



Public Safety and the Healthcare Facility

NFPA 99

- ▶ National Fire Protection Association
- ▶ 99 addresses healthcare facilities
- ▶ 99 specifically addresses installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment and appliances, including medical gas and vacuum systems.

NFPA 99

2012 Edition

2012 Edition

- ▶ The 2012 version of NFPA 99 is **risk based** and is organized accordingly.
- ▶ New chapters, new definitions and new procedures are noted throughout and biomedical technicians should be familiar with and be able to implement these changes.
- ▶ NFPA 99 is a code

Older Editions

- ▶ **Occupancy based**, such as an anesthetizing location or a wet location
- ▶ Older versions of NFPA 99 are standards

Risk Based

- ▶ Category 1 – Failure of this system (including facility and equipment) is likely to cause major injury or death
- ▶ Category 2 – Causes minor injury
- ▶ Category 3 – Not likely to cause injury but can cause discomfort
- ▶ Category 4 – No impact on patient care

Code Vs. Standard

Code

- ▶ A code is a standard that has been adopted by one or more governmental bodies and is enforceable by law

Standard

- ▶ A standard consists of technical definitions and guidelines that function as instructions for designers/manufacturers and operators/users of equipment. *Standards are considered voluntary because they are guidelines and not enforceable by law.*

Wet Procedure Locations

- ▶ Operating rooms “shall” be considered a wet procedure location, unless a risk assessment conducted by the healthcare governing body determines otherwise.
- ▶ Receptacles and equipment connected by cord and plug at intervals not exceeding six months (6.3.2.2.8.5)
- ▶ Wet procedure locations require GFCI or isolated power (new and existing)

Chapter 10 (New)

Electrical Equipment

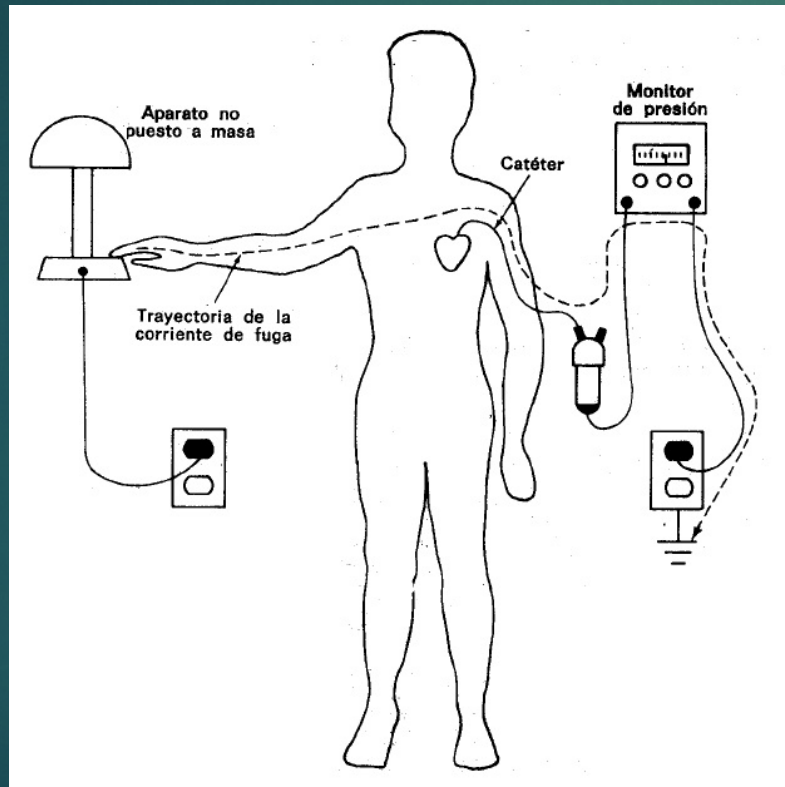
- ▶ Appliances grounding – Double insulated appliances shall be permitted to have 2 conductor cords *and shall be rated as a Class II device.*
- ▶ Leakage Current Fixed Equipment (hard wired) limit changed from 5mA to 10mA
- ▶ Touch Current – Portable Equipment – new term, leakage changed to touch current
- ▶ Touch Current standards have changed – current limit changed from 300uA to 100uA grounded, increased from 300uA to 500uA not grounded
- ▶ Cord and Plug Connected – Portable Equipment in Patient Care Room, Non patient care related equipment, facility or patient owned shall be visually inspected by staff or other personnel

Chapter 10 cont.

- ▶ Household and office appliances without a ground are allowed, just not in patient care vicinity (6ft x 7ft)
- ▶ Old edition stated each appliance must be tested every 12 or 6 months depending on location, new version states for patient care related electrical equipment. Now testing is required on incoming inspection and after repair or modification.
- ▶ Protection of Patients with Direct Electrical Pathways to the Heart – adds specific reference to IEC terminology, Cardiac Floating (CF) for such devices.
- ▶ Devices likely to be used during defibrillation – mandates that when a device critical to patient safety is likely to be attached to the patient during defibrillation, then it shall be rated as “defibrillator proof”

Microshock

IBP



Microshock is

- ▶ Low level current which has a
- ▶ **direct pathway to the heart.**

NFPA - Safety testing and limits

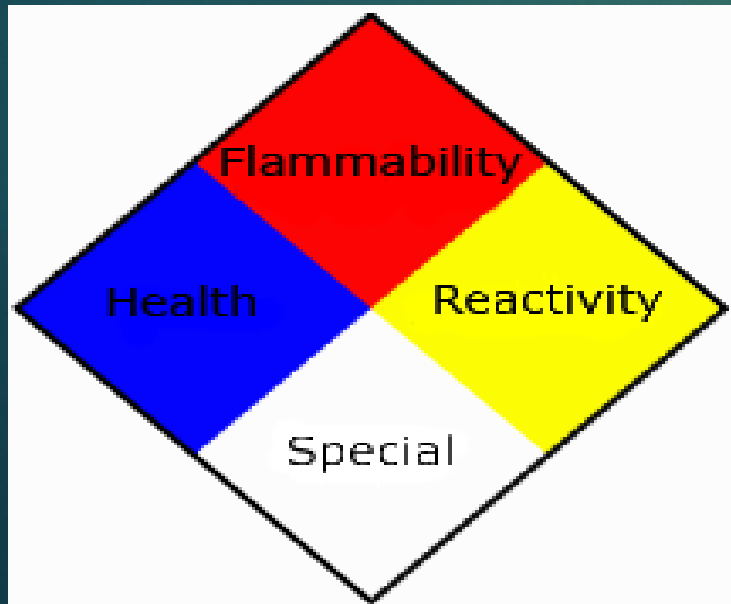
Normal polarity, on/off, ground open/closed

- ▶ Ground wire resistance - $.5\Omega$
- ▶ Touch Current (Leakage) – 100uA grounded, 500uA not grounded
- ▶ Lead to Ground – Isolated – 10uA grounded, 50ua ground open
- ▶ Lead to Lead – same as above
- ▶ Lead Isolation – Isolated 50uA Normal polarity, on/off, ground closed.
- ▶ **IEC 60601** is a series of [technical standards](#) for the safety and effectiveness of medical electrical equipment, published by the [International Electrotechnical Commission](#).

NFPA vs IEC Safety Standards

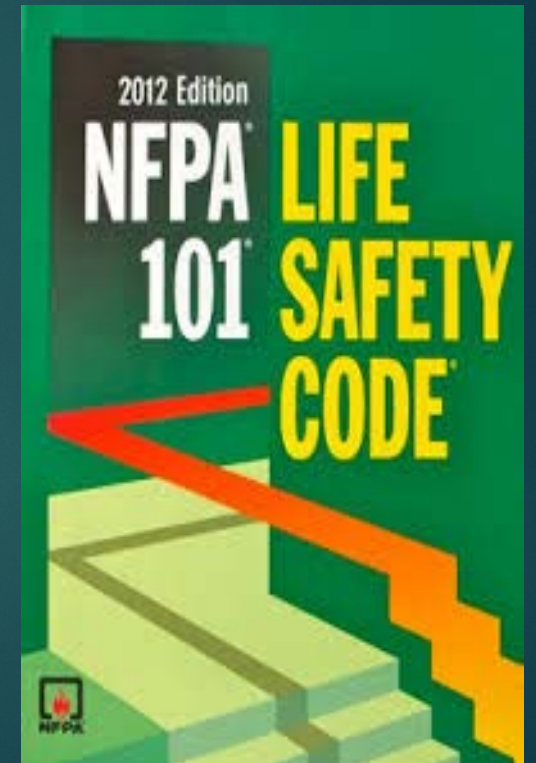
- ▶ NFPA 99
- ▶ Normal polarity, on and off, ground intact = 100uA
- ▶ Normal polarity, power on and off, ground open = 500uA
- ▶ INFPA = .5Ω
- ▶ All leads to ground, normal polarity, power on, closed ground = 100uA
- ▶ All leads to ground, normal polarity, power on, open ground = 500uA
- ▶ IEC 6060-1
- ▶ Normal condition- 100uA
- ▶ Single Fault condition – 500uA
- ▶ Class II (double insulated) ME equipment = 100uA, normal conditions
- ▶ Gnd. Wire - .3Ω
- ▶ Type B or Type BF applied parts – Normal = 100uA
- ▶ Single Fault = 500uA
- ▶ Type CF applied parts –
- ▶ Normal Condition = 10uA
- ▶ Single Fault = 50uA

Placards – NFPA 704



NFPA 101 – Life Safety Code

The bulk of the standard addresses "those construction, protection, and occupancy features necessary to minimize danger to life from the effects of fire, including smoke, heat, and toxic gases created during a fire. The standard does not address the "general fire prevention or building construction features that are normally a function of fire prevention codes and building codes.



SMDA – Safe Medical Device Act

- ▶ EC standard 02.04.01 - EP 5
- ▶ Report to mfg. and FDA when facility has information that reasonably suggests a device has or may have caused or contributed to serious harm or death.
- ▶ FDA form 3500A within 10 work days.
- ▶ www.fda.gov/cdrh/mdr

Safe Medical Device Act - SMDA

MAUDE/MedWatch

- ▶ The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters ¹(manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.
- ▶ MAUDE – manufacturer and user facility device experience.
- ▶ Maude replaced by **MedWatch**
- ▶ MedWatch will use a software system called PRIMO in 2015.
- ▶ PRIMO = Pharmacovigilance Report Intake & Management Output

PRIMO- software

- ▶ Allows regulatory agencies to capture, organize and review high volumes of adverse event reports.

MDR – Medical Device Report

- ▶ SMDA requires reporting of medical devices suspected of causing or contributing to death or serious injury.
- ▶ Requirements of reporting are found in 21 CFR 803 for manufacturer, importer and facility users.
- ▶ MedWatcher.org has downloadable APP for cellphones/tablets etc.

Reporting Requirements

- ▶ Form 3500A must be submitted to FDA within 10 working days of becoming aware of adverse event with medical device.
(Manufacturer, Importer or Facility)
- ▶ User facility must report annual report of death or serious injury on FDA form 3419 on Jan. 1 of following year.
- ▶ MDR reports can be searched on FDA website.

Current Thresholds

- ▶ Threshold of perception– 1 mA
- ▶ Max. Harmless current--- 5 mA
- ▶ "Can't let Go" ----- 10 – 20 mA
- ▶ Pain/exhaustion/fainting- 50 mA
- ▶ V Fib.----- 100 – 300 mA
- ▶ Sustained Myocardial Contraction----- 6 A

Power Systems

- ▶ Alternate power source must transfer within:
- ▶ 10 seconds
- ▶ Class A GFCI (Ground fault circuit interrupters) must trip when current reaches:
- ▶ Greater than 6mA

Isolated Power

- ▶ Line Isolation Monitor must alarm when total hazard current reaches:
 - ▶ 5mA
 - ▶ Isolated power?
 - ▶ Not referenced to ground same ground
 - ▶ Will not spark

Electrical Color Code

US vs. European

- ▶ United states color code for electrical systems
- ▶ Hot=black, Neutral=white, ground=green
- ▶ IEC color code?
- ▶ Hot=brown, Neutral=blue, ground=green

Isolated Power color codes

- ▶ Line 1 – Orange (neutral)
- ▶ Line 2 – Brown (hot)
- ▶ Ground - Green

Infection Control

- ▶ Airborne Infection Isolation (**AII**) room:
- ▶ Protects people in surrounding areas
- ▶ from airborne pathogens
- ▶ Negative pressure; external exhaust
- ▶ Protective Environment (**PE**) room:
- ▶ Protects patient from airborne
- ▶ pathogens in surrounding areas.
- ▶ Positive pressure; HEPA filtration

Electrical Receptacle

- ▶ Receptacle retention force on ground contact in Pt. Care area:
- ▶ 4 oz. Or 112g
- ▶ Testing intervals for receptacles – after repair or interval deemed by governing body with risk assessment
- ▶ Red – Emergency Power

Extension Cords

- ▶ Minimum gauge wire for cord less than 15 feet?
- ▶ 18awg
- ▶ Extension cords?
- ▶ New CMS standard!!!!

Fire Extinguishers

- ▶ Class A = wood, paper, rags, rubbish, linen, plastic
- ▶ Ash
- ▶ Class B = Flammable liquids
- ▶ Barrel
- ▶ Class C = Electrical
- ▶ Current
- ▶ Know Chemical Components

OSHA Blood Borne Pathogens

- ▶ <https://www.youtube.com/watch?v=gLeTNOVfh8o>
- ▶ PPE's – Personal Protective Equipment
- ▶ The purpose of personal protective equipment is to reduce employee exposure to hazards when engineering and administrative controls are not feasible or effective to reduce these risks to acceptable levels. PPE is needed when there are hazards present. PPE has the serious limitation that it does not eliminate the hazard at source and may result in employees being exposed to the hazard if the equipment fails.
- ▶ <https://www.youtube.com/watch?v=9NCV6-qGE8c>

Fire Extinguisher Chemicals

- ▶ ABC – Dry extinguisher uses - **monoammonium phosphate**
- ▶ Carbon Dioxide could be used in class B and C

Radiation Safety

- ▶ It is ionizing radiation
- ▶ Radiation exposure to healthcare workers are monitored by film badge
- ▶ Film badge.....reacts to beta and gamma radiation
- ▶ Do not react to microwaves
- ▶ Alpha Rays.....blocked by filtering
- ▶ Time, Distance and Shielding

Laser Safety - Retinal damage

- ▶ http://www.epa.gov/radiation/understand/protection_basics.html
- ▶ Laser safety: **ANSI Z136.3** – Safe Use of Lasers in Health Care
- ▶ LSO- Laser Safety Officer
- ▶ TJC has adopted ANSI standards.

PISS and DISS

- ▶ Gas Cylinder Safety
- ▶ The **Pin Index Safety System**, or PISS, is a safety system that uses geometric features on the yoke to ensure that pneumatic connections between a gas cylinder and a machine that uses pressurized gases are not connected to the wrong gas yoke. This system can be seen on an anesthesia machine
- ▶ **Diameter Index Safety System (DISS)**
- ▶ The Diameter Index Safety System, or DISS, was designed by the Compressed Gas Association for medical gases at 200 psig or less. It uses unique threaded connections to fit low-flow devices to station outlets. It is also used for the connection of additional features to a low-flow device, such as in fixing a nipple to an oxygen flowmeter. Although DISS takes more time to affix, this is by far the most popular system.

Trace Gas

- ▶ National Institute for Occupational Safety and Health
- ▶ NIOSH recommendation for NO₂ TWA (time weighted average) = 25ppm
- ▶ Only a recommendation!!!

Joint Commission

- ▶ EC – environment of care
- ▶ EP – element of performance
- ▶ Non Profit agency which holds authority of CMMS to accredit healthcare facilities.
- ▶ Without accreditation facility can not bill government for Medicare or Medicaid patients.

Code of Federal Regulation

CFR's

- ▶ The *Code of Federal Regulations* (*CFR*) is the codification of the general and permanent rules and regulations (sometimes called [administrative law](#)) published in the [Federal Register](#) by the executive departments and agencies of the [federal government of the United States](#). The CFR is divided into 50 titles that represent broad areas subject to federal regulation. - Wikipedia
- ▶ **42 CFR 482** contains the health and safety requirements that hospitals must meet to participate in the Medicare and Medicaid programs
- ▶ 42 CFR 482 is the document which all certifying bodies must use to ensure certification status in the United States.

Health Insurance Portability and Accountability Act

- ▶ The Office for Civil Rights enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; the HIPAA Breach Notification Rule, which requires covered entities and business associates to provide notification following a breach of unsecured protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety.
- ▶ <https://www.youtube.com/watch?v=mEu6NGPA0Cg>

IEC 80001-1

Network Security

- ▶ https://www.youtube.com/watch?v=_2IQSJXXvQQ
- ▶ The standard outlines a risk management strategy that will help facilities anticipate and resolve problems associated with networking their devices.
- ▶ All the information about IEC 80001 (deeper than the exam will go)
- ▶ http://www.ncbiomed.org/files/Download/IEC80001-an_introduction.pdf