THE IMPORTANCE OF RISK MANAGEMENT IN THE CERTIFICATION OF ELECTRO-MEDICAL PRODUCTS

A GUIDE TO IEC 60601-1 3RD EDITION

By Michel Brossoit, Eng.
Technical Advisor – Health Care Services
CSA Group

In recent years, electro-medical products have been subject to many new and complex safety standards. Usability engineering and software lifecycle standards have been added to previous software, bio-compatibility and electromagnetic compatibility standards, making it difficult for manufacturers to keep pace. Ongoing rapid technology advancement in this dynamic industry only adds to the challenge.

One of the most significant changes in safety standards for electro-medical products addresses the unique risk management requirements of an industry where progress could be constrained by standards written to address existing products and not potential products that are yet to be invented. IEC 60601-1 3rd edition was introduced to help address this need.

Addressing the Need for a Risk Management Approach

IEC 60601-1 3rd edition is a significant departure from IEC 60601-1 2nd edition, embedding risk management across the series of standards. It is a unique new approach that is intended to provide manufacturers with more flexibility to innovate and invent while remaining confident of equipment safety. The previous edition of the IEC 60601-1 reflected the traditional "snap-shot in time" approach which meant the standards were based on known models and types of medical devices. In an industry where innovation and invention are occurring rapidly, the previous standards inevitably lagged behind emerging needs.

The primary goal in the creation of IEC 60601-1 3rd edition was to create a standard that could follow the evolution or "life cycle" of medical devices and accommodate the needs of new design concepts. The previous two editions of the standard could not follow the technology evolution of components or support new innovations or inventions by medical device manufacturers. In effect, the standards could constrain innovation, limiting options while driving manufacturers to conform to standards designed to support past technology. IEC 60601-1 3rd edition contains elements intended to help ensure that pursuit of innovative new components or approaches is not stifled by a safety standard.

Closer Cooperation between Manufacturers and Testing Laboratories

Before the introduction of IEC 60601-1 3rd edition, testing laboratories charged with certifying that products conform to safety standards were typically engaged after initial risk analysis and device design had already occurred. Many manufacturers relied almost entirely on the engineering judgment of the laboratory performing the certification testing. Testing was the preferred method for demonstrating compliance to the standard because it provided objective evidence of compliance.

Risk management was initially introduced into clauses of IEC 60601-1 3rd edition where no test method was defined. But IEC 60601-1 3rd edition impacts the evaluation process more broadly, encouraging interaction with the testing laboratory from the initial stages of risk analysis and device design through final product testing and certification. In this regard, risk management in the design and manufacture of electro-medical equipment parallels approaches used for years by many other industries.

Some Nation-specific Adoption of IEC 60601-1 3rd Edition

ADOPTED IN	KNOWN AS
Canada	CAN/CSA-C22.2 No 60601-1:08
USA	ANSI/AAMI ES60601-1:2005
Europe	EN 60601-1:2006
Brazil	ABNT IEC/NBR 60601-1
Japan	JIS T 60601-1:2012
Russia	GOST R 60601-1:2010

Country-specific Requirements

IEC 60601-1 3rd edition, is an international standard formally known as IEC 60601-1-1:2005 (third edition, 2005-12) medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

Adoption of the standard is voluntary and not all countries have done so. In some countries that have embraced IEC 60601-1 3rd edition, the standard has been renamed and there may have been national deviations that change or add requirements to the IEC standard. This makes identification of the country or countries where the product will be used an essential element in the product design process.

Risk Management for Electro-medical Equipment

Electro-medical equipment manufacturers must address three requirements for the sale and use of medical electrical equipment:

- Safety requirements such as IEC 60601-1 3rd edition that provide objective evidence that a medical device is safe.
- Quality requirements. A quality management system such as ISO 13485 or equivalent must be in place. Compliance to the ISO 14971 risk management standard can be pursued as part of the quality system but the quality system alone does not address risk management requirements. Conversely, the risk management standard is not a quality standard.
- Clinical (or medical licensing) requirements must be met to provide evidence that the medical electrical device has been proven safe to patients through clinical trials or equivalent studies such as those addressed by the FDA/CDRH and/or Health Canada.

The three above requirements have risk management in common. Risk management is called out in a note in the ISO 13485 standard and in many guidance documents for medical licensing.

Safety risk management is a normative requirement of IEC 60601-1 3rd edition and is the main concern of the safety standard. Clause 4.2 of IEC 60601-1 3rd edition requires compliance with the ISO 14971 risk management standard. ISO 14971 is used only as a tool and the outcome of the exercise is safety certification to IEC 60601-1 3rd edition and not to the ISO 14971 standard.

Risk management was performed by many manufacturers before the introduction of IEC 60601-1 3rd edition, primarily to satisfy quality and medical licensing requirements. While the elements of safety risk management now defined in IEC 60601-1 3rd edition had not been pursued consistently in the past, the new standard clearly prescribes where risk management is required. The IEC 60601-1 test report form (TRF) indicates the minimal risk management requirements for compliance with the 3rd edition standard.

It should be noted that, under terms of an agreement between IEC and ISO, IEC will in the future continue to maintain the IEC 60601 set of standards for medical electrical equipment, but will publish new IEC standards as IEC 80601. Going forward, ISO will also publish its medical standards as ISO 80601 standards.

Defining Risk

Clearly understanding the definitions of three terms within the IEC 60601-1 3rd edition can help in understanding the intent of the safety standard and the definition of essential performance for a particular medical device:

- **Harm** – Physical injury to the health of people or animals, or damage to property or the environment.
- **Hazard** – A potential source of harm.
- **Risk** – The combination of the probability of the occurrence of harm and the severity of that harm.

The main objective of IEC 60601-1 3rd edition is to manage risk associated with all identified hazards that could cause harm, physical injury or damage to the health of people and animals, or damage to property or the environment.

IEC 60601-1 3rd edition places greater emphasis on essential performance than the prior edition. Essential performance is defined as the performance necessary to avoid unacceptable risk. It is most easily understood by considering whether its absence or degradation would result in an unacceptable risk. Essential performance requirements for a particular device intended for a specific use must be identified in order to define what testing should be performed and to justify the exclusion of any testing.

Considering Patient Safety

The IEC 60601-1 medical safety standards are unique because they are the only set of safety standards that address the safety of both users and patients. Other such standards address only user safety. Because IEC-60601-1 3rd edition focuses more on patient safety, patient characteristics should be addressed in the usability engineering process for medical electrical devices. Patients could be classified as pre-natal, neonate, pediatric, adult or geriatric. However classes could also be segmented more specifically. For example, in the pediatric class, the FDA has identified the following classes of children: intrauterine, neonate, infant, child, and adolescent. The International Conference on Harmonization (ICH) has identified classes including preterm newborn infants, term newborn infants 0 to 27 days, infants and toddlers 28 days to 23 months, children 2-11 years old, and adolescents 12 to 16-18 years old.

A Simplified Risk Management Process

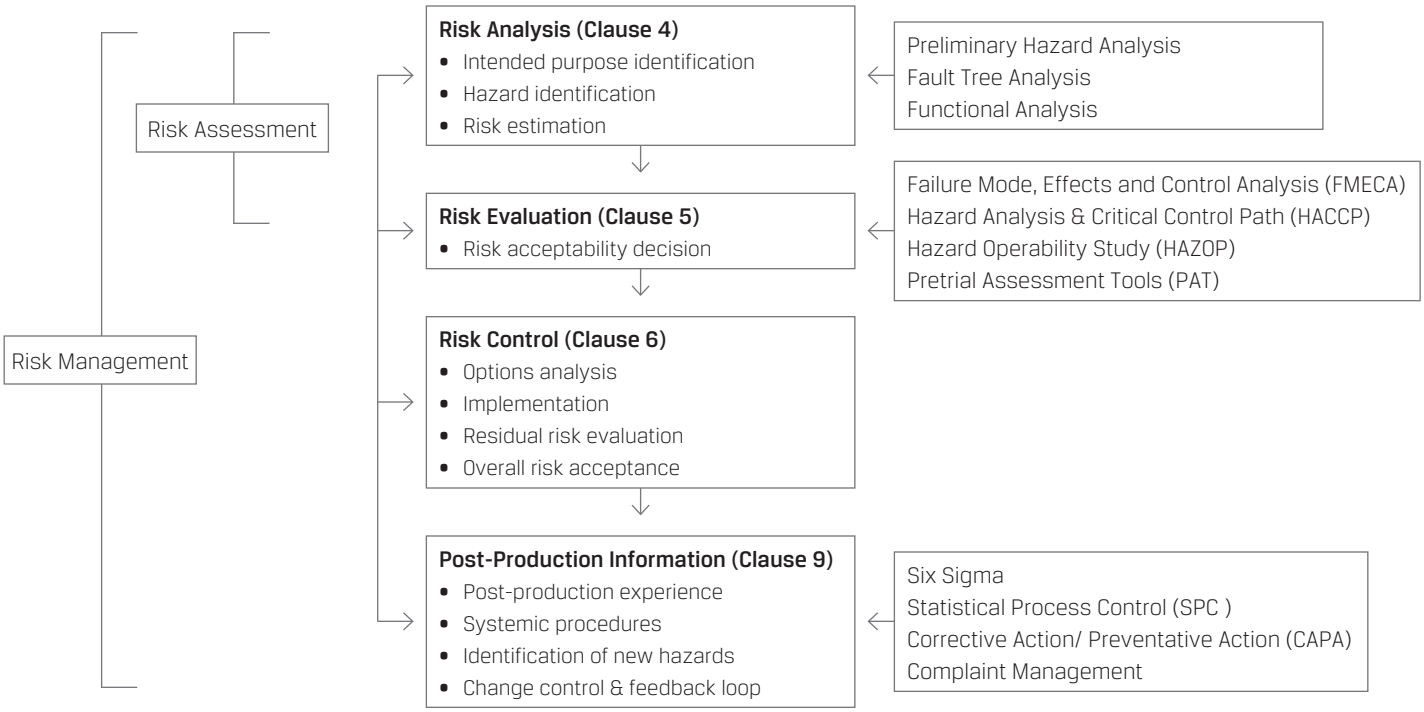
The diagram below illustrates the safety risk management process and commonly used risk assessment techniques identified in the clauses of the IEC 60601-1 3rd edition standard. The terms and definitions described in IEC 60601-1 3rd edition and in ISO 14971 are important and care should be taken not to re-write or create new terms and definitions if they have already been defined in the IEC or ISO standards. For example, this process illustration shows that the terms Risk Assessment and Risk Management Process encompass entirely different sets of clauses within ISO 14971. Interchanging the terms can create confusion and delay in the certification process.

Useful Standards for Risk Assessment

As noted in the simplified process illustrated below, a variety of additional standards can provide techniques useful in the risk management process. They include:

- **IEC 60812**: Analysis Techniques for system reliability – Procedures for failure mode and effects analysis (FMEA)
- **IEC 61025**: Fault Tree Analysis (FTA)
- **IEC 618882**: Hazard Operability Analysis (HAZOP)
- **CAN/CSA-ISO 31000-10** (ISO 31000:2009): Risk management – Principles and guidelines
- **CSA Q31001-11**: Implementation guide to CAN/CSA-ISO31000, Risk management – Principles and guidelines

Simplified Risk Management Process and Commonly Used Risk Assessment Techniques



- **CAN/CSA-IEC/ISO 31010-10** – Risk management – Risk assessment techniques (Note: risk management assessment techniques selected by manufacturers should use or reference ISO and IEC standards to simplify validation and verification or the techniques selected.)
- **CAN/CSA-Q850-97** – Risk Management – Guideline for Decision-Makers
- **ISO/IEC Guide 51** – Safety aspects – Guidelines for the inclusion in standards
- **ISO Guide 73** – Risk management – Vocabulary
- **CSA PLUS 114971** – ISO 14971:2007 – Essentials – A practical handbook for implementing the ISO 14971 Standard for medical devices

Amendment 1 Offers Improvements

Amendment 1 to the IEC 60601-1 3rd edition standard was issued in 2012 to correct issues and problems manufacturers and test laboratories were experiencing related to the risk management process, essential performance, usability engineering, software lifecycle and other aspects of the standard. Amendment 1 reduced ISO 14971 risk management clauses but added two additional standards as normative requirements of IEC 60601-1 3rd edition. The newly added standards are IEC 60601-1-6 (IEC 62366) and IEC 62304 Software Lifecycle. Both of the new standards require a process to be linked to the ISO 14971 risk management process.

IEC 60601-1 3rd edition and Amendment 1 are available as separate documents and as a consolidated document: IEC 60601-1 edition 3.1, which is technically equivalent to the two separate documents.

A Standard for the Future

The unique risk management requirements of the medical electrical equipment industry call for standards that support the need to manage safety risk along with quality and clinical risk without inhibiting innovation and invention necessary to support medical progress. IEC 60601-1 3rd edition accommodates new design concepts while supporting manufacturer needs to confirm that existing and future products are safe for users and patients.

Summary of Standards for Electro-medical Equipment

- **IEC 60601-1 2005 (Edition 3.0) —** Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- **Amendment 1 of IEC 60601-1 Edition 3.0 2012-07 —** Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- **IEC 606601-1 Edition 3.1 2012-08 —** Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (this standard is the combined equivalent of IEC 60601-1 3rd edition and Amendment 1 described separately above)
- **IEC 62304 —** Medical device software – Software lifecycle processes
- **IEC 60601-1-6 —** General requirements for basic safety and essential performance – Collateral standard: Usability
- **IEC 62366 —** Medical devices – Application of usability engineering to medical devices

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CSA Group provides complete testing and certification services to the medical devices industry globally. To learn more about the IEC 60601-1 3rd edition standard and safety testing and certification services for electro-medical products, contact us at 1.866.797.4272 or 1.416.747.2661 or visit **www.csagroup.org** or email us at **certinfo@csagroup.org.**