Joint Commission Update

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The Joint Commission

Session Description

This session will provide the most up to date information regarding Joint Commission and regulatory compliances changes in 2015-2016.

About Presenter

George Mills is the Director for the Department of Engineering at The Joint Commission. In this role, Mr. Mills provides standards interpretation and education to The Joint Commission's Surveyors and accredited organizations, reviews equivalency requests, and is a nationally recognized speaker. Previously, Mr. Mills served as Senior Engineer for the Standards Interpretation Group in the division of Accreditation and Certification Operations at The Joint Commission.

Mr. Mills has over 30 years of experience in the health care setting, and previous experience in the construction industry and structural steel fabrication. Prior to joining The Joint Commission, he served as a Director of Facilities; held national positions related to Codes and Standards, including serving as Director of Codes & Compliances for ASHE; and served as a consultant.

Mr. Mills earned an MBA from California Coast University in Santa Ana, California.

2016

The Healthcare Environment

Clinical Engineering

George Mills, Director

Engineering Department

The Joint Commission

Often Cited Medical Equipment EPs

Often Cited
EC.02.04.01, EP 2
EC.02.04.03, EP 2
EC.02.04.03, EP 3
EC.02.04.03, EP 4
EC.02.04.03, EP 5

3 of 10 from the ECRI Top 10 List

1. Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens
   - Failure to clean, disinfect or sterilize
   - Deaths were associated with the use of duodenoscopes that had not been successfully disinfected between uses
2. Missed Alarms Can Have Fatal Consequences
5. Insufficient training of clinicians on operating room (OR) technologies
   - ECRI Institute estimates that approximately 70% of accidents involving a medical device can be attributed to user error or the technique of use

Scopes

- Number 1 on ECRI Top 10 for 2016
- Score at IC. For infection control issues, and will result in follow-up survey under COP §482.42
  - IC.02.02.02 EP 1 &2 hi/lo level disinfection
  - IC.01.03.01 EP 1 – 5 risk assess & surveillance
  - IC.01.05.01 EP 1 for policy issues
- HTM asked to add scopes to inventory
  - Opportunity for outside observation of process
- Score at EC.02.05.01 EP 15 for ventilation issues, will result in follow-up survey under COP §482.42

18 of Top 20 Observations: LD.4.01.05 EP 4

- The hospital effectively manages its programs, services, sites, or departments
  - EP 4: Staff are held accountable for their responsibilities
    - Used when leadership has allowed non compliance to exist without correction

What is your approach to ESC?

- Do you have a team approach or is one person responsible?
- Do you do what you need to do to “make it go away” or are the issues analyzed to determine why the non compliance is present?
- Do you use this standard ESC response: “We have re-educated the “Fill In The Blank”?”
- Have you looked at patient safety events and near misses/close calls in relation to non compliance identified during your survey?
- Have you considered what the short term and long term impact will be if you are unsuccessful in correcting the RFIs?

Some things to consider…

- Do you have the right people at the table to address the issues identified?
- Are you focusing on systems and processes and how to improve them?
- Have you had an issue with this requirement on previous surveys?
- What kind of follow up monitoring have you planned to determine whether or not the ESC has been effective over the long term?
- If you find that your ESC hasn't worked how do you go about fixing that?

The Healthcare Environment

Standards Update

Time Defined

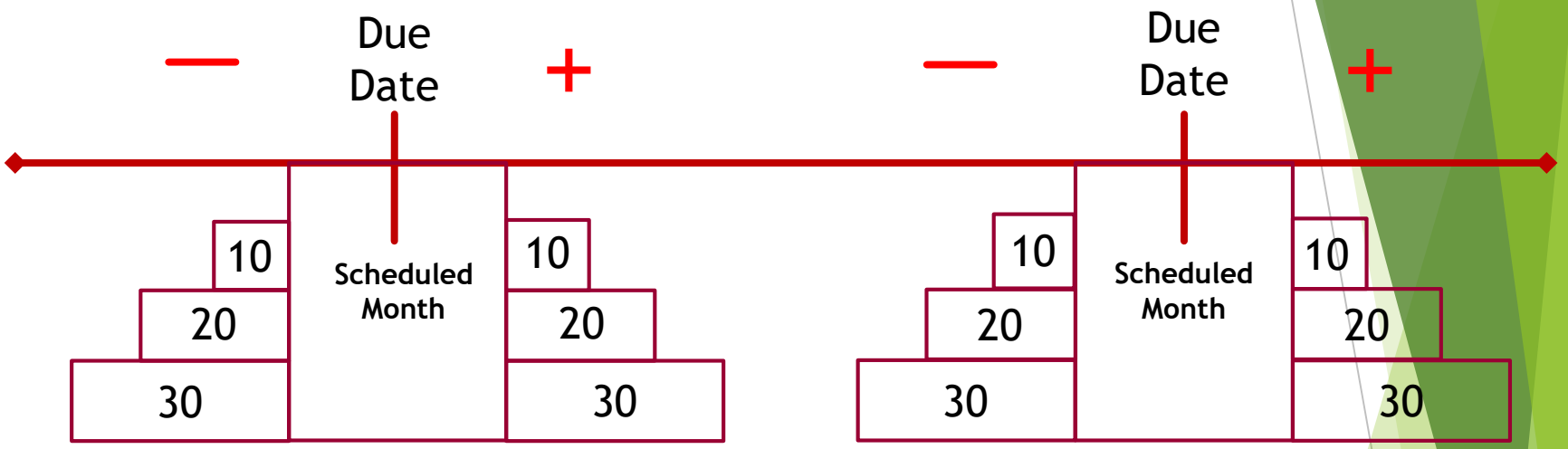
The Joint Commission EC chapter defines time as:

- Daily, weekly, monthly are calendar references
- Quarterly is once every three months +/- 10 days
- Semi-annual is 6 months from the last scheduled event month +/- 20 days
- Annual is 12 months from the last scheduled event month +/- 30 days
- 3 years is 36 months from the last scheduled event month +/- 45 days

NOTE 1: The above does not apply to required frequencies

NOTE 2: An alternative of developing either a unique, written policy or adopting NFPA definitions when available is acceptable

Quarterly: +/- 10 days
Semiannual: +/- 20 days
Annual: +/- 30 days



Quarterly	Jan	February										Apr
Semiannual	June	July		Aug		Sept		Oct		Nov		Dec
Annual	Jan	F	M	A	M	J	J	A	S	O	N	D	Jan

Frequencies required by Code may not be modified
(e.g. EC.02.05.07 EP 4 & 7)

Medical device alarm safety

Scope of problem

100s → 1,000s → 10,000s

100s of alarm signals per patient, per day = 1,000s of alarm signals on each unit = tens of thousands of alarm signals throughout a hospital per day

85–99% of alarms don't require clinical intervention

Contributing Factors

Nuisance Alarms

- May interfere with patient care.
- Are perceived as annoying.
- Are not the result of adverse patient conditions.
- Distract from other tasks or focus.

False Alarms

- Are detected by a medical device.
- Indicate the need for a response.
- Are triggered without a true patient event.
- Are usually the result of:
  - Parameters not set to actionable levels
  - Too tight thresholds

NPSG 06.01.01: Alarm Mgmt

- **In Phase I (beginning January 2014)**

Hospitals will be required to:

- establish alarms as an organization priority
- identify the most important alarms to manage based on their own internal situations.
  - Input from medical staff and clinical depts
  - Risk to patients due to lack of response, malfunction
  - Are specific alarms needed or contributing to noise/fatigue
  - Potential for patient harm based on internal incident history
  - Published best practices/guidelines

NPSG.06.01.01: Alarm Mgmt

- **In Phase II (as of January 2016)**

Hospitals will be expected to:

- develop and implement specific components of policies and procedures that address at minimum:
  - Clinically appropriate settings
  - When they can be disabled
  - When parameters can be changed
  - Who can set and who can change parameters and who can set to “off”
  - Monitoring and response expectations
  - Checking individual alarm signals for accurate settings, proper operation and detectability
- educate those in the organization about alarm system management for which they are responsible

NPSG.06.01.01 Analysis

- October 2014 study with 624 respondents
  - 79% indicated clinical alarm safety was established as a priority
    - Prioritization of clinical alarm safety
    - Starting a clinical alarm safety initiative
  - 59% encounter obstacles
    - Inability to retrieve alarm data from the equipment
      - Data retention by equipment is often limited to patient event

Medical Equipment: EC.02.04.01, EC.02.04.03

APPLIES ONLY TO

HOSPITAL & CRITICAL ACCESS HOSPITAL *PROGRAMS*

EC.02.04.01

Standard EC.02.04.01

The hospital manages medical equipment risks

EC.02.04.01 EP 1

The hospital solicits input from individuals who operate and service equipment when it selects and acquires medical equipment.

EC.02.04.01 EP 2

For hospitals that **do <u>not</u> use** Joint Commission accreditation for deemed status purposes: The hospital maintains either a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use (including all high risk equipment) and equipment incident history.

The hospital evaluates new types of equipment before initial use to determine whether they should be included in the inventory.

Maintaining Medical Equipment

- Inventory is populated based on one of two strategies:
  - All equipment inclusion
  - Physical risk based process
    - For example, evaluating:
      - Function
      - Risk Levels
      - Maintenance Requirement
    - Utilize resources, i.e. the FDA MAUDE report
- All high risk equipment is included
- All new types of equipment evaluated for inclusion

Joint Commission Medical Equipment

- Medical equipment includes equipment used in for monitoring, such as
  - Bedside monitors
  - Telemetry monitors

Joint Commission Medical Equipment

- Treatment, such as
  - Electro-surgery
  - Lasers
  - Diathermy
- Diagnostic, such as
  - Laboratory analyzers
  - Radiology equipment
  - Endoscopes
- Patient support, such as
  - Patient beds
  - Specialty beds
  - Lifts

Taken from the *Environment of Care Handbook*

Chapter 5 (page 73) 3rd edition

EC.02.04.01 EP 2
continued

For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital maintains a written inventory of all medical equipment.

CMS Inventory

- Medical Equipment includes
  - Biomedical equipment
  - Radiological equipment
  - Patient beds, stretchers
  - IV infusion equipment
  - Ventilators
  - Laboratory equipment
  - Etc.

Inventory Definitions

- **Medical equipment**—Fixed and portable equipment used for the diagnosis, treatment, monitoring, and direct care of individuals.
- **Life-support equipment**—Any device used for the purpose of sustaining life and whose failure to perform its primary function, when used according to the manufacturer's instructions and clinical protocol, will lead to patient death in the absence of immediate intervention (for example, ventilators, anesthesia machines, heart-lung bypass machines, defibrillators).
- **High-risk equipment**—Any device or components of building utility systems for which there is a risk of serious injury or death to a patient or staff member if the device or component fails. High-risk equipment ***includes*** life support equipment.

Source: Glossary from the *Comprehensive Accreditation Manual for Hospitals*, The Joint Commission.

See also September 2014 *Perspectives*

EC.02.04.01 EP 3

The hospital identifies high-risk medical equipment on the inventory for which there is a risk of serious injury or death to a patient or staff member should the equipment fail.

Note: High-risk medical equipment includes life-support equipment

Examples of High-risk Medical Equipment

- High-risk equipment (**NOT** All-Inclusive)
  - Includes Life Support
    - Heart/lung bypass machine
    - Anesthesia equipment
    - Circulatory Assist Equipment
      - IABP
      - LVAD
    - Ventilations
      - Adult; Infant; MRI-Compatible
  - Other High-risk equipment
    - Defibrillators
    - Robotic surgery devices

Scopes

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EC.02.04.01 EP 4

The hospital identifies the activities and associated frequencies, in writing, for maintenance, inspecting, and testing all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.

Note: The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice.

An example of standards for a medical equipment program is ANSI/AAMI EQ56:2013, Recommended Practice for a Medical Equipment Management Program

EC.02.04.01 EP 5

For hospitals that use Joint Commission for deemed status purposes: The hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations

- Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining be in accordance with manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements

EC.02.04.01 EP 5 *continued*

- Medical laser devices
- Imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)
- New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies

Note: Maintenance history includes any of the following documented evidence:

- *Records provided by the hospital's contractors*
- *Information made public by nationally recognized sources*
- *Records of the hospital's experience over time*

Service Manuals & Instructions

- The organizations should have a permanent file of service manuals, instructions, and procedures provided by the manufacturers, which shall be maintained and accessible. See NFPA 99-1999 7-6.3.1.1 and 9-2.1.8.1
  - *Note: in the event service manuals and instructions are unavailable, the organization is to follow established practices in determining maintenance activities and frequencies.*

EC.02.04.01 EP 6

For hospitals that use Joint Commission for deemed status purposes: A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternative manner that includes the following:

- How the equipment is used, including the seriousness and prevalence of harm during normal use

EC.02.04.01 EP 6 continued

- Likely consequences of failure or malfunction, including seriousness of and prevalence of harm
- Availability of alternative or back-up equipment in the event the equipment fails or malfunctions
- Incident history of identical or similar equipment
- Maintenance requirements of the equipment

(For more information on defining staff qualifications, refer to Standard HR.01.02.01)

EC.02.04.01 EP 7

For hospitals that use Joint Commission for deemed status purposes: The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.

EC.02.04.03

Standard EC.02.04.03

The hospital inspects, tests, and maintains medical equipment

Medical Equipment Testing

- EC.02.04.03 The hospital inspects, tests, and maintains medical equipment
  - EP 1: **For hospitals that do not use Joint Commission accreditation for deemed status purposes:** Before initial use of medical equipment on the inventory the organization performs safety, operational, and functional checks.

Medical Equipment Testing

- EP 1 (continued): **For hospitals that use Joint Commission accreditation for deemed status purposes:** Before initial use **and after major repairs or upgrades** of medical equipment on the medical equipment inventory, the hospital performs safety, operational, and functional checks.

Medical Equipment Testing

- EC.02.04.03 The hospital inspects, tests, and maintains medical equipment
  - EP 2. The hospital inspects, tests, and maintains all ~~life support~~ high-risk equipment. These activities are documented.

Note: High-risk medical equipment includes life support equipment

*Most cited medical equipment management EP in the first 6 months of 2015

Medical Equipment Testing

EP 3: The hospital inspects, tests, and maintains ~~non-life support~~ non-high-risk equipment identified on the medical equipment inventory. These activities are documented.

EP 4: The hospital conducts performance testing of and maintains all sterilizers. These activities are documented.

*2nd and 3rd most cited medical equipment management EPs in the first 6 months of 2015

Medical Equipment Testing

EP 5: The hospital performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented.

*5th most cited medical equipment management EP in the first 6 months of 2015

EP 14: **For hospitals that use Joint Commission accreditation for deemed status purposes:** Qualified hospital staff inspect, test, and calibrate nuclear medicine equipment annually. The dates of these activities are documented.

Equipment Survey Process

Documentation is completed for High-risk, life support and non-high-risk devices on the inventory

- Accuracy of Inventory
  - All High-risk and Life Support equipment must be on the inventory and identified
  - Preventive maintenance frequencies must be clearly defined in writing
- Confirm work done as per scheduled activities
  - Ensure appropriate work is scheduled based on maintenance strategies
  - Evaluate equipment failure and scheduled actions

Survey Process: Staff Interviews

- Department Leader
  - Evaluate the qualifications of the leader
    - Review appropriate documentation
  - Evaluate how the inventory was created
  - If an alternative maintenance program is in use, evaluate the inclusion process
  - Evaluate the Monitoring processes
  - Evaluate the effectiveness of the program
    - What criteria is used to evaluate
    - Evaluate the Completion rate of maintenance activities

Survey Process: Staff Interviews

- Equipment Maintainers
  - Evaluate their understanding of the maintenance process/strategies
  - Evaluate staff knowledge related to the alternative maintenance program
  - Evaluate assignment of maintenance activities
  - Evaluate competencies based on repeat work orders
  - Evaluate work scheduled against completed

Survey Process: Staff Interview

- Users of the Equipment
  - Evaluate equipment reliability
  - Evaluate response time when equipment fails
    - Evaluate emergency response process
  - Evaluate “Culture of Safety”
    - Appropriate training of staff related to equipment use
  - Customer satisfaction with department
- Contract Services
  - Evaluate the process used to ensure contractors use qualified personnel
  - Evaluate reliability of equipment serviced
  - Evaluate integration of the process

Evaluating Program Effectiveness

- The equipment management programs must have written policies & procedures
- Evaluating the program:
  - How is equipment evaluated to ensure no degradation of performance?
    - Consider miscalibration of equipment
    - Consider test equipment calibration confirmation
  - How are equipment-related incidents investigated?
    - Could the malfunction have been avoided?
    - Did the alternative maintenance strategy contribute to the malfunction?
    - How to sequester equipment deemed unsafe?

Evaluating Program Effectiveness

- Is there a performance process to evaluate if modifications to the maintenance strategy are needed?
- Evaluate the accuracy of the inventory
  - High-risk equipment segregated in the inventory?
  - Equipment in an alternative maintenance program segregated?
  - Grouping of like equipment is acceptable
  - Are imaging/radiologic equipment and medical laser devices exempt from the alternative maintenance program?

Equipment Not Found OR In Use

- If a device is not available because it is not found or in use
  - Manage the situation
    - Create policy describing how the device will be looked for
      - How will the users be involved
      - How it impact the users

Equipment Not Found OR In Use

- If the device was looked for “on time” then the PM Completion rate will not be impacted
  - The device must be reconciled
    - Surveyors will be reviewing those “equipment not found” or “in use” for reconciliation
      - Example:
        - Each month 500 activities are scheduled
        - One month 10 devices are “not available”
        - Next month the 500 scheduled devices will be done plus the missed 10 devices

Relocatable Power Taps (RPTs)

- Healthcare Interpretation Task Force (12/2007) stated NFPA 70, NFPA 99 and NFPA 101 all have regulations that control the electrical components and equipment in a patient room. *It appears that it is the intent of these documents to restrict RPT use so that it is not used in conjunction with medical equipment*
- CMS 3/2014:
  - "RPT's are not to be used with medical equipment in patient care areas.
    - This includes critical areas such as operating rooms, recovery areas, intensive care areas, and non-critical patient care areas such as patient rooms, diagnostic areas, exam areas, etc."

Relocatable Power Taps

- RPTs may be used in anesthetizing locations ***if*** they are part of the equipment assembly. See NFPA 99-1999 7-5.1.2.5(2)
- Ceiling drops are acceptable. See NFPA 99-1999 7-5.1.2.5(3)
- RPTs **may** be used for non-patient care equipment such as computers/monitors/printers, and in areas such as waiting rooms, offices, nurse stations, support areas, corridors, etc.
- Precautions needed if RPT's are used include:
  - ensuring they are never "daisy-chained"
  - preventing cords from becoming tripping hazards
  - installing internal ground fault and over-current protection devices
  - using power strips that are adequate for the number and types of devices used

S&C: 14-46-LSC 9/26/2014

- CMS is permitting a categorical waiver to allow for the use of power strips in existing and new health care facility patient care areas, if you are in compliance with all applicable 2012 LSC power strip requirements and with all other 2000 LSC electrical system and equipment provisions.
- The organization must follow all requirements of the categorical waiver process
  - This includes identifying where they are located at the unit level

Categorical Waiver Process

If the organization decides to use this categorical waiver they must

1. Ensure full compliance with the appropriate code reference
2. Document the decision to adopt the categorical waiver
   - The Relocatable Power Tap is not a LSC issue but an Environment of Care issue
     - For Environment of Care items document by Minutes in discussion at the Environment of Care Committee (or equivalent)
3. Declare the decision at the beginning of any survey

See also November 2013 *Perspectives*

Requirements

- Power strips may be used in a patient care vicinity to power rack-, table-, pedestal-or cart-mounted patient care-related electrical equipment assemblies, provided *all* of the following conditions are met, as required by section 10.2.3.6:
  - The receptacles are permanently attached to the equipment assembly.
  - The sum of the ampacity of all appliances connected to the receptacles shall not exceed 75 percent of the ampacity of the flexible cord supplying the receptacles.
  - The ampacity of the flexible cord is suitable in accordance with the current edition of NFPA 70, National Electric Code.
  - The electrical and mechanical integrity of the assembly is regularly verified and documented through an ongoing maintenance program.
  - Means are employed to ensure that additional devices or nonmedical equipment cannot be connected to the multiple outlet extension cord after leakage currents have been verified as safe.

Requirements

- Patient bed locations in new health care facilities, or in existing facilities that undergo renovation or a change in occupancy, shall be provided with the minimum number of receptacles as required by section 6.3.2.2.6.2.
- Power strips providing power to rack-, table-, pedestal-, or cart-mounted patient care-related electrical equipment assemblies are **not** required to be an integral component of manufacturer tested equipment. Power strips may be permanently attached to mounted equipment assemblies by personnel who are qualified to ensure compliance with section 10.2.3.6.

Requirements

- Power strips may ***not*** be used in a patient care vicinity to power non-patient care-related electrical equipment (e.g., personal electronics).
- Power strips ***may*** be used outside of the patient care vicinity for both patient care-related electrical equipment & non-patient-care-related electrical equipment.
- Power strips providing power to patient care-related electrical equipment must be Special-Purpose Relocatable Power Taps (SPRPT) listed as UL 1363A or UL 60601-1.
- Power strips providing power to non- patient-care-related electrical equipment must be Relocatable Power Taps (RPT) listed as UL 1363.

NEMA XR-29-2013

Standard Attributes on CT Equipment Related to

Dose Optimization and Management

NEMA XR-29-2013

Standard Attributes on CT Equipment Related to Dose Optimization and Management

Background: 4/1/2014 H.R. 4302 “Protecting Access to Medicare Act of 2014 (PAMA) signed into law

- Included provisions of XR-29
- Applicable to outpatient imaging
- Has financial penalty associated with performing CT exams on noncompliant scanners starting 1/1/2016 (technical component)

NEMA XR-29-2013

Identifies common CT system factors that focus on radiation dose optimization

- DICOM RDSR (Radiation Dose Structured Report)
- CT Dose Check (NEMA XR-25)
- Automatic Exposure Control
- Reference Pediatric and Adult Protocols

NEMA XR-29-2013

- RDSR
  - Structured report encoded in DICOM
  - Structured data is recoverable
  - Incorporates most study information including CTDI and DLP (used to estimate radiation dose)
- Reference Pediatric and Adult Protocols
  - Protocols pre-loaded on a CT system that may be selected at the operator's discretion
- CT Dose Check (NEMA XR 25-2010)
  - If estimated dose index exceeds established thresholds, operator is notified prior to beginning scan
- Automatic Exposure Control
  - Adjust radiation output based on patient size, shape, composition

NEMA XR-29-2013

Joint Commission revised requirements for diagnostic imaging services do **not** reference NEMA XR-29

HOWEVER…..

Verbiage in H.R. 4302 states: Secretary shall require information be provided and attested to by a supplier and hospital out-patient that CT meets the attributes of XR 29. The claim shall be verified as part of periodic accreditation of suppliers (*e.g. JC, ACR, IAC, etc.*)

NEMA XR-29-2013

- Estimated that 1/3 of OP CT scanners will need to replaced.
- In general these are systems over 10 years old
- Organizations will need to evaluate
  - Upgrade vs replace
  - Financial impact ($ loss vs upgrade/replace $)
    - 5% payment loss 2016, 15% in 2017 ….
  - Move scanners (or patients) around in system
- Manufacturer's can help determining compliance with standard (info on websites)

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Questions and discussion

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