




Training presentation for:  
2015 Midwest Healthcare Engineering Conf.


## CMS / TJC Alternate Equipment Management / Maintenance (AEM) Program Compliance



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**Major topics** *(high level overview of full-day course)* 



- CMS rules
- CMS interpretive guidelines
- TJC requirements to align w/ CMS
- The ASHE book
- Action plans for compliance

- *Inventory & AEM-related changes apply to both utility systems and medical equipment.*
- *Focuses on impacts to **utility systems management processes.***
- *Clarifications to date*

## Content Disclaimer



- These slides are only meant to be cue points, which were expounded upon verbally by the original presenter and are not meant to be comprehensive statements of requirements or best practices, nor represent all the content of the presentation. Thus, care should be exercised in interpreting content based solely on the content of these slides.

## CMS S&C Letter

### S&C:14-07-Hospital



- “Hospital Equipment Maintenance Requirements” dated 12/20/2013
- Introduces Alternate Equipment Management (AEM) Program for those hospitals that intend to deviate from simply following manufacturer’s activity & frequency recommendations.
- 11 pages of detailed guidance to state surveyors in *Appendix A interpretive guidelines*
- <http://tinyurl.com/CMS-AEM-PDF>
- <http://www.ssr-inc.com/pressroom/cms-changes-hospital-equipment-maintenance-requirements/>



### CMS: Equipment Inventory



- Complete inventory of equipment required to meet patient needs
  - regardless of ownership
  - *regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program*
- Must identify critical equipment
- Must identify AEM equipment

### TJC: Equipment Inventory



- Written inventory of all operating components of utility systems
- Must identify high-risk operating components
- Must identify AEM operating components

## CMS “Critical Equipment”



- Biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail”

CMS S&C Letter 14-07-Hospital  
from Appendix A – interpretive guidelines

## TJC “*High-risk Equipment*”



- Includes all life support equipment
- More than life support
- TJC term *high-risk equipment* “is equivalent in scope and nature to the CMS term *critical equipment*.”  
– TJC 9/2014 EC News
- TJC 2/3/2015 webinar and July 2015 ASHE session provided some more guidance.

## CMS: Manufacturer recommendations



“Hospitals comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. Hospitals may choose to perform maintenance *more frequently* than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer’s recommendations, the hospital must maintain documentation of those recommendations and the hospital’s associated maintenance activity for the affected equipment.”

## Summary of

## S&C: 14-07-Hospital



- May adjust ITM frequency/activities from manufacturer recs, based on a risk-based assessment by qualified personnel, **unless**:
  - Other Federal or state law; or hospital CoPs require adherence to manufacturer’s recommendations and/or set specific requirements. For example, all imaging/radiologic equipment must be maintained per manufacturer’s recommendations; or
  - The equipment is a medical laser device; or
  - New equipment without a sufficient amount of maintenance history has been acquired.

### Other CoPs: Manuf's recommendations



- “Other CoPs require adherence to manufacturer’s recommendations and/or set specific standards. For example:

The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 482.41(b) has some provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys.”

### Summary of

### S&C: 14-07-Hospital



- Must develop policies and procedures and maintain documentation supporting their Alternate Equipment Management (AEM) program
- Must adhere strictly to the AEM activities and/or frequencies established

## AEM Program



- Under certain conditions
- When activities and frequencies differ from those recommended by mfr
- Must develop, implement, and maintain a documented AEM program to minimize risks to patients and others
- AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance.


## “Generally accepted standards of practice”



- Physical plant equipment example
  - ASHE 2009 document: *Maintenance Management for Health Care Facilities* ([Reprinted in 2014](#))
- Medical equipment example
  - ANSI/AAMI EQ 56:1999/(R) 2008, *Recommended Practice for a Medical Equipment Management Program*
- “There may be similar documents issued by other **nationally recognized organizations which hospitals might choose to reference.**”
- CMS “welcomes identification of other recognized sources of recommendations for facility and equipment maintenance.”

## Some other possible AEM sources?



- ANSI: American National Standards Institute
  - Mechanical: NFPA, ASME, ASHRAE, ICC
  - Plumbing: NFPA, BOCA, ICC
  - Electrical: NFPA, NETA, IEEE
  - General: NFPA, ICC, BOCA
- 
- *Be careful about the statement, re: “nationally recognized organizations”*
    - *What about privately-produced industry handbooks?*
    - *What about service companies & manufacturers’ generic info intended for other equipment?*
    - *What about insurance company publications?*
    - *What about common wisdom / rules of thumb?*

## Other CMS guidance to surveyors



- Identify all critical equipment
  - Surveyor focus: factors/evidence used for AEM
- When not eligible for AEM
- Moving new equipment into AEM
  - “Hospital must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.”



## Evaluating AEM Safety/Effectiveness



- Must have PPPs: address effectiveness
  - Identify equipment malfunction incidents
  - Investigate equip. malfunction incidents
    - Could have been prevented?
    - Steps taken to prevent future failures?
    - Did AEM lead to malfunction?
  - Using performance data to determine if AEM changes are required

## CMS Guidance: Equipment



- Provisions to ensure availability & reliability
- Inspect & test for performance & safety before initial use; after *major repairs & upgrades*
- PPPs, inventories, activities, schedules fall under qualified personnel

### CMS: Interpretive Guidelines §482.41(a)



“... routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer’s recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair.

### CMS: AEM Risk Assessments



- How used; likely consequences of failure or malfunction – hospital-wide or specific setting – how serious – how widespread – health & safety risks
- Available info on Mfr reccs – the Mfr’s rationale
- Maintenance reqmts: simple/complex – compare AEM with Mfr reccs – explain how/why modifying; if not available how do you know what to do?
- Timely availability: alternate devices/backup systems
- Incident histories (internal, external): #, freq, nature of failures – How do you know AEM will not degrade performance?

## TJC: AEM Risk Assessments



- *Qualified individual* must make AEM decision
- Must consider these
  - How equipment/component is used
  - Consequences of failure, seriousness & prevalence of harm
  - Availability of alternative or a backup if component fails/malfunctions
  - Incident history of identical or similar equipment
  - Equipment maintenance requirements

## AEM Frequencies or Activities



- AEM Program: explain/document risk to patient health & safety considered in developing AEM strategies
- May use info from Mfr recommendations and other materials, nationally recognized expert associations, and/or hospital's (or its third party contractor's) own experience, etc.
- Maintenance strategies may be applied to groups or to individual pieces of equipment

**CMS: AEM Program documentation**



- **AEM activities & strategy**; “any other rationale used to determine those activities; the differences from the manufacturer’s recommended maintenance activities are made explicit, unless the hospital is unable to obtain the manufacturer’s maintenance recommendations, due to the age of the equipment or the manufacturer’s restricting the availability of its recommendations”

**CMS: AEM Program documentation**



- **AEM frequencies** if any & strategy  
– “any other rationale used to determine those frequencies....”

### CMS: AEM Program documentation



- *“For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as ‘every 12 – 24 months.’ It could also be acceptable to employ periodic “departmental sweeps” for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.”*

### CMS: AEM Program documentation



- *Date AEM activities performed and, if applicable, further actions required/taken*
- *“Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual...”*
- *“there is no requirement to include operator failures in equipment maintenance documentation”*

### CMS: AEM Program documentation



- “When the hospital has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.”

### CMS: Evaluating AEM safety / effectiveness



- PPPs on AEM Program effectiveness
  - How equipment malfunctions investigated
    - could have been prevented ... steps to prevent more
    - how determination made if it resulted from AEM
  - Process to remove unsafe/unsuitable equip.
  - Using performance data to determine if modifying the AEM program procedures is required
  - Degradation not readily apparent (miscalibration)

## CMS Survey Procedures §482.41(c)(2)



- Supplies maintained, safe, quality, stored per mfr, availability; needed in emergencies
- Failures, problems, inventories, critical IDed, AEM IDed, qualifications incl. maintainers & service orgs
- For mfr-recc PM: sample mostly (but not all) critical equip, mfr reccs available, being followed

## CMS Survey Procedures §482.41(c)(2)



- For AEM: only allowable equip, qualifs for AEM mgt/maintainers, activities/freqs for all, evaluating safety /effectiveness, evidence for aggregation is reasonable?
- AEM Samples: sample majority (but not all) is critical equip, risk/evidence methodology for AEM decisions, explain / info sources, activities/freqs per AEM, evaluating safety/effectiveness, corrections

## CMS Survey Procedures §482.41(c)(2)



- **Interview personnel in charge of facility, supplies and equipment maintenance**
  - Supplies maintained to ensure an acceptable level of safety and quality
  - Supplies stored as recommended by manufacturer
  - Supplies stored ... not to endanger patient safety
  - Identify supplies and equipment that are likely to be needed in emergency situation.
  - Adequate provisions to ensure availability of those supplies and equipment when needed

## CMS Survey Procedures §482.41(c)(2)



- ***Concerning facility & medical equipment***
  - *Determine if the hospital has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for the AEM program (if one is being used by the hospital) as well as for those performing maintenance.*
  - *Determine if the hospital is able to demonstrate how it assures contractors use qualified personnel.*



## CMS Survey Procedures §482.41(c)(2)



- ***If the hospital is following manufacturer equipment maintenance activities and frequencies:***
  - *Records on equipment observed while inspecting locations*
  - *Sample from inventory to determine whether the hospital is following the manufacturer's recommendations*
  - *Critical equipment should make up the sample majority*
  - *For the sample selected, determine if:*
    - *Hospital has mfr's recommendations (e.g., manufacturer's O&M manual, standards, studies, guidance, recall information, service records, etc.)*
    - *Hospital is following mfr's recommendations*

## CMS Survey Procedures §482.41(c)(2)



- ***If a hospital is using an AEM for some equipment***
  - *AEM on equipment not eligible for AEM?*
  - *Development of AEM activities and frequencies (as well as AEM activities) being performed by qualified personnel*
  - *Documented activities and frequencies for all equipment included in the AEM program*
  - *Hospital evaluating safety and effectiveness of the AEM program*
  - *Use of broad interval ranges or departmental "sweeps" – seem reasonable?*

## CMS Survey Procedures §482.41(c)(2)



- Select a sample of equipment in the AEM program.
  - Majority of sample must include critical equipment
- Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?

## CMS Survey Procedures §482.41(c)(2)



- *Describe methodology for applying maintenance strategies and determining AEM activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?*
- *Determine if maintenance is being performed in accordance with the maintenance activities and frequencies defined in the AEM program.*
- *Verify the hospital is evaluating the safety and effectiveness of AEM activities and taking corrective actions when needed.*

## ASHE book – you probably need it



- **Maintenance Inventory Control and Documentation**
- **Maintenance Procedures**
- Other content



## Intent of ASHE book's procedures



- Middle-of-the-road guideline to scheduled maintenance
- *Not intended as industry standards*
- Use as models only to define scope
  - Not for instructions or training
  - Each hospital to develop own procedures
  - Neither procedure content nor frequency considered as a fixed standard
  - Vary as necessary to reflect hospital's environment, staffing, equipment utilization & skill levels.
- Detailed procedures should be obtained from other sources, such as the equipment mfr.

## ASHE book's "Middle of the road approach"



- One major maintenance procedure (inspection, lubrication, calibration or testing for wear) per item, per determined frequency
- Plus minor procedures as required for
  - Reasonable performance
  - Required testing to meet compliance rules



## ASHE book's Inventory Control Concepts



- Environmental Unit (*Area*) Concept
- Functional Unit Concept
- Grouping Concept
  
- Essential equipment – *we will not cover this*
  - A little broader than CMS *critical equipment* and TJC *high-risk equipment*

## ASHE Book: Maintenance Procedures



- **80 procedures with details** ← **Be careful about AEM exclusions**
- Environmental Units #100F +
- Compressors #200F +
- Cooling Systems #300F +
- Electrical Systems #400F +
- Heating Systems #500F +
- Water Systems #600F +
- Central Services #700F +
- Conveyor Systems #800F +
- Dietetic Services #900F +
- Environmental Services #1000F +
- Refrigeration #1100F +

## ASHE Book Environmental Unit Concept



- Space of manageable size with a Maintenance ID# (**Asset #**). Manageable size is defined in terms of either a unit's function, such as an ICU, or time required (such as half floor)
- Hospital divided into environmental units; equipment within environmental unit is considered part of the unit.
  - Extensive list in book; however be careful: rules have changed over the years

## Operating components guidance



- *From ASHE Listserv drop box post*
- Individual listing of outlets, lights, breakers, steam traps, sprinkler heads, etc. unlikely needed to establish an effective utility system inventory and maintenance strategy.
- Effective course of action: establish the room, unit or floor as an inventory asset with a maintenance strategy for a defined scope to inspect all [*devices*] in that location at a defined frequency.
  - ***This sounds very similar to the ASHE book's Environmental Unit concept***

## ASHE book: Limiting the inventory



- Non-critical items incorporated into environmental units
- Entire environmental unit on maintenance schedule
- Cautions: portable units can be missed
- Exclusions: incidents, significant components, more intense schedule, external service company

### ASHE Book Functional Unit Concept



- Controls maintenance inventory of essential equipment
- Consider operating subsystem as one unit
  - Chiller subsystem with condenser, compressor, pumps, valves, controls, etc.
- Always occur together
- Require each other to be functional

### ASHE Book Functional Unit Concept



- Piece of equipment or easily identifiable system with several parts or modules
- Entire system is inspected at one time rather than individual parts being inspected separately
- One maintenance protocol: entire system together instead of individual parts separately
- Documentation is kept on system

## TJC: What's a utility operating component?



- Operating component
  - Performance related
  - Delivers measurable outcome
- Utility system may have components
- Support parts to the components, such as belts and filters, likely not individually listed, although they would likely be part of a PM program
  - Subcomponents
- *[TJC Perspectives & EC News, Sept 2014]*

## More operating components guidance



- *From ASHE Listserv drop box post*
- For complex components such as a chiller, sub-components such as motors and controls may or may not be on the on the inventory, depending on how the maintenance program is set up.
  - **This sounds very much like the ASHE book's *Functional Unit Concept*.**



## ASHE Book Grouping Concept



- Controls *maintenance inventory* of essential equipment
- Large quantities of essential equipment
- All considered together
- One work order; all inspected in one sweep of building





## Tracking and Trending



- Identify high risk components in order to manage them at 100% of maintenance schedule. Cannot defer high risk component maintenance.
- *Maybe track utility PMs like medical equip. PMs?*

EOC Report	Target	J	F	M	A	M	J	J	A	S	O	N	D	J
Critical / High Risk PMs on Time	100%	100	100	100	98	100	100	100						
Non-Critical / Non-High Risk PMs on Time	95% ?	98	97	98	95	96	98	97						
AEM-related failures	0	0	0	1	0	0	0	0						

**CMS Survey Procedures** *[detailed tracers]*  Smith  
Seckman  
Reid, Inc.

- Supplies maintained, safe, quality, stored per mfr, availability; needed in emergencies 
- Failures, problems, inventories, critical IDed, AEM IDed, qualifications including maintainers & service orgs
- For mfr-recc PM: **prove it**, sample mostly (but not all) critical equip, mfr reccs available, being followed
- For AEM: **prove it**, only allowable equip, quals for AEM mgt/maintainers, activities/freqs for all, evaluating safety /effectiveness, evidence for aggregation – reasonable
- AEM Samples: **prove it**, sample majority (but not all) is critical equip, risk/evidence methodology for AEM decisions, explain / info sources, activities/freqs per AEM, evaluating safety/effectiveness, corrections

**So where are changes needed?**   Smith  
Seckman  
Reid, Inc.

- Utility Management Plans
- New AEM policy/procedure
- HR records, contractor records
- Determine where mfr-recommended I/T/M is mandated by new rules
- Maybe split I / T / M – different regs?
- Determine critical / high-risk
- Operating components
- Obtain mfr recommendations for all
- More analyses
- Risk assessments to use AEM
- Justify I/T/M choices
- Justify what you do now or change
- Sources for decisions
- Use of test equipment
- What is a *major repair/upgrade*?
- Inventory: more records?
- Inventory: equipment definitions
- Inventory: CMS level of detail
- Inventory includes PM records
- Inventory: new reqd categories
  - Critical (high-risk) equip
  - Equipment with AEM
- Monitoring effectiveness
- Utility failure procedures, reports
- Track/analyze failures
- Incident reports
- EOC Committee reports
- Annual reports: AEM effective?
- Training, training, more training
- Internal/external tracers
- Be alert (more clarifications?)

## Action Plan A – UMP & Inventory changes



### ✓ Learning / Training

1. Update Utility Management Plan to reflect new inventory and high-level summary AEM requirements
1. Determine how you will apply the High-risk category to both existing and new inventory operating components.
1. Establish priorities for inventory expansion to “ALL” operating components
  - By risk? By building? By system? By some other category?
2. Determine your inventory expansion approaches – this usually includes aggregating into Environmental Units for some assets, Functional Units for other assets, or the third allowable Grouping Concept.
3. Start the inventory expansion.

## Action Plan B – Manuf’s Recommendations



1. Prioritize somehow (maybe high-risk 1st)
2. Obtain manufacturer’s recommendations
  1. Both Activities and Frequencies
  2. For Inspection, Testing & Maintenance
3. ... or be able to prove you tried
4. If not available [D]
  - Use recommendations from acceptable source

### Action Plan C – AEM P/P & Risk Assmnts



1. Create an AEM Policy / Procedure
2. Decide whether you will consider AEM for High-risk components (some will; some will not)
3. Set up an AEM risk assessment protocol and process.
4. Do AEM risk assessments only when you want to consider AEM – don't waste your time where not permitted.

### Action Plan D – Completion (from UMP)



- Modify all existing inventory assets to reflect High-risk (or non-High-risk)
- Obtain manufacturer's ITM recommendations (both activities and frequencies) for all operating components on the inventory
  - Document progress of obtaining manufacturer's ITM recommendations
  - Prioritize efforts by High-risk; by building, etc. as determined
- Expand inventory to reflect new requirements
  - More assets
  - Environmental units (area-based aggregations)
  - Enhance descriptions of functional units (system-based aggregations)
- Start testing after "major repairs and upgrades"

### Action Plan E – Completion (from AEM P/P)

- HR records, contractor records
- Where is manuf-recommended I/T/M mandatory?
- Compare existing PMs with manufacturer's ITM
- AEM risk assessments only where AEM is desired
- Compare AEM with manuf-recommendations
- Identify AEM = YES where applicable for I, T, M
- Justify or change I/T/M choices
  - Justify what you do now or change
  - Identify sources for decisions
- Review use of test equipment, calibration, etc.

### Action Plan F – Ongoing AEM Compliance

- Monitor AEM program effectiveness
  - Track/analyze failures / Incident reports
- EOC Committee reporting
- Annual UMP/MEMP reports: AEM effective?
- Refresher training of maintainers
- Discussions with contractors / service companies
- Test ongoing compliance with EC tracers

## Action plan for full compliance



- Email [DStymiest@ssr-inc.com](mailto:DStymiest@ssr-inc.com) for personal copy of:
  - *2015 ASHE Conference AEM White Paper*
- White paper includes very robust suggested action plan
  - Initial activities
  - Next steps based on Utility Mgmt Plan updates
  - Next steps based on new AEM Policy / Procedure
- Other approaches may be simpler.

## Thank You!



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Compliance News archives and sign-up available at:  
<http://www.ssr-inc.com/pressroom/>

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- Numerous articles at: <http://www.ssr-inc.com/pressroom/>