SPECIAL SERIES

A Clinical Engineer's Approach To CMS Compliance

David M. Dickey

In response to the Dec. 20, 2013, regulatory changes (Ref: S&C: 14-07 Hospital Equipment Maintenance Requirements) made by Centers for Medicare & Medicaid Services (and subsequently by the Joint Commission on Accreditation of Healthcare Organizations, The Joint Commission, and Healthcare Facilities Accreditation Program), most U.S. hospital-based healthcare technology management (HTM) programs have three options for consideration when determining how best to prepare for these changes:

1. **Do nothing**, as you believe your existing program is already in full compliance, and/or, hold off on making changes until your next CMS (or other regulatory) inspection takes place (i.e., wait and see).
2. **Make minor modifications** to your existing policies, inspection and maintenance procedures and equipment risk based assessment programs based upon program deficiencies that you have determined to exist (after reviewing the revised CMS documents).
3. **Perform an extensive review and assessment** of all of your medical equipment management plan and program documents and make changes where needed (i.e., a full makeover).

Obviously, option one is a bit risky, but the cost of full compliance may initially prohibit many healthcare organizations from jumping right into making changes that may be required, especially as it relates, for example, to the requirement that all imaging devices must have maintenance done "by the (OEM) book." While this has always been a requirement related to imaging devices that produce *ionization radiation*, these two words have been removed from the revised regulations, and has been verified to now include all diagnostic ultrasound devices. We have over 250 of these in our active equipment inventory).

McLaren Health Care's Clinical Engineering Services has taken an aggressive, proactive approach in how it is going about demonstrating CMS compliance, which started by performing a GAP analysis, evaluating 28 program elements (or indicators) as identified in the CMS document. Since our 12 member hospitals are inspected by TJC and/or HFAP, our challenge is to ensure that our program first meets all aspects of the CMS requirement, then the specific interpretations as imposed differently by TJC and HFAP (AOA). One would assume that both accrediting organizations interpret the CMS regulations the same, but this is not always the case, which makes development and implementation of a standardized corporate clincial enginerring (CE) program across all member hospitals a bit challenging.

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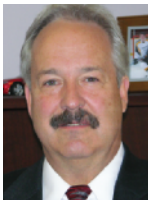
About the Author



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MCES

McLaren Clinical Engineering Services, an in-house CE/HTM program, consists of 70 full-time equivilents, managing or performing healthcare technology management services on 62,000 devices across 12 hospitals and over 100 external clinic and offsite locations throughout Michigan.

This series, presented in three parts, will outline the steps taken, including how we are using, and/or, customizing* the use of our existing computerized maintenance management system (CMMS) (AIMS, from Phoenix Data System) as a key documentation tool used for demonstrating compliance with the newly allowed alternative equipment management (AEM) program as defined by CMS. Also, as of this writing, we have recently undergone a TJC inspection, an HFAP program inspection, and, most recently, a full CMS inspection, all of which asked key questions of our program, looking specifically at how we are implementing an AEM program model.

Read the CMS Regulation Over, And Over, and Over Again!

As I read the CMS document (and the supporting revised State Operations Manual, Pub. 100-07, Appendix A), my first reaction was, "This is going to take a lot of work, and a lot of time." Each and every time I read it, I found myself scribbling all over the document, and after three or four passes through it, I realized that it was time to start capturing the key components of the regulation into a usable format. This led to the development of a simple table (see Table 1 for a *partial* listing) for use in determining how well our medical equipment management (MEM) program complies. For each CMS program requirement, we simply ask two questions: 1) "Do we currently comply?", and if so, 2) "How is that demonstrated or documented?" This document was distributed to all of our program managers, and they were asked to make the assessments for the hospitals they support. While the results were mixed, overall we found that we were not too far off the mark, especially as related to our current equipment scoring approach used in determining which device types do not benefit from having a scheduled inspection. After all, we have been using a risk scoring model to justify elimination of unnecessary preventive maintenance (PM) for years, especially at our hospitals that are inspected by TJC.

Figure 1 shows an example of a PM report from a major OEM of mammography equipment. From this report, there is no way to verify if the PM was done per its own (manufacturer) recommendations.

What Exactly Does This Mean?

Attempting to comply with the CMS document language can be a bit challenging, depending upon how you interpret the written word. For example, within section E, titled "Evaluating Safety and Effectiveness of the AEM program," it is stated that "the hospital must have policies and procedures which address the effectiveness of the AEM program." In evaluating the effectiveness of the AEM program the hospital is expected to address factors including, but not limited to:

- **How incidents of equipment malfunction are identified.** Easy answer: by a corrective maintenance (repair) work order!
- **How incidents of equipment malfunction are investigated.** Easy answer: by the service staff troubleshooting the failed device and by finding the faulty component or assembly, with work efforts documented in our CMMS. **CMMS opportunity:** It is important to remind all of your service staff to enter in details about the troubleshooting efforts and findings, typically in a notes section on the work order. In other words, you need to document how the malfunction was investigated. However, getting details from external vendors such as original equipment manufacturers may be a challenge, especially when devices are under warranty or contract.
- **Whether the malfunction could have been prevented.** Not so easy to answer! What exactly does this mean? One could argue that every failure could be prevented if you had proactively replaced every probable,

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*NOTE: Throughout this document, there will be periodic inserts called "CMMS opportunity" to outline where the use of a CMMS can support the specific CMS requirement being discussed.

	CMS Requirement	Can You Comply?	How Shown?
1	Hospitals comply when they perform maintenance in accordance with manufacturer's recommendations.	We can, but what about when the 'they' is the OEM?	Even the OEM's do not provide this. See example Figure 1 of an OEM PM service report that does not verify if it was done following manufacturers recommendations
2	The hospital is expected to maintain documentation of the manufacturers recommendations as well as of the hospital's maintenance activities	Yes	Do we have a manual on everything? Doubtful. Where to document this? Use custom fields within our CMMS system.
3	Under certain circumstances it may be consistent with regulation for a hospital to use maintenance activities or frequencies which may not be the same (an AEM) as recommended by the manufacturer, such as when the recommendations are not available to them, or they have, through experience, identified more efficient or effective maintenance activities that do not reduce the safety of the equipment	Yes	REVISED MEMP
4	Hospitals that choose to employ alternate maintenance activities or schedules must develop, implement and maintain a documented AEM program to minimize risks to patients and others associated with the use of medical equipment, based on generally accepted standards of practice. One example is AAMI EQ56.	Yes	REVISED MEMP NOTE: EQ 56 does not specifically address this.
5	The determination of whether it is safe to perform equipment maintenance in an alternate manner must be made by qualified personnel.	Yes	REVISED MEMP, to define who exactly is qualified.
6	Determination of whether or not it is safe to include equipment in the AEM program must take into account the safety risks associated with the equipment's use.	Yes	REVISED MEMP AND AIMS (CMMS) ASSESSMENT SCORING TOOLS
7	The hospital is expected to identify any equipment in the AEM that is critical (i.e., risk of serious injury or death should the equipment fail).	Yes	REVISED MEMP AND USE OF CRITICAL FLAG IN CMMS (AIMS)
8	Multiple factors must be considered when identifying risk to the patient, such as patient care setting where the device is being used.	Yes	REVISED MEMP AND CMMS (AIMS) ASSESSMENT SCORING
9	Factors used in determining risk of equipment should include: • How the equipment is used • Likely consequences of equipment failure or malfunction in causing patient harm or injury • Seriousness of harm related to device failure • How widespread is the harm • Information available from the manufacturer related to maintenance recommendations, including rationale for the recommendation • Maintenance requirements of the equipment • Timely availability of alternate device or backup systems in the event of equipment malfunction • Incident history of identical or similar equipment, and documented evidence based on hospital experience or by evidence reported by credible sources outside the hospital	Yes	MINOR REVISIONS TO THE MEMP AND CMMS (AIMS) EQUIPMENT ASSESSMENT SCORING DATA ELEMENTS AND POINTS USAGE
10	The hospital is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program	Yes	REVISED MEMP AND CMMS (AIMS) ASSESSMENT SCORING
11	An AEM strategy may rely upon information from a variety of sources, which may include its own experience.	Yes	LOTS OF CMMS (AIMS) DATA AVAILABLE WITHIN OUR OWN HEALTH SYSTEM
12	The hospital is expected to adhere strictly to the AEM activities or strategies it has developed	Yes	REVISED MEMP AND QUARTERLY/ANNUAL REPORTS

Table 1. A simple table describes several key components of the regulation into a usable format for use in determining how well a current MEM program complies. This is a partial list. Continued on next page.

	CMS Requirement	Can You Comply?	How Shown?
13	Maintenance strategies can include: • PM time based maintenance • Predictive maintenance that involved periodic condition monitoring • Run to fail maintenance • Reliability centered maintenance	Yes	Random Sampling is an acceptable AEM strategy
14	AEM program documentation must include: • Types and levels of risk to the patient • Alternate maintenance activities, to include the differences between the AEM in comparison to the manufacturers recommendations, unless not available • Devices on alternate inspection frequencies, such as random sweeps	Yes	REVISED MEMP AND CMMS (AIMS) RISK ASSESSMENET SCORING
15	Equipment not eligible for placement in an AEM program include: • Imaging/diagnostic equipment governed by 42DFR 482.26(b)2 (includes ultrasound, MRI, etc.) • Medical lasers • New equipment without sufficient maintenance history NOTE: If transitioned to an AEM, hospital must maintain evidence that it has first evaluated the maintenance track record, risk, and tested the alternate regimen	WIP	New issue for CE is diagnostic ultrasound 'PMs by the book. Also, not all imaging devices have had PMs done "by the book," as no manual is available from the manufacturer. GAP analysis underway.
16	The hospital must have policies and procedures which address the effectiveness of the AEM program	Yes	Annual CE program review
17	The decision to put equipment onto an AEM program must be made by qualified personnel, such as a clinical engineer a BMET. Records of qualification of individuals making the decision must be maintained, including on individual who are contracted personnel.	WIP	TBD, how to document qualifications of OEM staff. Is asking them to provide training records sufficient?
18	Evaluation of the AEM program should include, at a minimum: • How incidents of equipment malfunctions are identified • How incidents of equipment malfunction are investigated • Determination whether a malfunction could have been prevented, and what steps will be taken to prevent future malfunctions • Determination whether or not the malfunction was a result of the AEM • Process for removal from service equipment determined to be unsafe or no longer suitable for its intended application • The use of performance data to determine if modifications in the AEM procedure are required	Yes	• WOs • Incident Investigations • Failure code P • Other failure codes • PM outcome coding WO Reports/Data Analysis • Filter CM using 'II' • Filter CM using 'P'
19	Program surveyors must focus their review of an AEM program on critical equipment and on the hospitals documentation on how the decision was made to put the equipment onto an AEM strategy	Yes	REVISED MEMP, AEM Scoring Start with spreadsheet format, move into CMMS (AIMS) risk field, now re-defined
20	The hospital must identify the equipment required to meet its patients needs, for both day to day operation, and in an emergency/disaster situation.	Yes	New equipment committees; capital requests
21	All medical and facility equipment, leased or owned, is expected to be listed in an inventory which includes a record of maintenance activities.	Yes	From the vendor, when requested. Not using AIMs for patient owned, rented or leased equipment. Separate listing
22	All equipment using an AEM program *must be readily and separately identified as subject to the AEM, as must critical equipment*.	Yes	CMMS (AIMS) coding

Table 1 (continued). A simple table describes several key components of the regulation into a usable format for use in determining how well a current MEM program complies. This is a partial list.

predictable component (that could produce a failure in the future), such as all power supplies, interface boards, or computer disk drives, since they could (and will) most likely someday fail. Obviously, this is not practical for most, if not all, hospitals.
CMMS opportunity: Lucky for us, many years ago we started using a work order failure code of "preventable" on corrective maintenance work orders. We can run a report filtered by this outcome code to identify device failures that could have been prevented. We instruct all of our service staff to only use this code if they believe that a change to PM frequency or procedure would have prevented the unscheduled device failure. NOTE: We always remind our staff of when to use a failure code of "Use Error" when we are 100% sure that the equipment user was incorrectly using the device, such as a user setting not correct. "Abuse" (always an accident, right?) is when the device gets damaged, dropped, or smashed. While both of these failure codes refer to an event, or device failure, that could have, in theory, been prevented, we only use the preventable code as it pertains to a malfunction that could have been truly prevented by more, or different, scheduled maintenance.

- **And what steps will be taken to prevent future malfunctions.** I'm not 100% sure how to document this one, when the honest answer may be "nothing," as related to devices that have nonpredictable

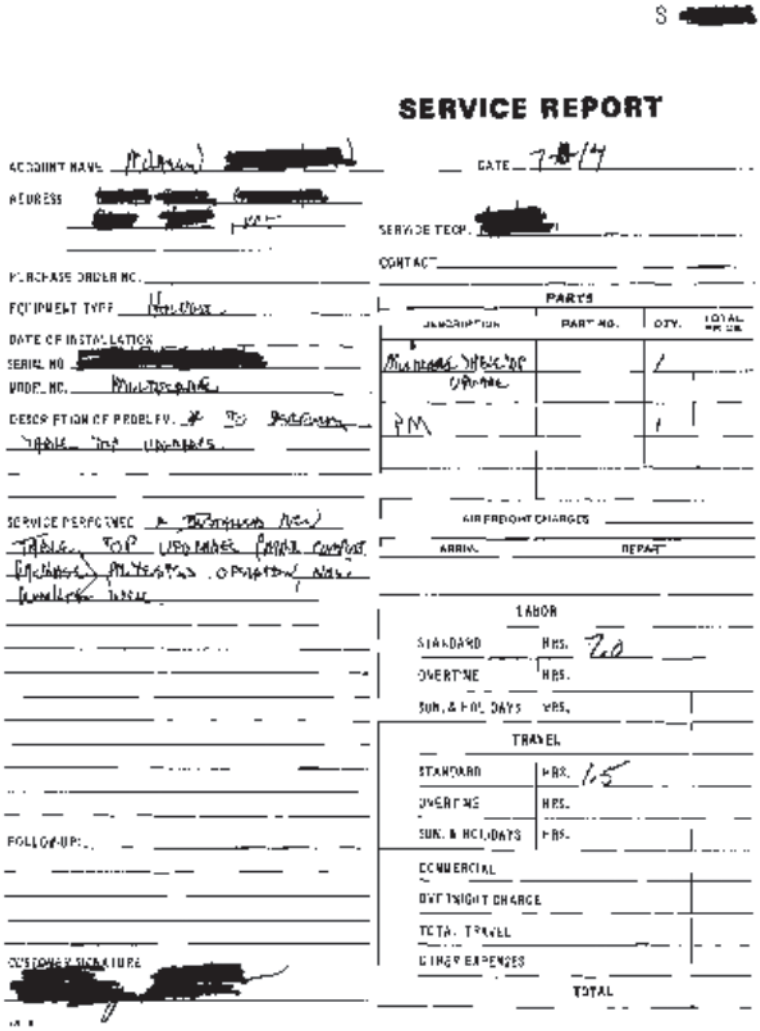

Figure 1. An example of a PM report from a major OEM of mammography equipment

Medical Device Inventory	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Electromyograph	16	16	16	16	16	16	16	16	16	16	16	16
# CM Work Orders	1	5	0	1	1	0	0	1	2	1	0	0
Light, Surgical	111	111	111	111	111	111	111	111	112	112	112	112
# CM Work Orders	9	5	15	7	9	7	11	8	7	6	11	0

Table 2. Monthly Corrective Maintenance Trend

random failures. If you believe in the theory that scheduled PM reduces equipment malfunction, then your immediate response may be by doing more PMs, or by modifying what is done during the PM. If this is your action taken to prevent future malfunctions, then make the change, and then find a way to determine if this indeed was the outcome. **CMMS opportunity:** Can your CMMS assist you with making this type of assessment, i.e., prove or disprove that your change to PM frequency or procedure had an impact on future malfunctions? A simple report that I asked our CMMS vendor to code for me is shown in Figure 1, which indicates, by month, the number of corrective maintenance (CM) work orders for a specific device type. Let's say that the average number of device failures for a specific device type is four per month, and you then make a change to your PM procedure or frequency, in month five of a given year. This type of report could then be used to identify a change in this trend, if any. Once a device failure trend is detected, we can then run a detailed work order report to drill down into the specific causes of the device failure, in order to make a determination as to whether or not the AEM program has had any impact on device failure rates—good or bad.

Your Medical Equipment Management Plan/Program

Does the CMS regulation require you to make changes to your MEM plan or MEM program documents/policies? Most likely, Yes.

I have always been a supporter of having two separate policy documents. The MEM plan is a high-level overview of the organization's commitment to medical equipment use and safety. This is not solely a clinical engineering responsibility, so this document needs to define the basic roles and responsibilities of administration, nursing education, equipment users, clinical engineering, and your external vendors that assist with maintaining or operating equipment. This document should include language related to the requirement for specific policies and procedures to be created related to such things as emergency procedures; back up equipment; processes for managing device alerts and recalls; equipment inspection procedures; inventory requirements; and more. The MEM program is the formal document to further define and describe the details on how the plan is being implemented. Based on our review, we determined that there were no substantial changes within the revised CMS regulations that would require us to grossly modify our MEM plan document, other than to include updated references to the new CMS documents.

Key sections of our MEM plan document are shown below:

Purpose

To describe the requirements for, and content of, MHC (McLaren Health Care) hospital's medical equipment management plan.

Scope

The U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, per 42 CFR 482.41 c requires that hospitals must maintain adequate facilities for their services and that hospital facilities, supplier, and equipment be maintained to ensure an acceptable level of safety and quality. The Joint Commission (TJC) requires that the hospital manages medical equipment risks. The American Osteopathic Association (AOA), under their Healthcare Facilities Accreditation Program (HFAP),

requires that all medical equipment be maintained and tested. To ensure that all MHC subsidiaries maintain compliance with CMS, TJC and/or HFAP regulations, a well-defined medical equipment management plan and related program shall be developed and implemented by each MHC subsidiary in support of the CMS guidance materials as described within the Survey Protocol, Regulations and Interpretive Guidelines for Hospitals of the State Operations Manuals related to hospital facility and medical equipment maintenance.

Requirements

1.1. Each MHC hospital subsidiary shall develop and implement a medical equipment management program that, includes, at a minimum, the following components:

1.1.1. Processes implemented to manage the effective, safe and reliable operation of medical equipment.

1.1.2. Processes for selecting and acquiring medical equipment.

1.1.3. Requirement for all equipment users to be properly trained on the safe use of the devices used in their department to treat and care for their patients.

1.1.4. Procedures for identifying, evaluating and creating an inventory of equipment to be included in the medical equipment management program based, minimally, on equipment function, risk and incident history, regardless of ownership.

1.1.5. Procedures for developing inspection scheduled and maintenance strategies for all equipment on the inventory in order to achieve effective, safe and reliable operation of equipment on the inventory.

1.1.6. Processes for monitoring and acting on equipment hazard notices and recalls.

1.1.7. Processes for monitoring and reporting incidents in which a medical device is suspected or attributed to the death, serious injury or serious illness of any individual, as required by the Safe Medical Device Act of 1990.

1.1.8. Processes for identifying and implementing emergency procedures that address actions to be taken when equipment failures; how to perform emergency interventions when equipment failures; access and availability of back-up equipment; and how to obtain repair services.

1.1.9. Documentation requirements of performance and safety testing of all equipment covered by the medical equipment management plan prior to initial patient use.

1.1.10. Documentation procedures of inspection and maintenance of equipment used for life support that is consistent with identified maintenance strategies to minimize clinical and physical risk.

1.1.11. Documentation procedures of inspection and maintenance of equipment used for non-life support that is consistent with identified maintenance strategies to minimize clinical and physical risk.

1.1.12. Documentation of performance tests on all sterilizers.

1.1.13. Documentation of chemical and biological testing of water used in renal dialysis, if applicable.

1.1.14. Requirement for an annual program review to include measurement of effectiveness of all aspects of the Medical Equipment Management Program. ■

Part II of this series will review how our medical equipment management program was modified to incorporate all new CMS requirements, and introduces a new equipment, risk, and AEM assessment numerical scheme which has been incorporated into our CMMS system, taking into account all of the assessment factors identified by CMS.