QuadTech

Application Note

National Deviations to IEC60601-1

This final installment (#8) in the IEC60601-1 Series discusses some of the national deviations to IEC60601-1. In the United States, UL 2601-1 is the national harmonized 60601-1 standard for medical electrical equipment. U.S. manufacturers (and those importing into the U.S.) may also be required to comply with regulations from the FDA, AAMI and NFPA 99 among others. The national 60601-1 harmonized standard in Canada is CAN/CSA C22.2 No. 601.1, in the European Union it is EN60601-1 and in Japan it is JSA JIS T0601-1. Although IEC60601-1 is the international governing standard to which most medical manufacturers comply, national standards may specify additional test requirements or altered test specifications. Let's take a look at some of these standards and investigate the differences.

By now we realize that complying with IEC60601-1 will translate into meeting requirements from multiple national standards. In certifying medical equipment to IEC 60601-1, it is important to keep in mind that the instruction manual, markings (both product and packaging) and software/firmware must also comply with the standard. Consider also the biocompatibility of applied parts and electromagnetic compatibility (EMC) of the entire unit. ISO 10993-1, Biological Evaluation of Medical Devices, is used to assess the biocompatibility of components and the medical equipment itself. The electromagnetic compatibility of components and equipment is assessed using the collateral standard IEC 60601-1-2, Electromagnetic Compatibility, Requirements and Tests.

Medical Device Approval

Simply designing and manufacturing a product in compliance to IEC 60601-1 and a national deviation, does not guarantee the product can be sold in said targeted market. Approval of the medical device for sale in the market is the next step. The FDA (United States), EU Medical Device Directive (European Union) and Canada Health (Canada) are three regulatory agencies specifying requirements for medical products to be sold in their respective countries.

The FDA (United States)

The Food and Drug Administration's Center for Devices & Radiological Health (CDRH) regulates businesses that manufacture, repackage, re-label, and/or import medical equipment sold in the United States. To obtain clearance from the FDA, the medical equipment manufacturer must define the equipment, classify the equipment and adhere to the basic regulatory requirements for medical products sold in the U.S.

The FDA classifies medical equipment into three categories based on the amount of regulation needed to ensure the safety and effectiveness of said medical equipment. Class I products are the least controlled and Class III products have the most stringent requirements.

Medical Device Approval

FDA CDRH Basic Regulatory Requirements:

Pre-market Notification 510(k), unless exempt, or Pre-market Approval (PMA)
Establishment Registration, Form FDA-2891, 21 CFR, Part 807
Medical Device Listing, Form FDA-2892, 21 CFR, Part 807
Quality System Regulation, 21 CFR, Part 820
Labeling Requirements, 21 CFR, Part 801
Medical Device Reporting (MDR), 21 CFR, Part 803

The Code of Federal Regulations (CFR) in 21 CFR, Parts 800-1299 contains regulations for medical equipment. For those regulations on the approval process refer to 21 CFR, Part 807, subpart E for Pre-market notification 510(k); Part 814 for Pre-market Approval and Part 812 for Investigational Device Exemption (IDE). For more information on medical device approval and the FDA, visit http://www.fda.gov.cdrh, the FDA's Center for Devices & Radiological Health web page.

The Medical Device Directive (European Union)

In the European Union, the **Medical Device Directive (MDD) (93/42/EEC)** or the Active Implantable Device Directive (AIDD) (90/385/EEC) regulates the release of medical equipment. The MDD requires a technical file on each medical product or family of products. This technical file includes: product description; design/production drawings and diagrams; product technical data; risk assessment; list of standards applied; tests performed; certificates and inspection reports; user's manual and Declaration of Conformity. A Notified Body may be required for testing of the manufacturer's medical device(s), certification of the manufacturer's Quality System and/or review of the technical file on the medical device. Refer to the third article in this series for information on the CE Mark and Notified Body certifications.

Health Canada (Canada)

Canada has a similar system to the EU. The major differences are the registration process, the classification system, the Post Market Surveillance method and the Quality System standards used. The classification system is slightly different and there is a registration process required for Class II, III & IV devices (Class IV being the highest risk class). Importers, Distributors and manufacturers of Class I devices must get an establishment license. The Quality System Requirements are ISO 13485 for Class III & IV devices and ISO 13488 for Class II devices. The Certification of the quality system needs to be conducted by a third party auditing firm accredited by the TPP. Class I devices do not require a Quality System.

Specifications from National Standards

UL2601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety

UL2601-1 is the US national standard for safety testing electrical medical devices. In terms of electrical medical devices, Underwriter's Laboratories (UL) provides standards, training, testing and certification. For more information visit http://www.ul.com/medical or for standards visit http://ulstandardsinfonet.ul.com. This is a separate site just for UL standards.

Outlined herein are some of the differences between UL2601-1 and IEC60601-1. Note: some of the deviations are based on the National Electrical Code, NFPA 70. Refer to the respective standards for complete information.

Specification	UL2601-1
Leakage Current:	1. Specifies deviations for earth and enclosure leakage current 2. Differentiates between Patient Care Equipment (6' around and 7.5' above patient) and Non-Patient Care Equipment. 3. For Non-Patient Care Equipment: Allows opening of the earth conductor and one of the supply connections simultaneously. 4. Specifies leakage current limits in Tables 19.100 & 19.101: Class I Product (Typical value) = 300µA within patient area Class I Product (Typical value) = 500µA outside of patient area
Power Supply Cords:	Modified requirements of power cords.
Protective Earthing:	Added requirements for X-ray equipment.
Mains Supply Plug:	Specifies use of 'hospital grade' and 'hospital only' mains plugs (UL 498) and additional markings on cord or product.
Transformers:	Specifies transformer tests with PTC's in the test circuit. Specifies direct plug-in transformer(s).
Components:	Some internal and external components must comply with UL or internationally harmonized standards (Refer to Table 1).
Mechanical:	Maximum travel of moving parts must be limited by end stops. Requirements for Emergency Stop(s) modified. Requirements for Suspension System(s) modified Requirements for polymeric enclosures modified.
Conductive Coatings:	Added compliance requirements with UL 746C
Flammability:	Polymeric enclosures and covers must comply with flammability requirements (UL 746C); transportable equipment minimum (UL 94V-2) and fixed or stationary equipment minimum UL 94V-0.
Oxygen:	Added requirements for medical devices with oxygen or used in an oxygen enriched environment (which is currently in many IEC60601 particular standards).
Markings:	Signal Words: Letter height minimum = 2.8mm (CAUTION, DANGER, WARNING); Other Words: Letter height minimum = 1.6mm Contrast: Good contrast of letters Factory Code: If multiple factories an additional marking or code is required
Production Line:	Test requirements are more clearly defined.

Specifications from National Standards

UL2601-1 (Continued):

UL 2601-1 requires that certain internal and external components of the medical equipment meet a nationally recognized standard such as UL or ANSI or an Internationally-Harmonized Component Standard. Table 1 lists some of these components. The third column lists some reference UL standards that may be used in evaluating the compliance of components in the medical equipment under test. Some of the reference standards listed in Table 1 are used to evaluate components in non-medical equipment.

Table 1: Components Requiring Compliance

Component	Description	Reference Standards
Primary Circuit Components	> 15W: Power supplies, transformers, X & Y capacitors, switches, fuses, circuit breakers	UL 1012, 1310, 1778, 1989, 2601-1 UL 506, 1561, 1562, 1585 UL 810
Lithium Batteries		UL 1642
Cathode Ray Tubes (CRT's)	> 5" (12.7cm)	UL 1418, 61965
Printed Wiring Boards	> 15W	UL 796
Wiring/Tubing	> 15W	UL 44, 83, 244, 1581, 1653
Optical Isolators	> 15W	UL 1577
Conductive Coatings	UL R/C process	UL 746C
Software/Firmware	If required for mitigating fire, shock, mechanical hazards	IEC60601-1-4, ISO/IEC 12207, ANSI/UL 1998 2nd Edition

Specifications from National Standards

CSA C22.2 No. 601.1: Canada's National Harmonized IEC 60601-1 Standard

CSA C22.2 No. 601-1 is the Canadian national standard for safety testing electrical medical devices. CSA International (http://www.csa-international.org) provides standards, testing and certification for electrical medical devices. Outlined herein are some of the differences between CSA C22.2 No. 601-1 and IEC60601-1. Note: some of the deviations are based on the Canadian Electrical Code. Refer to the respective standards for complete information.

Specification	CAN/CSA C22.2 No. 601-1
Ground/Earth Test:	Specifies a 30A, 2-minute test with a maximum 4V voltage drop for devices rated to 15A.
Power Supply Cord:	Modified requirements for power supply cord.
Plugs:	Requires Hospital Grade plug for CAN/CSA C22.2 No 21 and/or 42.
Gas Connectors:	Added requirements for Gas Connectors
Rub Test:	Specifies Rub Test compound Methylated Spirits equal to: 90.0% Ethanol, 9.5% Methanol and 0.5% Pyridine.
Markings:	Written Safety Instructions on equipment and in accompanying documents must appear in English and French.

JSA JIS T0601-1: Japan's National Harmonized IEC 60601-1 Standard

JIS T0601-1 is the Japanese national standard for safety testing electrical medical devices. Outlined herein are some of the differences between JIS T0601-1 and IEC60601-1. Refer to the respective standards for complete information.

Specification	JIS T0601-1
Leakage Current:	For Frequency > 1kHz, Leakage Current measurement ≤ 10mA.
Power Supply Cords:	Restricts vinyl insulated power cord for temperature ≥ 60°C.
Test Voltage:	Focuses on 100V at 50Hz and 60Hz.
Environmental:	Specifies Humidity Test at values ≥ 85% RH.
Standards:	References JIS standards for the IEC/ISO standards referenced within IEC 60601-1.

AS/NZ 3200.1: Australia's & New Zealand's National Harmonized IEC 60601-1 Standard

AS/NZ 3200.1 is the national standard for safety testing electrical medical devices in Australia and New Zealand. Outlined herein are some of the differences between AS/NZ 3200.1 and IEC60601-1. Refer to the respective standards for complete information.

Specification	AS/NZ 3200.1
Test Voltage:	Focuses on 240V/50Hz (Australia) & 230V/60Hz (New Zealand).
Mechanical:	Removes certain mechanical strength requirements.
Standards:	References AS standards for the IEC/ISO standards referenced within IEC 60601-1.
Supplier:	Requires Name & Address of Manufacturer/Supplier in Australia or New Zealand.

Specifications from National Standards

NFPA 99: A U.S. Standard for Health Care Facilities

NFPA 99, 'Standard for Health Care Facilities', is a national code authored by the National Fire Protection Association (NFPA). NFPA 99 deals with the entire health care facility not just medical electronic equipment. It specifies criteria for "minimizing the hazards of fire, explosion, and electricity in health care facilities providing services to human beings. A medical manufacturer should also be cognizant of NFPA 70 (National Electrical Code) and NFPA 101 (Life Safety Code).

The medical manufacturer must understand NFPA 99 for the requirements his product must meet in terms of eliminating direct electrical or fire injury to patients or personnel in a health care facility. How safe the medical device functions is just as important as to how it works within a medical environment. Once again, the issues of electromagnetic interference (EMI) and biocompatibility cannot be ignored. NFPA 99 deviates from IEC60601-1 in very physical specification of power cords, oxygen environment use and leakage current tests.

Specification	NFPA 99
Leakage Current:	Patient to Ground (non-isolated): ≤100μA Patient to Ground (isolated): ≤10μA (GND intact); ≤50μA (GND open) Between Leads (isolated): ≤10μA (GND intact); ≤50μA (GND open) Between Leads (non-isolated): ≤50μA (GND intact or open)
Power Supply Cords:	Cord: Listed for use at voltage ≥ rated power line voltage of medical device and ampacity ≥ current rating of medical device (NFPA 70). Cords & Plugs polarized per ANSI C73.13 Grounding Conductor ≥ 18AWG (≥ 16AWG for conductor ≥15 feet) Allowances for 2-wire power supply cords (double insulation) Resistance of power supply cords used in vicinity of patient care ≤0.5Ω.
Oxygen:	Specific physical construction requirements: electrical medical equipment must be 'listed' for use in oxygen environment; sealed, ventilated, contain no hot surfaces (≥300°C, specifically for Oxygen-Enriched Atmospheres) and no exposed switching/sparking points.

UL2601-1 has incorporated the appropriate requirements of the National Electrical Code (NFPA 70) into the standard. Also, CSA C22.2 No. 601.1 has incorporated the appropriate Canadian Electrical Code requirements.

ANSI/AAMI ES1-1993: A U.S. Standard for Medical Equipment

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. Contact AAMI (Association for Advancement of Medical Instrumentation) at http://www.aami.org or ANSI (American National Standards Institute) at http://www.ansi.org for complete information on the ANSI/AAMI ES1-1993 standard.

Summary & Contacts

Summary

With all the different specifications from multiple standards, how does a manufacturer of medical electronic products get his product to market? Which standard is the governing standard? Though confusing when presented with all the standards, a manufacturer must design and test to the most stringent standard specific to his product and its particular application, then work his way down the correlating standards. Safety and proper function of the electronic medical device is paramount. IEC60601-1 is simply the starting point.

Contacts:

Eisner Safety Consultants:

To find out more about IEC60601-1 and national regulatory requirements for medical electrical products, please contact Eisner Safety Consultants at (503)-244-6151, 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 product evaluation to safety standards, Agency coordination, CE Mark, Quality Systems and training.

QuadTech:

For complete product specifications on the 6100 Production Safety Analyzer for electronic medical devices or any of QuadTech's products, visit us at http://www.quadtech.com/products. We hope this series of eight articles has been helpful in understanding IEC60601-1; it's purpose, structure and requirements. To find out more about QuadTech, call us at 1-800-253-1230 or email your questions to info@quadtech.com.

DISCLAIMER

The organizations listed in this application note do **not** have any formal relationship, agreement or representation with QuadTech, Incorporated. Any web links to organizations are provided for general information only. Organization logos are registered trademarks of the specific organization and are used with express permission from the specified organization.

Telephone: 1- 800-253-1230, Website: http://www.quadtech.com
Printed in U.S.A. P/N 035123/A1 January 2003