

Conventional engineering courses may teach students how to design functional products, but they rarely address the very practical problem of meeting regulatory requirements. Designing equipment to meet the complex safety certification and regulatory requirements can be very costly and time consuming, especially if these requirements are not known in the early stages of design.

Medical equipment is highly regulated and held to a higher level of safety than nearly all other types of equipment on the market. The main reasons for this are that medical equipment may be used on patients who are not able to respond to hazardous conditions or pain, an actual electrical connection between the equipment and patient may exist, and certain types of medical

Regulatory Requirements for Medical Equipment

Become familiar with safety certification and regulatory requirements early in the design phase to save time and money.

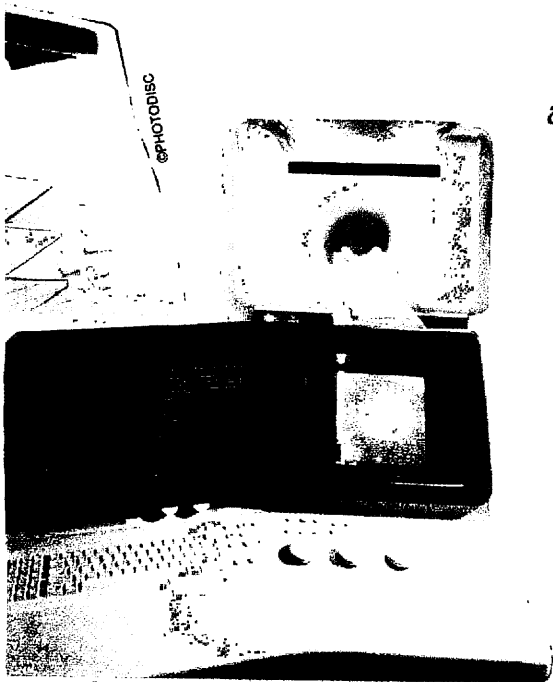
*Michael L. Marcus
and Brian R. Biersach*

equipment function as life support, the failure of which could result in the death of the patient. While engineers spend years in school and the workplace learning about how to design equipment, they usually do not learn about the certification and regulatory requirements that the equipment must meet to comply with the U.S. and international codes and laws. Understanding these requirements before the design phase of the equipment will result in a reduction of product development cost, faster certification turnaround, and increased product safety.

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

Medical Equipment for the United States and Canada (FDA, UL)

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



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assurance of their safety and effectiveness. Class I devices are subject to premarket notification, registration and listing, prohibitions against adulteration and misbranding, and rules for good manufacturing practices. Class II devices also need performance standards, and Class III devices need premarket approval from the FDA. A 510(k) is a collection of documents and forms used to show substantial equivalence to a device that was either in commercial distribution before 28 May

1976 or has been reclassified into Class I or II [1]. The FDA or an accredited third-party reviewer examines the documentation and determines whether the device is substantially equivalent to the specified predicate device or not. If the device is found to be substantially equivalent, it can be legally marketed and sold in the United States. If the device is not substantially equivalent to a predicate device, due to new technology or differences in intended use, then the submitter must present detailed information, such as clinical trial data, statistical data, and safety testing results to the FDA to show that the device is safe and effective. If the FDA finds the information and data adequate, they will grant premarket approval for the device, allowing it to be legally marketed and sold in the United States.

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Underwriters Laboratories Inc. (UL) is the major product safety certification organization in North America. Manufacturers of medical equipment submit product samples and information to UL for evaluation to applicable safety standard(s), and products that meet these requirements are authorized to apply the appropriate UL mark for the United States and Canada.

Medical Equipment for the European Union (CE Marking)

All but low-risk, nonmeasuring, nonsterile medical devices used in Europe must bear the CE mark with the notified body's identification number. A notified body is a third party designated by European authorities to assess compliance with the Medical Device Directive (93/42/EEC) [2]. The Medical Device Directive is essentially the European "law" for medical devices. The assessment by a notified body evaluates compliance with the medical device directive requirements for safety, performance, suitability for intended use, and risk analysis. Manufacturers can choose from several conformity assessment routes, most involving a quality assurance assessment of the manufacturer's facilities. Low-risk, nonmeasuring, nonsterile medical devices also require a CE mark, but these are allowed to "self declare" compliance to the medical device directive without the intervention of a notified body.

The FDA Federal Food, Drug, and Cosmetic Act requires that all medical devices be "safe and effective" and recognizes safety standards as a means to support a declaration of conformity. Many "authorities having jurisdiction" (AHJ) and purchasers of medical electrical equipment in the United States and Canada require a safety certification mark on the equipment. Therefore, a product that carries a safety certification mark will usually reach its full market potential.

Table 1. Example of UL standards.

UL Standard Number	Title
UL 73	Standard for Motor-Operated Appliances
UL 94	Standard for Tests for Flammability of Plastic
UL 101	Leakage Current for Appliances
UL 187	Standard for X-Ray Equipment
UL 248-6	Low-Voltage Fuses
UL 250	Household Refrigerators and Freezers
UL 498	Standard for Attachment Plugs and Receptacles
UL 508	Standard for Industrial Control Equipment
UL 544	Standard for Medical and Dental Equipment
UL 745-1	Portable Electric Tools
UL 998	Humidifiers
UL 1577	Standard for Optical Isolators
UL 1740	Standard for Robots and Robotic Equipment
UL 1995	Heating and Cooling Equipment
UL 60601-1	Medical Electrical Equipment
UL 61010A-2-020	Standard for Electrical Equipment for Laboratory Use

Medical Electrical Safety Standards

Product safety certification agencies use safety standards to evaluate many different types of products. These safety standards

are documents that define the minimum construction and performance requirements. Table 1 provides an example of UL standards that cover medical and related product categories, in addition to some standards for nonmedical equipment. A complete list of UL standards, covering more than 5,000 product categories, can be found at <http://ulstandardsinonet.ul.com> [3].

Electrically operated medical equipment used in the United States is evaluated to standard UL 2601-1 "Medical Electrical Equipment," currently published as UL 60601-1. The previous U.S. medical standard, UL 544 "Medical and Dental Equipment," will be withdrawn 1 January 2005. All medical products evaluated to UL 544 must be reevaluated to UL 2601-1/UL 60601-1 to continue applying a safety certification Mark after this date [4].

UL published its UL 2601-1 standard in 1994, with the plan to phase it in over ten years. UL 2601-1 was written as an IEC 601-1 (renamed IEC 60601-1) harmonized standard. Prior to this harmonization initiative, manufacturers were required to comply with different standards for different countries. This often required that multiple product models had to be designed and manufactured to meet different national standards if the equipment was to be marketed in more than one country. Using an internationally harmonized safety standard meant that a product could be designed and evaluated for compliance with a single standard, such as UL 2601-1/UL 60601-1, and be eligible for marketing in many different countries. Other countries that use an IEC 60601-1 harmonized standard include the European Union, Canada, Brazil, Japan, Korea, and Australia. In addition to being the base of so many harmonized standards, IEC 60601-1 is an FDA recognized consensus standard, used to support a manufacturer's declaration of conformity, required to place a medical device on the market in the United States. Visit the FDA Web site to see all the FDA recognized standards at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

The UL 2601-1 safety standard contains the full text of IEC 60601-1 and adds U.S. deviations, as shown in Figure 1 [5]. The U.S. deviations contain national requirements, such as those for the mains circuit, component requirements, lower leakage current limits, enclosure flame ratings, and production line testing. Since these deviations do not conflict with the base standard, equipment that complies with UL 2601-1 is also in compliance with IEC 60601-1. The UL 60601-

1 standard, published in April of 2003, is an editorial change to UL 2601-1. It merges the U.S. deviations, Appendix 1, and Appendix 2 into the body of the document but does not change any requirements.

The current (second) edition of IEC 60601-1 has two amendments. These amendments contain additions and corrections to the base standard. The standard also has collateral (horizontal) standards, numbered IEC 60601-1-x, and particular (vertical) standards, numbered IEC 60601-2-xx. The collateral standards include requirements for specific technologies or hazards and apply to all applicable equipment, such as medical systems (-1-1), EMC (-1-2), radiation protection in diagnostic X-ray equipment (-1-3), and software (-1-4). The particular standards apply to specific equip-

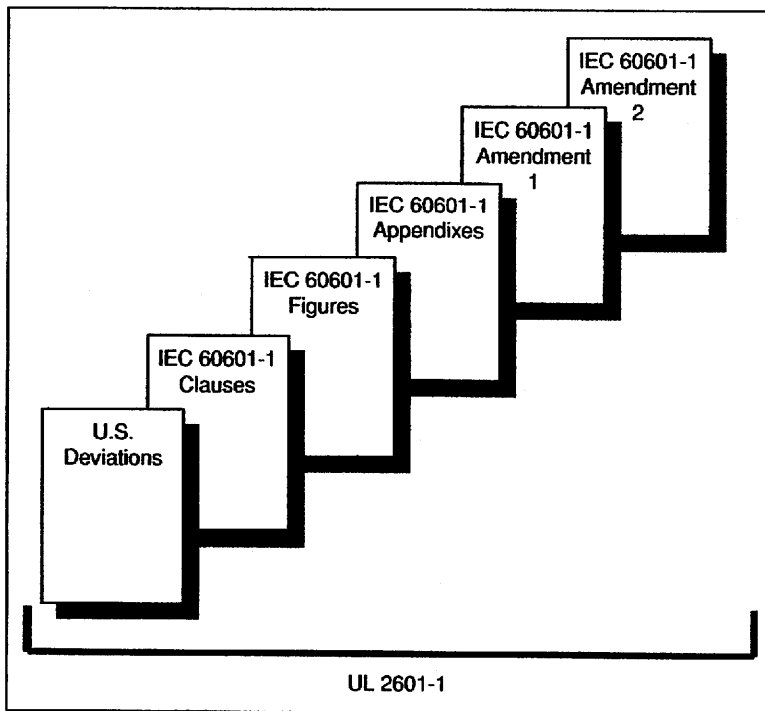


Fig. 1. Structure of UL 2601-1.

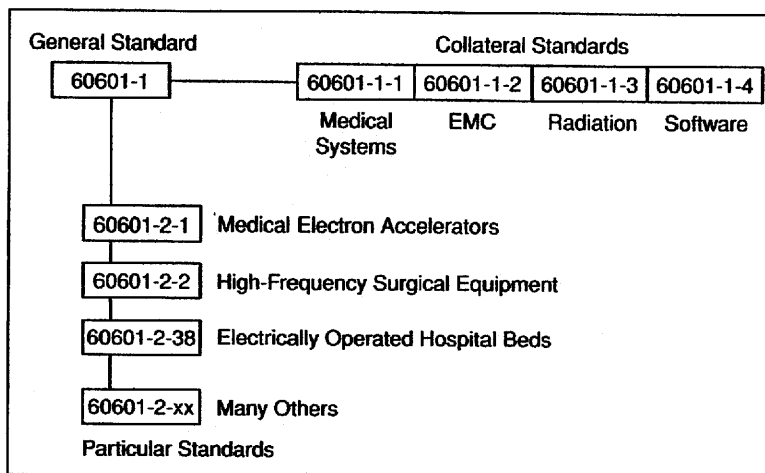


Fig. 2. Organization of the IEC 60601-1 Standard.

ment types, such as medical electron accelerators (-2-1), high frequency surgical equipment (-2-2), and hospital beds (-2-38). Figure 2 illustrates the organization of the collateral and particular IEC 60601 standards. The U.S. deviations, amendments, collateral, and particular standards are used together to evaluate the medical electrical equipment. All the '601 standards use the same clause numbering system, which allows cross referencing of the requirements between the base standards, collaterals, particulars, and amendments [5].

IEC 60601-1 Requirements

Philosophy

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). To understand the electrical safety requirements, we need to first define a few terms.

- ▶ An applied part is any piece of the equipment that can intentionally or unintentionally be brought in contact with the patient.
- ▶ Creepage is spacing along a surface (as an ant crawls).
- ▶ Clearance is spacing through the air (as a bug flies).
- ▶ LOP is a level of protection (two required by standard).
- ▶ Basic insulation (BI) is a specific spacing or a physical insulation barrier providing 1 LOP.
- ▶ Supplemental insulation (SI) is also a spacing or a physical insulation barrier providing 1 LOP.
- ▶ Double insulation (DI) is BI + SI and provides 2 LOP.

The underlying philosophy of the IEC 60601-1 harmonized standards is that equipment must be safe in normal condition and single fault condition.

- ▶ Reinforced insulation (RI) is a single spacing or physical insulation barrier that provides 2 LOP.
- ▶ Protective impedance is a component (such as a resistor) that provides 1 LOP.
- ▶ Protective earth (PE) is a well-grounded part that provides 1 LOP.
- ▶ Class I equipment is defined as using PE as 1 LOP.
- ▶ Class II equipment (also known as double insulated) is defined as not using PE as 1 LOP.

For electrical safety, the standard requires 2 LOP against excessive unintentional current, defined as leakage current, passing through the patient or operator. Figure 3 graphically depicts the 2 LOP between the live part (mains) and the patient (1A and 2A), and between the live part and the enclosure (1B and 2B). In the case of 1A and 2A, the levels of protection are BI and SI. For 1B and 2B, they are BI and PE.

Table 2 provides an example of the minimum spacing requirements and dielectric (hipot) requirements for these barriers. If the insulation does not meet both the dielectric and the spacing requirements, it cannot be considered as a level of protection and can be shorted as a normal condition. Note that BI and SI spacing requirements are the same; however, the SI dielectric values are greater than the BI values, above 50 V working voltage. To be considered protectively earthed, the grounding path of the equipment must pass 15 A or 1.5 times rated current for five seconds from the protectively earthed part to the earth connection, with $\leq 0.1 \Omega$ resistance for equipment with a detachable power supply cord or $\leq 0.2 \Omega$ for equipment with a nondetachable power supply cord. The Canadian requirement changes the current to 30 A or 2 times rated current for two minutes. Since this is the only major difference between the U.S. and Canadian standards, the test is typically done only at 30 A for two minutes as the "worst case" for testing protective earthed parts.

To demonstrate that medical equipment is safe in normal and single fault condition, the following conditions must be addressed when designing and evaluating the equipment. These conditions are specified in the standard.

Likely to Occur (Normal Condition)

- ▶ reverse polarity of supply mains
- ▶ failure of insulation less than basic (operational).

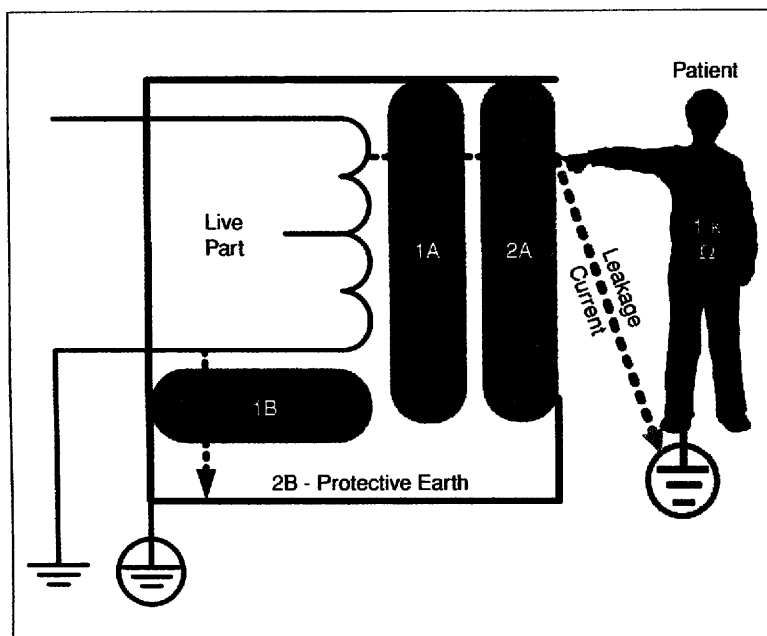


Fig. 3. Two levels of protection (2 LOP).

Could Occur (Single Fault Condition)

- ▶ interruption of protective earth
- ▶ interruption of one supply conductor
- ▶ mains voltage on floating (f-type) applied part(s)
- ▶ mains voltage on communication ports
- ▶ failure of electrical components, one at a time
- ▶ failure of mechanical parts, one at a time
- ▶ failure of temperature limiting devices, one at a time
- ▶ shorting of basic or supplemental insulation
- ▶ overload of mains supply transformers
- ▶ interruption and short circuit of motor capacitors
- ▶ locking of moving parts
- ▶ impairment of cooling (fans, vents blocked).

Unlikely to Occur (Not Evaluated)

- ▶ total breakdown of double or reinforced insulation
- ▶ loss of protective earth on permanently installed equipment
- ▶ more than one single fault condition at a time
- ▶ failure of a UL-recognized optocoupler barrier
- ▶ failure of a UL-recognized Y1 capacitor, acting as a barrier.

Evaluation of Medical Equipment

The process of evaluating medical equipment for compliance with the requirements in UL 2601-1/UL 60601-1 includes not only the equipment itself but the user's manual, markings, software (if it mitigates a hazard), biocompatibility of applied parts, and electromagnetic compatibility (EMC). Before submitting equipment for evaluation, the following information should be developed:

- ▶ Does equipment fit the scope of the standard?

- ▶ Does equipment fit the scope of any IEC 60601 Collateral or particular standards?
- ▶ Are all equipment functions and accessories that can be used with the basic product listed?
- ▶ Is the medical equipment connected to other equipment, such as a computer, printer, or compressor?
 - Any other connected equipment must have IEC certification (evaluated to the applicable IEC standard) or be part of the medical equipment evaluation.
 - Does equipment have electrical data ports? If so, what could be connected to them?
 - Computers and other IT equipment are considered to have 50 V, in normal condition, mains in single fault condition on their data ports.
- ▶ Create an insulation diagram (graphic illustration of the LOPs).
- ▶ Determine the equipment classifications from the standard.
- ▶ Document all components that cross barriers per insulation diagram.
- ▶ Verify creepage and clearance spacing requirements, per the insulation diagram (printed wiring boards, transformers, relays, etc.).
- ▶ Examine enclosure openings
 - EC test finger (access to live parts)
 - IEC test pin (access to live parts)
 - must need a tool to access any live parts.
- ▶ Determine potential mechanical hazards, pinch points, sharp edges.
- ▶ Determine potential hazards under normal use and misuse.

Table 2. Insulation spacing and dielectric requirements.

Creepage and clearance requirements (in millimeters)						
Voltage	DC	< 15	< 36	< 75	< 150	< 300
Voltage	AC	< 12	< 30	< 60	< 125	< 250
BOP	Creepage	0.8	1.0	1.3	2.0	3.0
	Clearance	0.4	0.5	0.7	1.0	1.6
BI/SI	Creepage	1.7	2.0	2.3	3.0	4.0
	Clearance	0.8	1.0	1.2	1.6	2.5
DI/RI	Creepage	3.4	4.0	4.6	6.0	8.0
	Clearance	1.6	2.0	2.4	3.2	5.0
Dielectric withstand voltages [in Volts]						
Reference Voltage		0 < V < 50	50 < V < 150	150 < V < 250		
BI		500	1 K	1.5 K		
SI		500	2 K	2.5 K		
DI/RI		500	3 K	4 K		

- ▶ Document components that must meet a nationally recognized standards (UL or ANSI) in the United States:
 - primary circuit components (including wiring), up to mains transformer(s)
 - lithium batteries (also requires reverse charge protection circuitry)
 - CRTs > 5 inches
 - printed wiring boards with > 15 W available
 - wiring/tubing with > 15 W available
 - optical isolators with > 15 W available and/or acting as barrier per insulation diagram
 - conductive coating process.
- ▶ Verify that component ratings meet the equipment's ratings.
- ▶ List enclosure materials
 - UL 94 flame rating requirements for polymeric enclosures if there is > 15 W available power in the enclosure
 - V-2 min. for mobile, portable equipment
 - V-0 min. for fixed or stationary equipment.
- ▶ Verify mains fuse requirements (equipment or wall plug-in power supply):
 - Class I: Line and neutral
 - Class II with functional earth: line and neutral
 - Class II: line only
 - permanently installed equipment: line only.
- ▶ Verify protective earth conductors are green with yellow stripe.
- ▶ Verify wires secured from hazardous movements.
- ▶ Verify equipment marking requirements (labels).
- ▶ Provide illustrations of equipment, complete with all accessories, showing critical components (digital * JPG files).

Once this information is developed, the safety evaluation of the equipment can be initiated. One or more samples are required, depending on the equipment type and time requirements. Multiple samples of components may be needed to perform destructive tests (e.g., transformers, relays, plastic enclosures, or motors). For medical equipment, it may be advantageous for the preliminary investigation or testing to be conducted at the manufacturer's facility to allow for more expedient changes to the equipment if the device is damaged or if there are non-compliances.

A typical evaluation of medical electrical equipment begins with a preliminary investigation to generate or review the information previously identified. It also includes a construction inspection and anticipated test list. Next, the required testing is performed. This includes

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electrical, mechanical, temperature, and abnormal condition testing. If software is required for mitigating fire, shock, mechanical hazards, or requirements of particular standard(s), IEC 60601-1-4 + ISO/IEC12207 + ANSI/UL1998, second edition is used to evaluate the software design process and implementation. While not currently required for UL classification, EMC testing per collateral standard (IEC 60601-1-2) and the review of biocompatibility documentation on patient

contact parts per ISO 10993-1 is optionally conducted. The critical component list is then developed. Any component that may affect compliance with the requirements of the standard(s) used or had an effect on the testing results is considered a critical component.

The Process of Documentation

The documentation developed as a result of a safety evaluation depends on the manufacturer's requirements. The three common types of documentation are a UL report, an informative test report, and a certified body (CB) report. A UL report (consisting of a product description and test report) authorizes the manufacturer to apply the UL/C-UL (United States/Canada) mark to products covered in the report. It describes the equipment evaluated and its critical components. UL conducts quarterly audits using this report to verify that the equipment bearing the UL/C-UL mark is the same as the equipment that was tested. An informative test report is a complete documentation of all the requirements in a standard (N/A, pass, or fail), a test record, insulation diagram, illustrations, equipment markings, and other applicable information. It is the preferred document for MDD technical files (required for CE marking) and required by some international hospitals and clinics for equipment purchases. A CB report is similar to an informative test report but also contains a certificate from the issuer, who is required to be a member of the IECEE CB Scheme. A CB report is used to obtain third-party certification marks (TUV, VDE, SEMKO, etc.) in different countries without repeating the full evaluation of the equipment. The informative test report or CB report is very important to have for the equipment's technical files, as they act as an international "passport" for the device.

Common Noncompliances

There are many common noncompliances that could have been easily avoided had the designers been aware of the safety standard requirements early in the design phase. The most common noncompliance item relates to the accompanying documents. All the '601 standards have very

specific requirements for inclusions in the accompanying documents. Since most companies have separate departments that create these documents, they are often not aware of the requirements. The next most common (and likely the most costly) noncompliance is the power supply selection. The best advice is to use a UL 2601-1 recognized power supply (evaluated to UL2601-1/UL 60601-1 by UL). By doing this, compliance with spacing, leakage current, and mains component requirements is assured. Also, the cost to evaluate the power supply and the required UL quarterly inspections at the power supply manufacturer is avoided. Many designers begin with a non-UL recognized power supply, only to change to a UL recognized one when they discover the associated costs of using a nonrecognized power supply, or when they realize that the one chosen does not comply with the requirements. When designing medical equipment, it is also important to be aware that there are minimum spacing requirements for electrical barriers. Inadequate spacings on circuit boards are another typical mistake. An example of this is dc-dc converters. Nearly all dc-dc converters, including UL recognized models, do not provide the spacing or insulation barrier required by the medical standards. Make sure you get the specifications on the spacings or barriers (more than varnish or enamel on windings) from input to output. For equipment with plastic enclosures, there will also be flammability requirements for the plastic material. Make sure the plastic chosen for the enclosure has at least a UL recognized V-0 flame rating for fixed equipment or a UL recognized V-2 flame rating for all other types of equipment. The last typical mistake relates to indicator lights. Red indicator lights can only be used for a warning, yellow for caution. Keep this in mind when selecting LEDs for any indicator lights. These common noncompliances can be easily avoided with knowledge of the applicable standards, and they are the major reasons that preliminary investigations of medical equipment are best done in the early design phase.

Conclusion

Medical equipment is highly regulated and held to a higher level of safety than nearly all other types of equipment on the market. Understanding the certification and regulatory requirements before the design phase of the equipment will result in a cost reduction in equipment development, faster certification turnaround, and increased product safety.

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Michael L. Marcus received his B.S. degree in electrical engineering from Pennsylvania State University, State College, in 1972 and an M.S. degree in electrical engineering from Fairleigh Dickinson University, Teaneck, New Jersey, in 1989. He worked in industry for 17 years in the biomedical instrumentation field and is currently an assistant professor of engineering at Pennsylvania State University.

Brian R. Biersach is the founder of Medical Equipment Compliance Associates, LLC (MECA), which provides medical companies with certification and regulatory compliance assistance and acts as an agent for medical submissions to Underwriters Laboratories (UL). He holds a B.S. degree in biomedical engineering and a B.A. degree in economics and currently serves as a U.S. expert for AAMI on the IEC/ISO medical standards writing committee JWG3. Prior to founding MECA, he was a medical device services project engineer and reviewer for Underwriters Laboratories Inc. He was an instructor for UL's IEC 60601-1 technical seminars and workshops, an accredited FDA 510(k) reviewer, under the FDA Third Party Review Program, and an ISO 9000 and medical device directive expert auditor.