



ARAZY GROUP
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PRINCIPAL CHANGES OF THE THIRD EDITION OF IEC 60601-1

Since 2005 there is a new standard for medical electrical equipment. IEC approved the 3rd edition of IEC 60601-1. Here you will find the most important changes, the introduction of new concepts and the impact in the regulatory world of this new standard.

a) Scope

Scope of IEC 60601-1 was significantly modified and expanded. The first major change was the elimination of the phrase *'under medical supervision'* from the definition of medical electrical equipment. This change ended the debate over whether or not equipment that met all the other characteristics of medical electrical equipment, but was not intended to be used by or under the close supervision of a trained professional, was within the scope of IEC 60601-1. Under the revised scope of the third edition, there is no question that all medical devices are covered by IEC 60601-1.

b) Definition of Medical Electrical Equipment

Other major change was adding the phrase *'or compensation or alleviation of disease, injury or disability'* to the definition of medical electrical equipment. Historically, medical electrical equipment was limited to devices intended by their manufacturer to *'diagnose, treat or monitor a patient'*.

c) Collateral standard

Another issue that was extensively debated during the development of the third edition was the relationship of the collateral standards in the IEC 60601 family. For the third edition, a collateral standard becomes a normative part of the general standard on the date of its publication. In effect, this approach allows for an unlimited number of amendments to add new general requirements to IEC 60601-1 because each new collateral standard becomes a normative part of IEC 60601-1 when published.

d) Risk Management

The most important change was the requirement Manufacturers must now have a formal risk management system in place according ISO 14971. In IEC 60601-1 we can find decision points where the manufacturer must estimate the risk of its device and take an action dependent upon how that risk compares to its predefined levels of risk acceptability to achieve compliance, define necessary pass/fail criteria,

determine testing parameters, add a particular safety feature etc according with the statement *"In all cases, the risk management process will determine whether the requirements of the standard are appropriate and acceptable."* In other words, the manufacturer is free to tailor the standard to the needs of the device. It is important to note that this risk management process must address the entire life cycle of the device, not just the design.

The incorporation of a risk management process into the third edition of IEC 60601-1 closely aligns the standard with other regulatory needs, because it establishes a baseline for the safety and effectiveness of electromedical equipment and systems.

In all cases, where the third edition requires application of the risk management process in whole or in part, certification bodies are required to ensure the analyses have been performed and that the data required is in the risk management file. Is important to recognize that the certification bodies are not required to judge the quality of the risk management process and files but they will be completely justified in refusing to issue certifications in cases where the risk management process does not meet a minimum level of quality and diligence.

This fusion of ISO 14971 and IEC 60601-1 will require that both manufacturers and certification bodies must adjust to a more comprehensive view of assuring device safety.

e) FDA recognition

Recognizing the significant changes from the second to the third edition of IEC 60601-1, the Foods and Drugs Administration (EEUU) is currently developing a guidance document on the use of the third edition in pre-market submissions (PMN included in the 510k file). It is not yet clear whether the FDA will recognize the third edition as a Consensus Standard as they did with the second edition of IEC 60601-1. Also, it has not been the FDA's policy to allow transition periods for recognized standards. Once a new edition of a standard is recognized, the PMN may no longer reference the previous edition. However, because of the significant changes between the second and the third edition of IEC 60601-1, the FDA is discussing possible changes to their policy to allow a transition period.

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