity test

To assist device manufacturers in developing a test plan that meets the requirements of the standard, the fourth edition includes a sample template. The template, which can be found in Annex G of the standard, can be modified or adapted as necessary to help ensure that the actual testing thoroughly evaluates all issues identified in the risk assessment of the device.

The fourth edition also includes revised documentation requirements. Device manufacturers must provide the facility conducting the device testing with a copy of all documentation used in the development of the risk assessment, as well as the assessment findings. Any exclusions regarding the use of the medical device that are supported by the risk assessment must also be noted and documented. And manufacturers must supply a copy of all instructions and instructional labels describing the use of the device, consistent with Section 5 of the standard.

The role of guidance in IEC 60601-1-2, 4th Edition

The test plan requirements in IEC 60601-1-2, 4th Edition are likely to place a new and significant burden on many device manufacturers seeking to achieve compliance with the standard. Appropriately, the fourth edition includes a number of informative Annexes that provide guidance in understanding many aspects of the test plan requirements and other provisions of the standard, as well as how those requirements should be applied to their particular medical device.

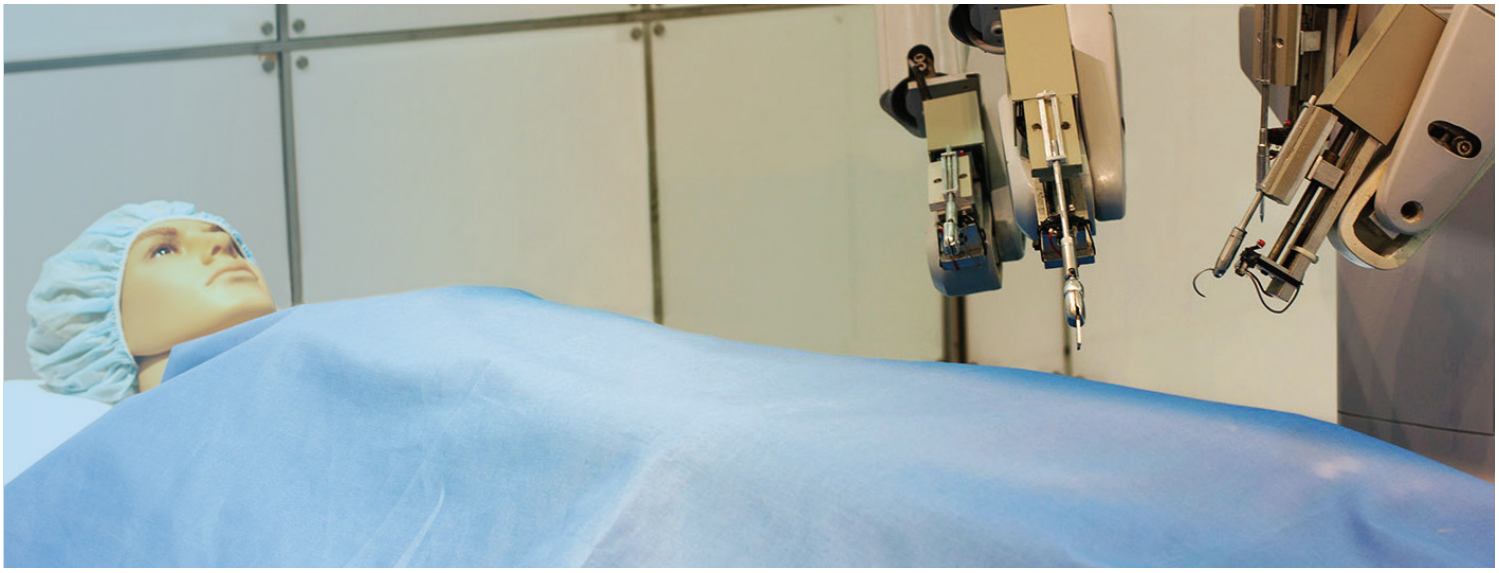
Here is just a sampling of the topics addressed in the nine Annexes in the fourth edition:

- Guide to marking and labeling requirement for ME equipment and systems (Annex B)
- Determination of immunity test levels for special environments (Annex E)
- Risk management for basic safety and essential performance with regard to electromagnetic disturbances (Annex F)
- Test plan (Annex G)
- Identification of immunity pass/fail criteria (Annex I)

Similar to guidance documents issued by the U.S. FDA, the Annexes in the fourth edition are intended to be informative in nature, and are not a substitute for the actual requirements detailed in the standard. Device manufacturers can follow the recommendations contained in the Annexes or employ alternative approaches as long as they satisfy the essential requirements of the standard.

Regulatory implementation timetable

Today, medical devices based on advanced technologies can take years to develop and bring to market. While often actively encouraging medical device manufacturers to quickly adapt their devices for compliance with the requirements of updated or revised standards, regulators have typically provided formal implementation timetables that can provide manufacturers with three years or longer to conform with updated requirements.



Such is the case with IEC 60601-1-2, 4th Edition. First published in 2014, regulators in the U.S., Canada and the EU have each set Dec. 31, 2018 as the mandatory date for compliance with the provisions of the standard. As of that date, all new medical device applications submitted for review and approval by regulators in those jurisdictions will need to demonstrate conformity with the requirements of the fourth edition.

It is important to note that the application of the fourth edition to legacy devices differs between the U.S. and Canada and the EU. In general, medical devices approved to edition 3.0 of the standard on or before Dec. 31, 2018 by the U.S. FDA and Health Canada are not required to demonstrate compliance with the provisions of the fourth edition to continue to be legally sold in these countries. The exception to this grandfathering provision is in cases where a given medical device has been updated and would typically be required to be resubmitted to regulatory authorities for review and approval. In these cases, manufacturers will need to ensure that their devices conform with the fourth edition requirements.

However, in the EU, the EU Commission has set a date of withdrawal of Dec. 31, 2018 for the third edition of IEC 60601-1-2 to be replaced by the fourth edition. As a result, EU regulators have mandated that both newly approved and previously approved medical devices placed on the market on or after Jan. 1, 2019 meet the requirements of the fourth edition.

In jurisdictions other than the U.S., Canada and the EU, the implementation timetable for meeting the requirements of IEC 60601-1-2, 4th Edition varies widely. Indeed, some jurisdictions have yet to formally implement the provisions of the third edition. Therefore, device manufacturers are advised to investigate the specific transition schedule that may be applicable in other target markets.

Summary + Conclusion

The fourth edition of IEC 60601-1-2 presents a number of compliance challenges for medical device manufacturers, most notably the requirements for the manufacturer to conduct an analysis of the risk to the essential performance and basic safety of their device in connection with the effects of EMI and to develop a comprehensive test plan to evaluate compliance with fourth edition requirements in light of those risks. While the fourth edition does provide helpful guidance on the development of a test plan and compliance with other key aspect of the revised standard, many device manufacturers may not possess the requisite knowledge to complete these tasks consistent with the standard's essential requirements. This can lead to unnecessary delays in the successful completion of the regulatory review and approval process, and result in a loss or reduction in anticipated revenue and market share.

UL's Health and Safety team has extensive expertise in medical device safety, EMC and risk management. We can assist medical device manufacturers in their efforts to meet the requirements of IEC 60601-1-2, 4th Edition by reviewing their EMC risk assessments, test plans and supporting documentation as required under the scope of the standard. For manufacturers of legacy devices that may be subject to retesting, we can conduct a GAP analysis against fourth edition requirements to assess the scope of work that may be required to achieve compliance. UL's EMC testing facilities in Northbrook, IL and Research Triangle Park, NC are recognized under the IECEE CB Scheme for IEC 60601-1-2, 4th Edition, enabling us to conduct testing to the standard and prepare test reports that are recognized by regulators in jurisdictions around the world.

For more information on how UL's testing services can help your company meet the changes of IEC 60601-1-2 4th Edition, contact Medical.Inquiry@ul.com