Proposed CMS Requirements to Follow OEM Guideline for Medical Equipment Maintenance

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Authorized Copy For ACCE Members

Understanding the Impact of the New CMS Maintenance Rule

- This session will provide you with background and an update on the December, 2011, announcement from the U.S. Centers for Medicare and Medicaid Services (CMS) regarding manufacturer-recommended maintenance frequencies and procedures, and how these requirements will impact your work.
- The announcement created an instant stir in the healthcare technology management community because it indicates that biomeds and clinical engineers can adjust PM schedules
  - *only* for non-critical equipment and
  - *only* as a result of an evidence-based assessment that shows "the frequency adjustment will not adversely affect patient or staff health and safety."
- In addition, all equipment, without exception, must be maintained according to manufacturer recommendations

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Dec 2011 Revision of Interpretive Guidelines

- 42CFR482.41(c)(2) Conditions of Participation

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

- On December 2, 2011 the Centers for Medicare and Medicaid Services (CMS) issued
  - a clarification of hospital equipment maintenance requirements (S&C: 12-07-Hospital)
  - a revision of its Interpretative Guidelines (IGs) contained in the CMS State Operations Provider Certification manual (pub. 100-07)

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- Maintenance Schedules
  - manufacturer–recommended maintenance frequencies are required for
    - all equipment *critical* to patient health and safety
    - any new equipment until a sufficient amount of maintenance history has been acquired
  - hospitals may adjust maintenance, inspection, and testing frequencies for some [*non-critical*] 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

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- Maintenance Methods
  - 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 activities

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Volunteer Group of Industry Experts Formed to Address Common Concerns about new CMS Guidelines

Binseng Wang, Aramark
Tim Ritter, ECRI Institute
Matt Baretich, Baretich Engr
George Mills, Joint Commission
John Collins, ASHE
Britt Berek,
Steve Grimes, ABM Health
Paul Sherman, Veterans Admin
Malcolm Ridgway, Aramark
Chris Nowak, UHS
Patrick Bernat, AAMI
Mario Castaneda, ACCE
Mark Newell, Trinity Health.
Randy Snelling, DNV
Carol Davis-Smith, Kaiser Perm
Barbara Maguire, ISS
Bob Stiefel , RHS BME Consulting
Jonathan Gaev, ECRI Institute
Dale Woodin, ASHE
Karen Waninger,
Mary Logan, AAMI

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Responses Since Dec 2011

- Volunteer Group
  - met regularly (weekly) since issuance of guidelines to articulate a response and develop a strategy
  - conducted industry surveys and collected evidence to be shared with CMS in hope that the guidelines would be modified
  - worked on a definition of critical equipment that is reasonable and simple enough to be used to identify a limited number of equipment categories on which CMS might reasonably expect to require scheduled maintenance
  - prepared representatives of The Joint Commission, AAMI and ASHE for meetings with CMS representatives

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Common Concerns about New CMS Guidelines

- Contrary to Widely Followed Risk Based Approach
  - TJC & DNV had adopted a more flexible, outcome based maintenance approach which had previously received the blessings from CMS
  - the more flexible risk-based approach has been widely adopted by hospitals
- Costs vs Benefit
  - new CMS guidelines appear to have potential for *substantially increasing costs* by requiring what is likely to be substantial additional maintenance, but
  - available evidence suggests that additional maintenance requirements *would not contribute to safety or quality of care*
- Poor use of already limited resources
  - hospitals already challenged with limited resources and the challenges of dealing with consequences of increasingly complex technologies and systems of systems
  - focusing limited resources on maintenance with unsubstantiated benefits takes resources from some known issues we should be dealing with

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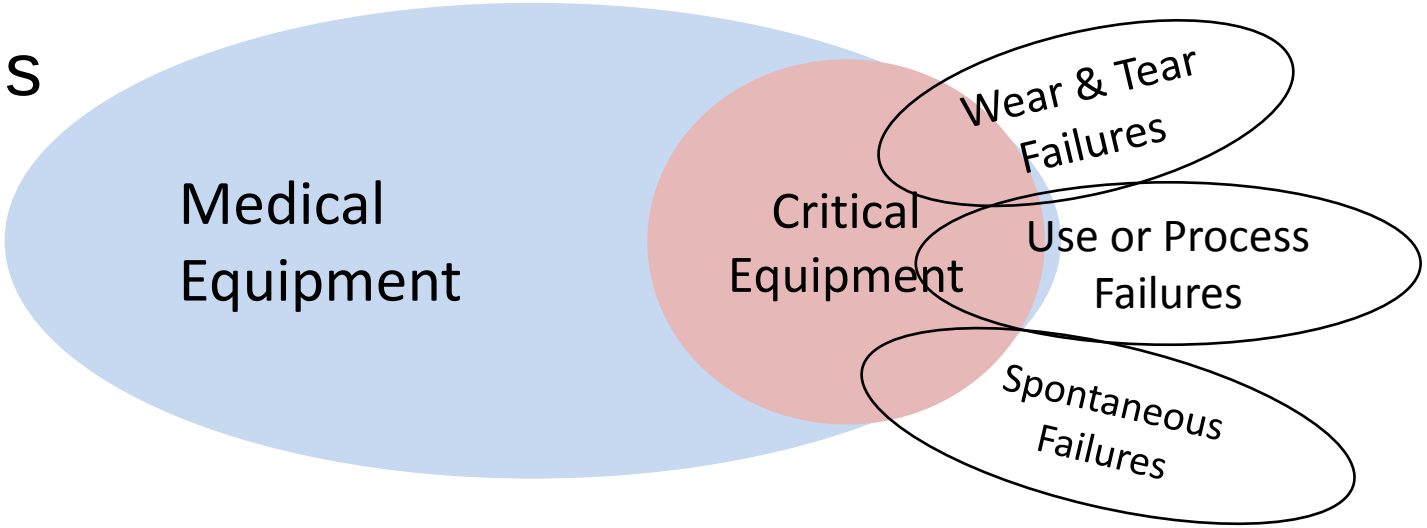
Definitions



What makes equipment "critical" from a *safety* or *quality of care* view?

- ✓ Failure could *reasonably* cause death or serious injury
- ✓ Failure or *misuse* could *reasonably* cause death or serious injury
- ✓ Failure or misuse *under normal operating conditions* could *reasonably* cause death or serious injury

What equipment failures can be mitigated from

- ✓ Scheduled maintenance?
- ✓ User training or "re-engineered" processes?
- ✓ Backups (alternates) or replacement?

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Responses Since Dec 2011

- April 2012 Meeting with CMS representatives
  George Mills (Dir of Engineering for **The Joint Commission**)
  - suggested a moratorium (unsuccessfully) on new guidelines until additional information could be considered
  - explained how new guidelines placed additional resource and financial burden on providers without considering any evidence of real benefits
  - explained trend has been for medical technologies (particularly critical systems) to self test reducing (or in some cases eliminating) benefit from routine maintenance
  - Mills presented letters of support from major CE industry representatives and extensive service history analyses demonstrating that safety not compromised when risk based approach to scheduled maintenance is applied.

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Responses Since Dec 2011

- June 2012 Meeting with CMS representatives
  AAMI (*Karen Wininger, Bob Stiefel, Patrick Bernat, Mary Logan*) and
  ASHE (*Dale Woodin*)
  - CMS admitted to being surprised by industry's negative reaction to their new guidelines
  - CMS requested more meaningful data that would
    - ✓ provide justification for a change in their Dec 2011 guidelines and
    - ✓ allow them to move toward a practical standard that would accommodate evidence-based adjustments to maintenance intervals
  - AAMI/ASHE committed to compile and supply CMS with published articles, guidance documents, and other resources (www.aami.org/cmspacket.pdf) that detailed
    - ✓ algorithms and practices used to determine methodologies & frequencies
    - ✓ maintenance guidelines currently in use
    - ✓ examples of evidence based maintenance programs
    - ✓ typical service trends for equipment categories
    - ✓ estimates of impact of CMS December 2011 guidance on the industry

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Subject to CMS Review of Material Provided by TJC, AAMI, ASHE and a Revision to the December 2011 Guidelines

- CMS continues to allow TJC and DNV to accept a risk based approach toward scheduled maintenance
- Providers should begin process of analyzing and documenting aspects of their medical equipment maintenance programs that are not strictly in compliance with new CMS guideline and administration should be advised.
- Providers who may undergo a state-implemented validation survey should be prepared to justify (based on "*an assessment by qualified personnel*") why any equipment not be maintained according to manufacturer's interval is not "*critical to patient health or safety*"
- Validation survey findings that indicate a provider is not in compliance with new guidelines could result in citations … but CMS notes that not all citations require immediate correction (i.e., guidelines may be changed before correction is required) AND waivers can be granted for situations that could create a financial hardship

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- Because TJC and DNV are not changing their current requirements (and the likelihood that of a provider being subjected to an validation survey is small), most providers are unlikely to make changed to their current maintenance programs until a more definitive strategy is developed

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