New Maintenance Requirements from CMS
• Conditions of Participation (COPs)
• Interpretive Guidelines
• State Operations Manual
§ 482.41(c)(2): Buildings

- Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.
CMS Memorandum S&C 12-07-Hospital

Clarification of Hospital Equipment Maintenance Requirements
Concerns: Inventory

- Risk-based inventory criteria?
- Definition of critical equipment?
- Compatibility with Joint Commission?
Concerns: Procedures

- Manufacturer recommendations?
- Access to information?
- Access to test equipment?
- Procedures from ECRI and others?
Concerns: Scheduling

- Manufacturer recommendations?
- Documentation for schedule change?
- NFPA 99 (2012) changes?
Concerns: Fundamental

- Current practice is safe and effective
- Increased time, effort, expense
- No demonstrated benefit
Meeting: CMS and Joint Commission

- Results of AAMI online survey
- CMS is open to evidence
- CMS will not withdraw the memo
- JC standards can stand unchanged
Meeting: CMS and AAMI (and ASHE)

- CMS is open to evidence
- CMS wants standard practice
- CMS is enforcing the changes
- CMS moves slowly
Activities: Short Term

- AAMI and ASHE take the lead
- Report to CMS: 244 pages
- Interim guidance to the profession
Activities: Long Term

- Develop a practice standard
- Work with CMS on survey process
Recommendations

- Keep doing what you’re doing
- Carefully review what you’re doing
- Hope CMS doesn’t show up
Why do we do what we do?

- Inventory
- Procedures
- Scheduling
Inventory
Joint Commission

- Physical risk associated with use
- Equipment incident history
- All life-support equipment
Fennigkoh & Smith (and derivatives)

• Severity (primarily)

• Maintenance requirements
Ridgway, Wang (and others)

- Risk = Severity × Probability
- Maintenance benefit
Procedures
Joint Commission: Examples of strategies for maintaining, inspecting, and testing all equipment on the inventory

- Predictive maintenance
- Reliability-centered maintenance
- Interval-based inspections
- Corrective maintenance
- Metered maintenance
How do you set decide what to do?

- Manufacturer
- ECRI Institute
- Professional judgment
Scheduling
Joint Commission: Criteria such as ...

- Manufacturers’ recommendations
- Risk levels
- Current hospital experience
How do you set the schedule?

- Fennigkoh *et al.*
- Manufacturer
- ECRI Institute
How do you adjust the schedule?

- Professional judgment
- Data analysis
- Trial and error
Practice Standard for the Profession
Standard of Practice?

- EQ56: Recommended practice for a medical equipment management program.
- Manufacturer’s recommendations (the CMS Gold Standard)
- NFPA, AAMI, ASHE, ACCE, ECRI Institute
- Compilation of current practice
- Evidence-based maintenance
NFPA 99 (2012)
Health Care Facilities Code
NFPA 99 History

• **1979:** Committee decides to combine NFPA 56F, 76A, 76B-T, and others
• **1984:** First issuance of NFPA 99
• **1987:** Restructured into chapters
• **2005:** Most recent previous edition
• **2005-2011:** Full review and rewrite
NFPA **Standard** versus **Code**

- NFPA 70: National Electrical Code
- NFPA 99: Standard ➔ Code
  - Enforceable minimum requirements
  - Suitable for adoption into law
Building System Category 1

Failure of such equipment or systems is likely to cause major injury or death of patients or caregivers. Systems are expected to work or be available at all times to support patient needs.
Building System Category 2

Failure of such equipment is likely to cause minor injury to patients or caregivers. Systems are expected to provide a high level of reliability; however, limited short durations of equipment downtime can be tolerated without significant impact on patient care. Category 2 systems support patient needs but are not critical for life support.
Building System Category 3

Failure of such equipment is not likely to cause injury to patients or caregivers, but can cause patient discomfort. Normal building system reliabilities are expected. Such systems support patient needs, but failure of such equipment would not immediately affect patient care. Such equipment is not critical for life support.
Building System Category 4

Failure of such equipment would have no impact on patient care and would not be noticeable to patient in the event of failure.
Medical equipment – general changes

• Delete manufacturer requirements
• Delete special requirements for equipment in anesthetizing locations
• Delete references to laboratory equipment
NFPA 99 (2012) testing requirements

- Physical integrity of power cord assembly (visual inspection)
- Resistance between the appliance chassis and the ground pin: 0.50 Ω
Touch Current

• Leakage current flowing from accessible equipment parts, excluding patient connections, through an external path other than the grounding conductor to ground
NFPA 99 (2012) testing requirements

- Chassis leakage current (touch current):
  - 100 µA (ground wire intact)
  - 500 µA (ground wire open)

Normal polarity **only**
NFPA 99 (2012) testing requirements

- Lead leakage current
  
  All leads together to ground **only**
  
  **100** µA (ground wire intact)
  
  **500** µA (ground wire open)
  
  Normal polarity **only**
10.5.2.1.2 All patient care related electrical equipment used in patient care areas shall be tested in accordance with 10.3.5.4 [chassis leakage] and 10.3.6 [lead leakage] ... 

... before being put into service for the first time 

... and after any repair or modification that might have compromised electrical safety.
What will we do when routine electrical safety testing is no longer required?
Isolated Power Systems and Wet Locations
Appliance operates normally because there is still 120 volts between “phase” wires.
LINE ISOLATION MONITOR SIGNALS

TOTAL HAZARD MILLIAMPERES

NORMAL

ALARM

TEST

SILENCE
POST GLOVER LifeLink
MARK IV
LINE ISOLATION MONITOR

TOTAL HAZARD CURRENT
1.93 mA

SAFE
HAZARD
SILENCE

“CAL” LIM IS RECALIBRATING
“Err” LIM FUNCTION HAS FAILED

PUSH TO TEST
PUSH TO SILENCE
Wet location patient care areas shall be provided with special protection against electric shock

- IPS shall be permitted as a protective means capable of limiting ground fault current without power interruption
- Where power interruption is tolerable, use of GFCI shall be permitted
Wet (Procedure) Location: A patient care area where a procedure is performed that is normally subject to wet conditions while patients are present, including standing fluids on the floor or drenching of the work area, either of which is intimate to the patient or staff.

Annex: Routine housekeeping procedures and incidental spillage of liquids do not define a wet location.
Who decides? NFPA 99 (2005) says ...

- The governing board of the facility shall designate the following areas in accordance with the type of patient care anticipated:
  - General Care Area
  - Critical Care Area
  - Wet Location
Who decides? NFPA 99 (2012) says ...

- ORs shall be considered to be wet procedure locations unless a risk assessment by the governing body determines otherwise.

- Annex: ... consult with all relevant parties, including clinicians, biomedical engineering, and facility safety engineering.
Should all ORs be regarded as wet locations?

• **Yes**: ORs get wet so IPS is needed (AORN, NFPA 99 committee member, some anesthesiologists)

• **No**: No evidence of hazards that IPS would mitigate (ASHE, ECRI, VA, DoD, Kaiser, Baretich)