Clinical Engineering

Law, Standard & Regulation In Medical Device Perspective

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Topics

- Law, Standard & Regulation
- Patient & Medical Device Safety
- Electrical Safety Testing of Medical Devices

Law, Standard & Regulation

Standard

Norm or requirement. It is usually a formal document that establishes uniform engineering or technical criteria, methods, processes and practices.

Law

A system of rules, usually enforced through a set of institutions, used to underpin civil obedience, politics, economics and society in numerous ways.

Regulation

Legal restrictions promulgated by government authority

Medical Device - Definition

(GHTF/SG1/N29R16:2005)

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by manufacturer to be used, alone or in combination, for human beings, with some kinds of purpose (diagnosis, prevention, monitoring, treatment, etc)

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception

Medical Device - Active

European Directive 93/42/EEC

GHTF/SG1/N15:2006

Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity, and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

Medical Device - Categories

Categories	Example
Non-active implantable devices	Stent, hip implant
Electromechanical devices	Electrocardiograph
Single use (disposal) devices	Bandage, dressing, syringe
Active implantable devices	Cardiac pacemaker, neurostimulator
Hospital equipment (hardware)	Patient bed, patient trolley
Dental devices	Dentistry tools, drills, alloys & resins, dental floss
In-vitro diagnostics	Devices for clinical chemistry, microbiology, genetic test
Ophthalmic & optical devices	Contact lenses, optical lens, eye glasses, ophthalmoscope
Anesthetic/respiratory equipment	Oxygen mask, anesthesia, breathing circuit, medical gas delivery unit
Technical aids for disabled	Wheelchair, crutch, standing support, electrical bed
Diagnostic & therapeutic radiation	X-ray machine, linear accelerator

Medical Device - Classification

Based on level of risk associated with a medical device
Purpose : As a registration issue in Regulation of Medical Device

Europe	*FDA*	*GHTF*	*Examples of medical devices*	**Risk Level**
Class I	Class I *	Class A	non sterile items, or sterile items with a low potential risk: surgical instruments, urine bags, stethoscope, examination gloves, etc.	Low Risk
Class IIa	Class II	Class B	sterile items surgical gloves, urinary catheters, stomach tubes, needles, tracheal tubes, IV giving sets etc.	Low-Moderate
Class II b		Class C	blood bags, condoms, non-absorbable sutures, anaesthesia machines etc.	Moderate-high
Class III	Class III	Class D	absorbable sutures etc.	High Risk

* with or without GMP

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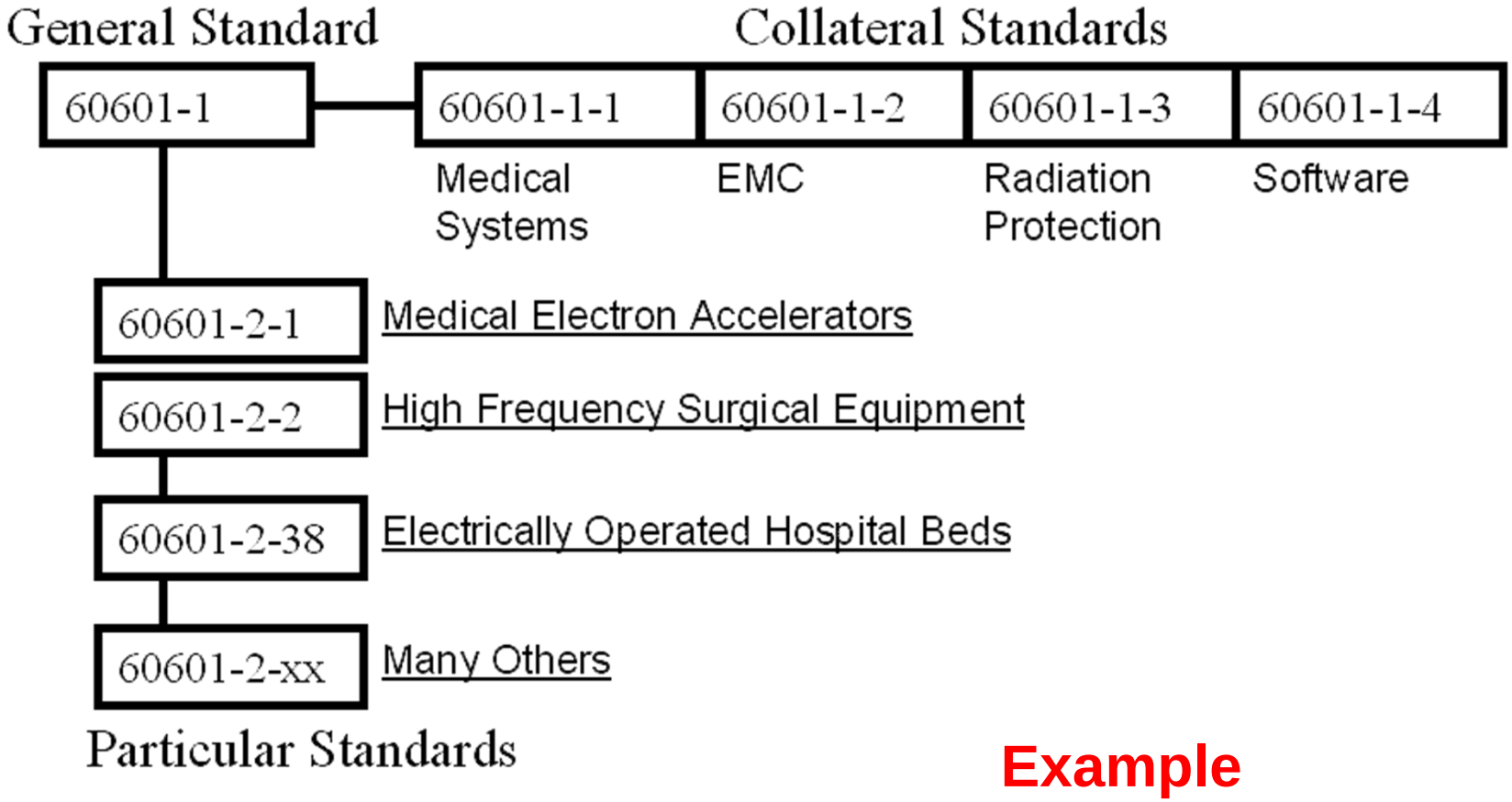
IEC 60601



Example

TYPES OF STANDARD		
Basic safety standards-Horizontal Standard	Indicates the general safety requirements to a wide range of product and or process	• IEC 60601-1, General safety requirements of medical electrical equipment • ISO 13485:2006 basic international standard for quality management system in medical devices industry
Group safety standards-Semi horizontal standard	Indicates requirements applicable to similar products and or process	• IEC 60601-1-2, general requirement of safety of medical electrical equipment, electromagneticcompatibility
Product safety –Vertical standard	Are used for specific products and or process	• IEC60601-2-12, particular requirements for the safety of lung ventilators

Medical Device - Classification

Based on IEC 60601-1, EN 60601 UL 2601-1, UL 60601-1, CSA C22.2 No 601.1, etc

- **Protection against electrical shock**
  - Class I, Class II, Class III
- **Degree of Protection Against Electric Shock (Applied Parts)**
  - B, BF and CF.
- Installation & Use of Product
  - fixed, hand-held, mobile, permanently installed, portable, stationary and transportable equipment
- Ingress of Liquids
  - IEC 529
- Equipment Mode of Operation
  - continuous, short-time, intermittent, continuous operation with short-time loading and continuous operation with intermittent loading.
- Use with Flammable Anesthetics
  - AP or APG.

Medical Active Device - Classification

- **Protection against electrical shock**
  - Class I, Class II, Class III
- **Degree of Protection Against Electric Shock (Applied Parts)**
  - B, BF and CF.
- **Risk Level Associated with Usage**

Medical Device - Classification

Based on Protection against electrical shock
For electrical safety requirement standard of a medical device

Class I

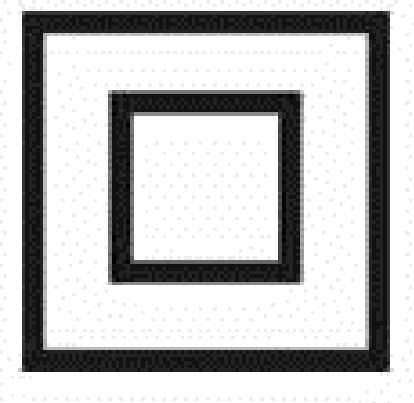
- protection is the insulation between live parts and exposed conductive parts
- supplementary protection (i.e. the protective earth)
- have fuses at the equipment end of the mains supply lead in both the live and neutral conductors
- 3-prong power cord

Medical Device - Classification

Based on Protection against electrical shock
For electrical safety requirement standard of a medical device

Class II

- protection is double insulation or reinforced insulation preventing contact with live part
- have fuses at the equipment end of the mains supply lead
- 2-prong power cord



Medical Device - Classification

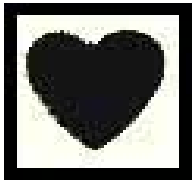
Based on Protection against electrical shock
For electrical safety requirement standard of a medical device

Class III

- protection relies on the fact that no voltages higher than safety extra low voltage (SELV) are present.
- SELV is defined in turn in the relevant standard as a voltage not exceeding 25V ac or 60V dc.
- battery operated or SELV transformer
- Not recognised for electrical safety requirement anymore
  - Limitation of voltage is not deemed sufficient to ensure safety of patient

Medical Device - Classification

Based on Degree of Protection Against Electric Shock (Applied Parts)
For electrical safety requirement standard of a medical device

Type	Symbol	Definition
B		Equipment providing a particular degree of protection against electric shock, particularly regarding allowable leakage currents and reliability of the protective earth connection(if present).
BF		As type B but with isolated or floating (F – type)applied part or parts.
CF		Equipment providing a higher degree of protection against electric shock than type BF, particularly with regard to allowable leakage currents, and having floating applied parts

Medical Device – Classification

Based on level of risk associated with a medical device
Purpose : As a registration issue in Regulation of Medical Device

A classification to categorize medical devices based on risk associated with the vulnerability of the human body, the technical design and the manufacture of the medical device. It uses a set of classification rules based on:

- Intended use
- Duration of use (transient, short-term and long-term)
- Part of human body (non-invasive or invasive with respect to body orifices, surgically invasive interventions, central circulatory system, central nervous system)

Scope of Regulation: Medical Device

Pre-Market	Placement on market	Post-Market
• Product safety & performance • Quality system	• Distribution & supply c h a i n • Advertising (product representation)	• Installation, T&C • Maintenance, calibration • Operation, usage • Decommission, disposal • Surveillance & vigilance

Patient & Medical Device Safety

Hazards of Medical Electrical Equipment

1. Mechanical Hazards
2. Risk of Fire or Explosion
3. Absence of Function
4. Excessive or Insufficient Output
5. Infection
6. Misuse
7. Risk of Exposure to Spurious Electric Currents

Examples

- Electro surgery unit (ESU) burns due to poor contact with grounding plate.
- Punctured intestine due to insulation breakdown on laparoscope
- Death caused by vacuum & suction lines reversed on portable suction machine
- Infant brain damage due to defective valve design on portable oxygen unit
- Microshock electrocution due to broken ground wire in die injector line cord

Safety in Clinical Environment

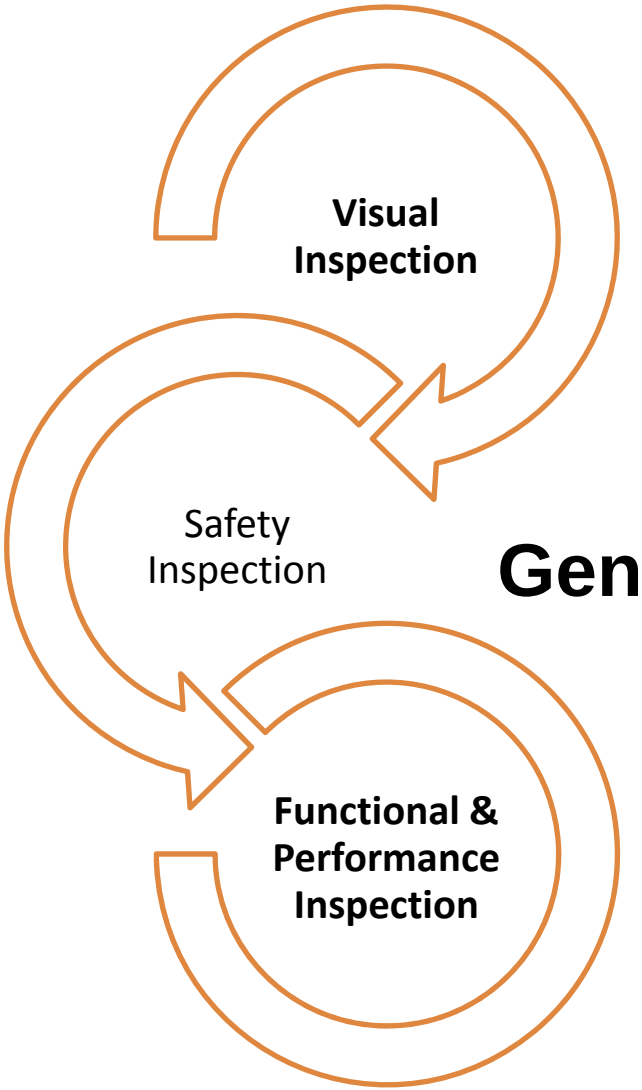
- Electrical hazards
  - Electrical shocks (micro and macro) due to equipment failure, failure of power delivery systems, ground failures, burns, fire, etc.
- Mechanical hazards
  - mobility aids, transfer devices, prosthetic devices, mechanical assist devices, patient support devices
- Environmental hazards
  - Solid wastes, noise, utilities (natural gas), building structures, etc.

Safety in Clinical Environment

- Biological hazards
  - Infection control, viral outbreak, isolation, decontamination, sterilization, waste disposal issues
- Radiation hazards
  - Use of radioactive materials, radiation devices (MRI, CT, PET), exposure control

Electrical Safety Testing of Medical Devices

Test Method



General Checks

Marking

General Electrical Safety Checks

Before we start…

- NC – Condition in which all means provided for protection against hazards are intact
- SFC – condition in which a single means for reducing a risk Is defective or a single abnormal condition is present.

For detail, refer MS IEC 60601-1 2006 see 8.1

General Electrical Safety Testing - Measurement

Earth Continuity

Insulation

Leakage Current

Electrical Measurement – Leakage current

Leakage current is the residual flow of current after high voltage (greater than normal operating voltage) has been applied to the equipment under test.

- Earth Leakage Current
- Enclosure Leakage Current
- Patient Leakage Current

Functional & Performance Inspection

A competent user or technical staff with a thorough knowledge of the equipment and its operation should carry out the functional checks. If no such person is available, a representative of the manufacturer or supplier could do this under close supervision.