INTERNATIONAL STANDARDIZATION AND REGULATIONS FOR MEDICAL ELECTRICAL EQUIPMENT

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Medical electrical equipment is highly regulated and held to a higher level of safety than nearly all other types of equipment on the market.

This kind of equipment refers to any piece of equipment that runs on electric power, battery or mains (plug-in or permanently connected). Over the last 50 years, medical offices have become increasingly populated with highly complex equipment used to diagnose and treat medical conditions. The complexity of the task of ensuring that this equipment maintains the safety of the patient and the operator has grown as the equipment's complexity has grown.

Product Safety certification agencies use safety standards to evaluate many different types of products. These safety standards are documents, which define the minimum construction and performance requirements. Electrically operated medical equipment is evaluated to the standard IEC 60601-1 "Medical Electrical Equipment-General requirements for Basic Safety and Essential Performance". The standard also has collateral (horizontal) standards, numbered IEC 60601-1-x, and particular (vertical) standards, numbered IEC 60601-2-xx. The underlying philosophy of the IEC 60601-1 harmonized standards is that equipment must be safe in normal condition (NC) and single fault condition (SFC). Using an internationally harmonized safety standard meant that a product could be designed and evaluated for compliance with a single standard, such as IEC 60601-1, and be eligible for marketing in many different countries. The process of evaluating medical equipment for compliance with the requirements in IEC 60601-1 includes not only the equipment itself, but the user's manual, markings, software (if it mitigates a hazard), biocompatibility of applied parts, risk management, usability, alarms and electromagnetic compatibility (EMC).

The Medical Device Directive is essentially the European "law" for medical devices. All medical devices used in Europe must bear the CE mark according with the Medical Device Directive (93/42/EEC amended by 2007/47/EC). In the United States, the Food and Drug Administration (FDA) sorts devices into three categories (Class I, II, or III), depending upon the degree of regulation necessary to provide a reasonable assurance of their safety and effectiveness.

The paper is intended to increase awareness of product safety certification requirements by exploring the requirements for medical equipment both in the EU and internationally. We will look at the applicable safety standards and review their philosophy of safety, then show the process of evaluation and documentation. We will then discuss the most common noncompliances seen when evaluating medical equipment to safety standards.