

Why Product Safety Test Your Electrical Medical Products?

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It is important to realize that the patient is more susceptible to shock and other hazards than a healthy person using a piece of computer equipment. Many electro-medical products may have a part that touches or is placed in the patient for a short time or indefinitely which makes the patient more susceptible to shock hazards. Also, many patients have reduced immune systems that make them more susceptible to leakage currents. That is why the electrical medical device standards have stricter levels for **earth** and **enclosure leakage current** requirements over other types of device standards. In addition, electrical medical device standards have requirements for **patient leakage currents**.

A basic concept for the IEC60601-1 standard is that two levels of protection throughout the product must be provided. A good example of ‘two-level’ protection is the use of a protectively earthed (grounded) enclosure **plus** spacing between powered parts (defined as live parts in the standard) and the protectively earthed enclosure. Thus, if a fault occurs in one of these (i.e. a short in the spacings or the ground fails) the patient, doctor, nurse or user is not hurt because the other level of protection should maintain the safety of the device. Future articles will address such areas as grounding, leakage currents, spacings, dielectric withstand (Hi-pot) and other electrical safety test parameters.

Beyond user safety, there are several reasons why a manufacturer would benefit from having its product tested and potentially certified by a Third Party Test Agency to IEC60601-1 or equivalent National Standards.

- Legal requirements: Entry into a market, local, region.
- Litigation Risks: Reduce risks with increased product safety testing.
- Market Recognition: Third Party Certification Mark or a self Certification Mark.

Legal Requirements

There are many legal requirements in various jurisdictions throughout the world. Although product safety requirements vary from country to country, for the purpose of simplifying this discussion, we will focus on U.S. requirements. Let’s take a look at how IEC60601-1 is implemented within some U.S. consumer health and safety agencies:

- Food & Drug Administration (FDA)
- National Fire Protection Agency & National Electrical Code (NFPA 70)
- National Fire Protection Agency & Health Care Facilities (NFPA 99)
- ANSI/AAMI ES1-1993
- Occupational Health & Safety Administration (OSHA) & NRTL’s
- Underwriter’s Laboratories (UL)
- Local Regulations (City, State, County)

Food & Drug Administration (FDA)



What does the FDA have to do with medical equipment and the IEC60601-1 standard? Plenty. As an element of the FDA requirements for electrical medical equipment in the United States you need to meet safety requirements under UL2601-1 (IEC60601-1 with US National Deviations) or UL544. UL544 is an older US standard that will be obsolete by January 2005 and no new submittals will be allowed after January 2003. The FDA may also require additional standards as applied to the specific product. On top of this you will need to meet the EMC requirements typically met by testing to IEC60601-1-2 (Medical electrical equipment. Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility).

Other FDA requirements include product biocompatibility, sterilization, risk analysis, clinical data, etc. plus the QSRs (Quality System Regulations). The above requirements are typically in FDA category specific guidance documents. Once you have gathered all this information, test data, etc. your company will need to submit to the FDA for a 510(k), PMA, or an IDE. FDA approval may seem to take a long time but it is one of the most thorough approval systems in existence today.

National Electrical Code (NFPA 70)



The National Fire Protection Agency (NFPA) has two codes that are pertinent to medical electrical product safety testing and UL2601-1. The National Electrical Code (NEC) defined by NFPA 70, requires products covered under the NEC to be Listed or Labeled as described in Article 90-7, second paragraph: “It is the intent of the *Code* that ... the construction of equipment need not be inspected at the time of installation of the equipment ... if the equipment has been listed by a qualified electrical testing laboratory that is recognized as having the facilities described above and that requires suitability for installation in accordance with this *Code*.”

In addition NEC Article 110-2 indicates: “... equipment required or permitted by this *Code* shall be acceptable only if approved.” Approved is defined in the NEC as: “Acceptable to the authority having jurisdiction.”

So what does the NEC mean to you? An AHJ (authority having jurisdiction) such as a local electrical inspector in a city or county will exam the installation of your product in a hospital, clinic, doctor’s office, etc. (see NFPA 99 section below for definition of health care facilities). If the product doesn’t have the appropriate Certifications (Listing and/or Labeling per the NEC) your product or the construction of a building could be stopped until you are able to prove to the AHJ that you meet the requirements for the specific product.

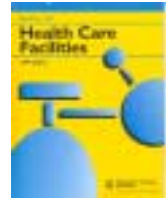
When you get your product Listed by a “qualified electrical testing laboratory” the lab will conduct periodic inspections of your product at your factories approximately once a quarter to make sure the device they tested is what is being produced. If the device is modified you will need to contact the lab to update your files as appropriate.

UL2601-1 has incorporated the appropriate requirements of the NEC into the standard. Also, CSA C22.2 No. 601.1 has incorporated the appropriate Canadian Electrical Code requirements.



Health Care Facilities (NFPA 99)

Next we touch on the Health Care Facilities and the NFPA 99 requirements. NFPA 99 is another code that deals directly with health care facilities. Therefore, it is important that manufacturer's of medical equipment be aware of it. The scope of the document states: "... is to establish criteria to minimize the hazards of fire, explosion, and electricity in health care facilities providing services to human beings. These criteria include performance, maintenance, testing, and safe practices for facilities, material, equipment, and appliances and include other hazards associated with the primary hazards." A health care facility is defined as 'buildings or portions of buildings in which medical, dental, psychiatric, nursing, obstetrical or surgical care is provided'. "Health care facilities include, but are not limited to, hospitals, nursing homes, limited care facilities, clinic, medical and dental offices and ambulatory care centers (permanent or movable)."



ANSI/AAMI ES1-1993



Another national standard often seen in conjunction with NFPA 99 is ANSI/AAMI ES1-1993. This standard sets risk current limits and test methods for electro-medical apparatus. The leakage current limits are comparable to IEC60601-1 but not identical. ES1-1993 defines safe limits within the three parameters: frequency, equipment function and (intentional) contact with the patient. AAMI (or the Association for Advancement of Medical Instrumentation) in existence since 1965 seeks a continued increase in the safe and effective application of today's technology **and** the fostering of new technologies.

OSHA & Nationally Recognized Test Laboratories (NRTL)

The Occupational Safety & Health Administration (OSHA) also requires certain products be certified by a NRTL. OSHA certifies NRTLs, identifies the scope of standards, and type of work the NRTLs can do. To view a current list of organizations recognized by OSHA as NRTLs and for the specifics of their certification go to <http://www.osha-slc.gov/dts/otpc/nrtl/index.html>. We at Eisner Safety provide an 'Agency News' web page containing press releases from product safety agencies such as TÜV Product Service, Underwriters Laboratories, NEMKO and NSAI.



Underwriter's Laboratories (UL)



Underwriter's Laboratories (UL) is an independent non-profit product safety testing organization that tests products, certifies products, produces product safety standards and assesses company quality processes. UL was founded in 1894 and today is one of the most recognized names in product safety. Three UL Standards that deal with Medical Equipment are UL187, UL544 and UL2601-1. UL187 and UL544 are in the process of being phased out. UL2601-1 contains the national deviations of IEC60601-1 for the United States. To view a catalog of standards or the scope of a particular standard, the UL Standards Department now has a separate website: <http://ulstandardsinfontet.ul.com>. Please note there is no 'www' necessary in this address.

Other Local Regulations

Believe it or not there can be additional legal requirements that may apply to your product depending on the locale in which the product is used. To ensure your design addresses all safety issues check into the city, county or state regulations for your products destination. For example, if you are installing a big X-ray or Gamma Imaging System into a California health care facility you will need to deal with the Office of Statewide Health Planning and Development (OSHPD) to meet requirements dealing with Earthquake issues.

Next IEC60601-1 Installment

Can there possibly be any more product safety test requirements? Tune in next time for the continuing saga of 'Why safety test your product to IEC60601-1?' We'll discuss litigation risks and 'mark' recognition - two important factors in understanding medical product safety testing and the standards that guide it.



To find out more about IEC60601-1, product safety requirements or the CE mark please contact Eisner Safety Consultants at (805)-884-9680 visit us on the web at <http://www.eisnersafety.com/> or e-mail us at Leo@EisnerSafety.com. Eisner Safety Consultants specializes in assisting clients with obtaining the European CE Mark and meeting US and Canadian regulatory safety standards. Specialties include product evaluation to safety standards, Agency coordination, CE Mark and training.

For complete product specifications on QuadTech's Electrical Safety Test (EST) or passive component test (LCR) instrumentation, please visit us at <http://www.quadtech.com/products>.

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