

CMS Revised Equipment Maintenance Requirements – An Update

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Introduction

- The Centers for Medicare and Medicaid Services (CMS) issued on December 2, 2011, a revision of the Appendix A of the State Operations Manual (SOM) through a memorandum (S&C: 12-07-Hospital) to State Survey Agencies.
- This memo's subject line is "Clarification of Hospital Equipment Maintenance Requirements"
- This is thus known as "CMS Clarification," "S&C 12-07," or "CMS equipment maintenance mandate"
- A copy of this document can be found at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter1207.pdf>

Historical Background

- Regulatory background
- Discrepancy background
- The prelude
- CMS-TJC discussion
- The second prelude

Regulatory Background

- In 1935, President Franklin D. Roosevelt signed into law the Social Security Act
- In 1965, President Lyndon B. Johnson signed the Social Security Amendments that created the Medicare and Medicaid programs
 - This law has a provision that states [hospitals accredited by JCAH is "deemed" to be in compliance with most of the Medicare Conditions of Participation for Hospitals](#) and, thus, able to participate in the Medicare and Medicaid programs.
 - Medicare => Social Security Administration (SSA)
 - Medicaid => Social and Rehabilitative Service Administration (SRS)
- In 1977, the Health Care Financing Administration (HCFA) was created to manage both Medicare and Medicaid programs
 - In 2001, HCFA was renamed as CMS

Regulatory Background

- In 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008
 - MIPPA revoked the unique deeming authority of the Joint Commission and placing all accreditation organizations (AOs) under the Secretary (i.e., HHS or, effectively, CMS)
- In 2009, CMS approved the continuation of deeming authority for The Joint Commission
- In other words, TJC (and AOA) was independent from HCFA/CMS from 1965 to 2008 (i.e., 43 years) and, thus, was able to evolve its accreditation standards without consultation with CMS

Discrepancy Background

- The Social Security Amendments of 1965 (that created Medicare & Medicaid programs) also established the minimum requirements for healthcare organizations to participate in those programs, known as “**Conditions of Participation**” (CoP)
- The relevant CoP for equipment maintenance is codified in 42CFR482.41(c)(2), which states:

Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

- This sentence is interpreted in different ways by CMS and some AOs until 2008

Discrepancy Background – CMS Interpretation

- Until December 2011, CMS interpretation of the CoP, known as “Interpretive Guidelines” (IGs) is found in the “Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals” of the State Operations Manual (SOM)
 - Used by state agencies for surveys on behalf of CMS
- The medical equipment maintenance IG:
 - **A-0724** ... There must be a regular periodical maintenance and testing program for medical devices and equipment. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person must **monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer’s recommendations** and Federal and State laws and regulations. Equipment maintenance may be conducted using hospital staff, contracts, or through a combination of hospital staff and contracted services.

Discrepancy Background – AOA Interpretation

- 11.08.06 Medical Equipment and Systems - Maintenance (Biomedical):
 - There is an established, scheduled preventive maintenance program for equipment relating directly or indirectly to patient care and building conditions. All biomedical equipment shall be **maintained and tested periodically in accordance with the manufacturer's recommendations.**
- Scoring Procedure
 - DOCUMENT REVIEW: Review records and/or equipment for evidence of routine inspections and documentation of the hospital's biomedical preventive maintenance program. Are inspections conducted in a timely manner? Are past-due inspections common or rare?
 - INTERVIEW: Can the staff recognize whether the equipment they are using has been inspected or is due for inspection? Is the preventive maintenance process one that alerts the staff to potentially unsafe equipment?

Discrepancy Background – DNV Interpretation

- Interpretive Guidelines:

- There must be a regular periodic maintenance and testing program for medical devices. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person must monitor, test, calibrate and maintain the equipment periodically **in accordance with the manufacturer's recommendations and Federal and State laws and regulations**. Equipment maintenance may be conducted using hospital staff, contracts, or through a combination of hospital staff and contracted services.

- Surveyor Guidance:

- Review and validate that there is a process in place to address the repair/periodical maintenance program for equipment.
- Review and validate, through a document sampling, that a clinical or biomedical engineer routinely checks medical devices and equipment.
- Review and verify that the hospital maintains maintenance logs for significant medical equipment (e.g. cardiac monitors, IV infusion pumps, ventilators).
- Interview the person in charge of medical equipment and determine if there is an adequate repair/periodical maintenance program.
- Verify that all medical devices and equipments are routinely checked by a clinical or biomedical engineer.
- Review maintenance logs for significant medical equipment (e.g., cardiac monitors, IV infusion pumps, ventilators, etc.)

Discrepancy Background – TJC Interpretation

- Mostly EOC Standards
 - EC.02.04.01 The hospital manages medical equipment risks.
 - EC.02.04.03 The hospital inspects, tests, and maintains medical equipment.
 - EC.04.01.01 The hospital collects information to monitor conditions in the environment.
 - EC.04.01.03 The hospital analyzes identified environment of care issues.
 - EC.04.01.05 The hospital improves its environment of care.
 - Many other standards outside of the EOC chapter
- Primary differences from CMS IGs
 - **Maintenance strategy (aka equipment inventory):** all equipment or selected equipment based on “physical risk associated with use (including all life support equipment) and equipment incident history” and segregated into life support and non-life support equipment
 - **Maintenance procedure:** “The hospital identifies the activities, in writing, for maintaining, inspecting, and testing for all medical equipment on the inventory.”
 - **Maintenance frequency:** “The hospital identifies, in writing, frequencies for inspecting, testing, and maintaining medical equipment on the inventory based on criteria **such as manufacturers’ recommendations, risk levels, or current hospital experience.**”

The Prelude

- In 2006, the second “Gang of Six” => TJC official => CMS (private, confidential conversation). The TJC official said “**let sleeping dogs lie.**”
- In 2006, an Indiana hospital obtained **waiver** from that state. Subsequently, numerous Indiana hospitals obtained the same waiver.
- Between 2007-2009, a hospital system received some citations from state surveyors (but not Indiana) after successfully passing TJC surveys. A person from this system called CMS and CMS officials were surprised to learn that there is a “**discrepancy.**”



CMS-TJC discussion

- Early 2010, CMS => TJC: follow the CoP (42CFR482.41(c)(2))
- Instead, TJC explained EOC standards to CMS
- In October 2010, CMS Deputy Director => TJC “I am happy to inform you that the Joint Commission’s approach of utilizing a preventive maintenance schedule has been approved.”
- DNV received similar communication later allowing it to continue using the NIAHO standards.

Second Prelude

- Early 2011, an “expert” referenced by TJC was contacted by a CMS staffer who “is developing surveyor guidance for ‘**evidence-based**’ maintenance at Medicare/Medicaid participating facilities” and asked for assistance.
- The “expert” suggested two additional “volunteers” and, together, they provided to CMS numerous published articles, internal documents, suggestions, etc. via email and telephone calls until May .
- Sometime around November, CMS sent a draft of the S&C 12-07 to AHA for comments but **did not receive any feedback**.
- On December 2, 2011, CMS issued the S&C 12-07.

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The 2011 Revision (S&C 12-07)

- Summary
- Improvements
- Challenges
 - Critical equipment
 - Test & measurement equipment & software
 - Equipment maintenance history
 - Additional labor requirements
 - Lack of OEM recommendations
 - Diversion from user assistance
 - Diversion from medical device integration

S&C 12-07 Summary

- This summary was provided by CMS in its 12/2/2011 memo:
 - **Alternate equipment maintenance schedules permitted in some instances:** Hospitals may adjust maintenance, inspection, and testing frequencies for some facility and medical equipment below those recommended by the manufacturer, based on an assessment by qualified personnel of the risk to patient and staff health and safety.
 - Manufacturer-recommended maintenance frequency is required for:
 1. All equipment critical to patient health and safety; and
 2. Any new equipment until a sufficient amount of maintenance history has been acquired.
 - **Alternative equipment maintenance methods are not permitted:** Hospitals must continue to follow the manufacturer's recommended techniques for maintaining equipment, even if the hospitals alter the frequency of maintenance

Improvements Introduced by S&C 12-07

- Maintenance frequency no longer determined by OEM recommendation but
 - Only for non-critical equipment
 - Only when there is **evidence-based assessment** based on maintenance history
- “Corrective,” “Reactive Maintenance” or “Run to Failure” maintenance strategy is acceptable based on the example provided.
 - “Scenario #3 - In this case, the car owner drives an inexpensive car, does not want to take the time for maintenance, and does not care if lack of maintenance means having to replace the car sooner rather than later. Based on this particular owner’s atypical priorities, a “Reactive Maintenance” strategy could be used, i.e., the owner would run the car without changing the oil until it breaks down.”

Critical Equipment

- CMS did not provide a definition but characterized it as

At a minimum such critical equipment includes, but is not limited to, life-support devices, key resuscitation devices, critical monitoring devices, equipment used for radiologic imaging, and other devices whose failure may result in serious injury or death of patients or staff.

- This suggests that these devices should be considered critical and, thus, maintained per OEM recommendation (both frequency and procedure):
 - Life support equipment
 - Defibrillator, suction pump, Ambu bag, etc.
 - Monitoring systems in ICU, surgery, and other critical areas, including physiological monitors, pulse oximeters, etc.
 - Radiological imaging equipment

See a proposed definition in 24x7 Soapbox of Aug 2012

Test & Measurement Equipment & Software

- Proprietary or specific brands and models of test and measurement equipment in some maintenance recommendations
- Proprietary software claimed as the only way to test, measure, and calibrate certain equipment
- Total cost of additional test & measurement equipment & software: ~\$250,000 per hospital => **~\$1-3 billion for all healthcare organizations**

Equipment Maintenance History

- CMS: maintenance frequency can only be reduced by qualified personnel after assessing a sufficient amount of maintenance history.
- Challenge for small inventories:
 - Ultrasound machines: 5 units with annual failure rate (FR) of 0.45 => 2-3 repairs/year; thus, 5 years would yield only 10-15 records. By then the machines are likely replaced.
 - Pulse oximeters: 200 units with annual FR of 0.3 => 60 repairs/year; thus one year is sufficient for meaningful statistical analyses, if these have been standardized for the same brand/model.

Lack of OEM recommendations

- No legal requirement for OEMs to provide service manuals*.
- Some OEMs refuse to sell SM or replacement parts.
- Some state equipment must be returned to the OEM regularly for “inspection, preventive maintenance, and factory calibration”
 - A dermatome manufacturer recently issued a “Safety Advisory” stating “improperly maintained [redacted] are causing [redacted] injuries.”
- Per hospital cost >\$100,000/year for additional service contracts and T&M services => **>\$800M/year for the nation.**

* FDA only requires AIAT (assembly, installation, adjustment & testing) information for radiation-emitting devices

Diversion from user assistance

- FDA and TJC equipment related incident data* => negligible amount of incidents due to maintenance omissions (estimated at .00011-.0006 per million equipment uses).
- Majority of incidents are caused by human factors and other clinical issues => CE professionals have redirected their attention from SM to CE management activities such as:
 - Equipment planning, purchasing and replacement (required by TJC standards)
 - Technical training of clinical users
 - Assistance to material management (accessories and consumables), risk management (incident investigation and RCA), emergency management (planning, preparation, drills), etc.

* Bruley, 1998; Wang et al., 2012

Diversion from medical device integration

- The Health Information Technology for Economic and Clinical Health Act (HITECH) provides federal incentives for adoption of electronic health records (EHR).
- CMS manages the Medicare and Medicaid EHR incentive programs.
- Hospitals and clinics aggressively integrating medical devices into EHR to meet the “meaningful use” requirements => assistance and cooperation of CE professionals.
- Anecdotal studies show ~5-20% of CE staff time spent on “CE-IT” integration.

CMS-TJC Meeting

- George Mills, TJC Director of Engineering, met with CMS officials on 4/9/2012, with data and documents provided by the “Monday Ad-hoc Group” & ECRI Institute’s survey
- The discussion was “collegial and productive”
- Two clarifications were obtained:
 - No need to use specific test & measurement equipment or software specified by OEM in its maintenance recommendations
 - Equipment maintenance history from other similar facilities can be used for maintenance frequency assessments
- CMS: further research & data needed to validate TJC current practice of allowing hospitals to establish their own maintenance strategies, procedures and frequencies.

DNV Announcement

- DNV Healthcare announced in June 2012

DNV has suspended its equipment maintenance program and standards that are impacted by CMS 12-07- Clarification of Hospital Equipment Maintenance Requirements. DNV will reinstitute its previous equipment maintenance program and standards effective for all surveys beginning on or after May 1, 2012.

On March 12, 2012 CMS approved DNV program adjustments effective January 15, 2012 to reflect the policy concerning equipment maintenance as put forth in S&C 12-07. Due to feedback from the field, DNV requested a moratorium from CMS on April 13, 2012 on enactment of S&C 12-07. CMS approved the DNV request on April 18, 2012 to reinstitute our previous equipment maintenance program and standards until such time as CMS reviews whether additional clarification of its S&C 12-07 is needed.

CMS-AAMI & ASHE Meeting

- AAMI and ASHE representatives met CMS on June 28
- The meeting was “cordial and productive.”
- CMS officials were “surprised by the field’s response to the December 2011 Clarification, because they thought they were giving us more opportunity to optimize our programs than we had previously.”
- AAMI and ASHE committed “to collect and provide more information that CMS believes will be meaningful to them. It is our understanding from the meeting that **CMS wants an evidence-based standard, something national in scope, so that their surveyors can use an objective, scientifically sound approach to assess whether a healthcare organization’s preventive maintenance program meets some minimum performance standards, based on sound risk assessment.**”

AAMI & ASHE Response₁

- AAMI and ASHE provide a packet (244 pages) to CMS on July 17, 2012:
 - Executive summary
 - Analysis, with information on financial impact, different treatment of life-support versus non-life support equipment, methodologies for frequency changes, maintenance strategy selection, evidence-based maintenance examples, fail-safe features, etc.
 - 15 exhibits, including
 - Sample OEM maintenance recommendations
 - Sample ASHE and ECRI Institute maintenance procedures
 - Sample maintenance frequency change policy and decision flowchart
 - AAMI 2009 Medical Equipment Management Manual (R. Stiefel)
 - AAMI EQ 56:1999 Recommended Practice for a Medical Equipment Management Program
 - Sample Risk Assessment models
 - AAMI new standard Work Item Proposal with outline

Packet available at <http://www.aami.org/cmsspacket.pdf>

AAMI & ASHE Response₂

- The AAMI and ASHE executive summary states:
 - “... the enclosed evidence that current maintenance processes are at least as effective as manufacturer recommendations...”
 - “While there is variation among the programs currently being used, two basic elements are evident: [equipment risk analysis](#) and [EBM strategies](#).”
 - and the [new standard Work Item Proposal](#) “will address the development of acceptable methods of variation for inspection intervals and procedures. Additionally, it will offer a standardized approach for assessing equipment risk in the facilities, requiring input from the clinical users and risk management teams.”

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Where Are We Now?

- DNV: reinstated its prior program with CMS permission.
- TJC: not (yet) revising EOC standards.
- AOA: no announcements.
- CMS officials told AAMI & ASHE representatives that while it has not asked the AOs to revise their standards, **the state agencies are still required to follow S&C 12-07.**
- In addition, CMS officials believe **all deviations from S&C 12-07 should cited but that does not mean corrective actions are required.**

Discussion & Conclusions

- The “Truth”: CMS is correct, there is not a consistent, verifiable process in most CE departments:
 - The “risk-based criteria” is actually a “severity” criteria.
 - The combination of device design improvements, excessive SM, user resilience, etc. explains the low incident rate.
- Let’s take this as a (very loud and clear) wake up call and work together to find a common solution that helps CMS, AOs, hospitals, CE professionals and, above all, the patients!

Risk versus Maintenance

$$\text{risk} = \text{probability} * \text{severity}$$

considering James Reason's Swiss cheese model, the equation becomes

$$\text{risk} = \left(\prod_i P_i \right) * \text{severity}$$

where P_i denotes individual "cheese slice" probability.

In other words, CE's job is to minimize P_{maint} ("direct") and contribute to minimization of other P_i s ("indirect" and "future")

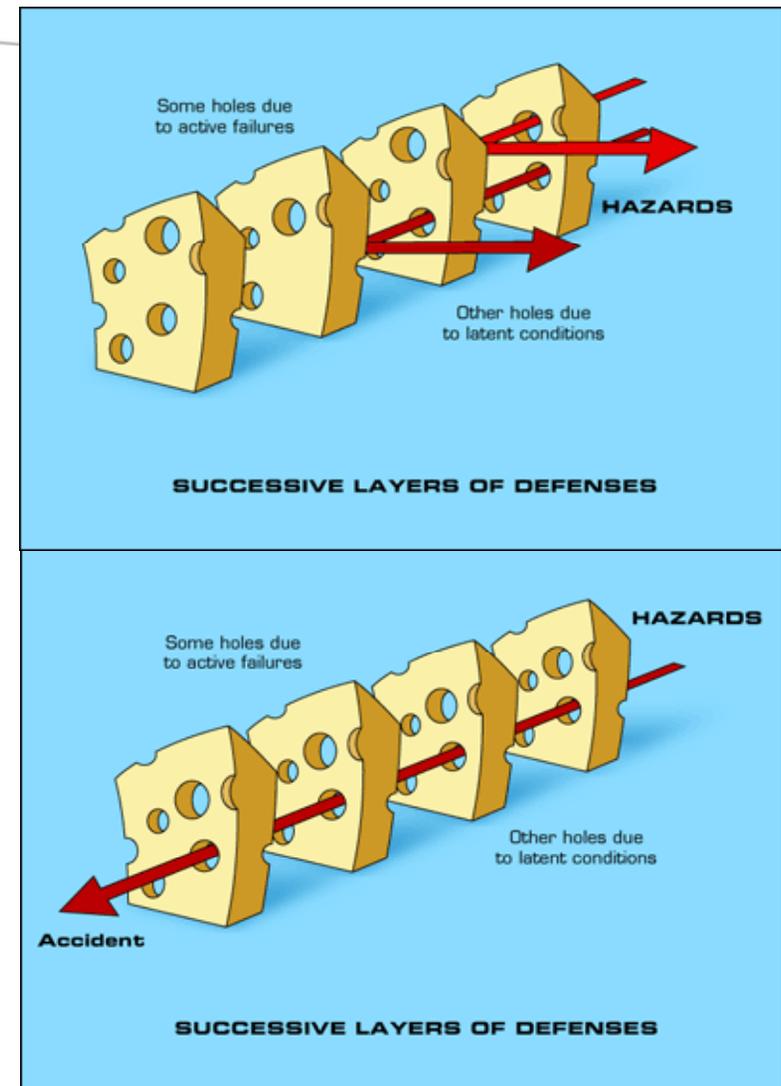


Figure adapted from Reason (2000), Duke Univ. MC
patientsafetyed.duhs.duke.edu/module_e/swiss_cheese.html

What needs to be done?

- Find a **long-term** solution acceptable to all stakeholders
 - Evidence-based maintenance
- Assist CMS in finding an acceptable **interim solution**
- Plan B, Plan C or **else?**

Evidence-Based Maintenance

- **Evidence-Based Maintenance** is a continual improvement process that analyzes the effectiveness of maintenance resources deployed in comparison to outcomes achieved previously or elsewhere and makes necessary adjustments to maintenance planning and implementation.



Fishing = **Process**



Catching = **Outcome**

Evidence-Based Maintenance

- EBM Objectives:
 - Equipment is safe operating according to its specifications
 - Highest level possible of availability of equipment for clinical users
 - Continuously seek quality improvement and cost reduction
 - Reduce the need of premature replacement of equipment
 - Comply with applicable regulations, codes and standards
 - Reduce unnecessary and repetitive workload
 - Refocus attention to areas where clinical user needs and expectations are higher
- EBM Scope:
 - **Maintenance strategy** (aka inventory criteria): what maintenance (PM, SPI, repair, replace) should be done for each type (or piece) of equipment?
 - **Maintenance procedure**: which tasks (replacement, tests, calibration, etc.) should be performed?
 - **Maintenance frequency**: how often each task should be performed?

Evidence-Based Maintenance

- EBM Elements

- **Maintenance Planning & Implementation:** Selecting and implementing appropriate maintenance strategy, procedure, and frequency for each type, group or piece of equipment using basic sets of knowledge, i.e.:

- engineering principles
- technical education and training
- hospital maintenance experience
- industry-wide experience, and
- OEM recommendations

- **Maintenance Monitoring:** Verifying that the Plan is implemented properly by monitoring the accuracy and completion rates, as well it effectiveness by measuring

- Downtime for mission-critical equipment
- Failure rate for non-mission critical equipment
- Amount of equipment-maintenance related patient incidents
- Statistics of failure root causes

Evidence-Based Maintenance

- EBM Elements (cont.)
 - **Maintenance Improvement:** Reviewing monitoring data, as well as data shared by other similar organizations (benchmarking) and other stakeholder input, to determine opportunities for improvement such as:
 - Change in maintenance strategy, procedure and/or frequency
 - Replacement of unsafe or unreliable equipment
 - Standardization of equipment
 - Strengthen user training & assistance
 - More interaction with other non-clinical support departments (e.g., facility management, material management, and information technology)

In the meanwhile...



Interim solution

- Unfortunately, a standard like what was outlined will take at least 2-3 years to develop. In the meanwhile, one has to explain to their senior leadership why his/her program was cited by state surveyors while passing AO surveys, thus putting ~47% the hospital's revenue in jeopardy
- Possible interim solutions
 - Waiver for those accredited by AOs and follow AO standards
 - Waivers for those who follow ASHE or ECRI Institute's recommended procedures and frequencies
 - Waivers for those who have performed evidence-based assessment on maintenance frequency and/or procedure
 - Individual waivers from CMS or state agencies
 - Other better ideas?

THANK YOU!

- Please contact me if you have any questions or suggestions

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Questions and Answers

