

Special Series

A Clinical Engineer's Approach to CMS Compliance: Part Three

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About the Author



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The December 2013 regulatory changes from the Centers for Medicare & Medicaid Services (CMS) resulted in additional components being added to our medical equipment management program (MEMP) and alternate equipment management (AEM) strategies. Our annual review documenting effectiveness of the MEMP and AEM programs now incorporates the following language:

“On an annual basis, components of the Medical Equipment Management Plan and Medical Equipment Management Program will be reviewed and evaluated for effectiveness, with recommendations for any required changes documented and reported to the hospital Safety/Environment of Care Committee for endorsement, where appropriate. (Note: While such changes are no longer required to be reviewed and approved by a hospital ‘safety or EC committee,’ we have elected to continue to report our program changes to the various hospital committees.) The annual review shall include a review of key program and data elements (by running various computerized maintenance management system [CMMS] maintenance data reports), which may lead to changes to device-specific equipment

maintenance assessment scores as listed in the CMMS database and other equipment listings. These scoring changes may result in a change to the maintenance strategy used, such as use of an AEM or non-AEM program maintenance model.”

Annual Assessment of MEMP Effectiveness: Time to Rethink

Historically, program effectiveness has been measured by focusing on the ability to answer questions that regulatory agency inspectors have always asked. While important, questions such as “What are your preventive maintenance (PM) completion rates?” and “How do you find missing equipment?” are not by themselves measures of MEMP effectiveness. In the author’s opinion, MEMP effectiveness would be more appropriately measured by answering the question, “How effective was (or what was the impact of) X in maximizing the safety, operational status, and availability of medical equipment for the use in delivering patient care?,” where X is the equipment inspection program, equipment user education program, or repairs performed on broken or damaged equipment.

To accomplish this, specific data elements to be assessed at all of our hospitals as a component of our annual MEMP assessment now include, at a minimum, the following:

- Review of PM inspection outcome findings, including detailed assessment of all inspection work orders that had a “major

failure” PM outcome, in order to determine what caused the failure and if the failure could have been prevented by changes to inspection frequency or procedure

- Identification and trend analysis of any identified equipment user errors or nonduplicative equipment operational problems (i.e., problem not found or could not be duplicated, which may be another indicator of use error)
- Identification and review of devices with high repeat failure rates
- Identification and review of all equipment failures that were coded as “preventable” (an indicator that increased inspections may have prevented or reduced the equipment failure rate)
- Review of any device-related patient or staff incidents as reported to McLaren Clinical Engineering Services (MCES), to determine if the device failure was related to, or caused by, inappropriate maintenance
- Review of device recalls and hazard alerts through various publications (e.g., vendor mailings, ECRI, StayAlert, TJC Alerts) and addressed by MCES
- Review of educational in-service training provided (or recommended to be given) by MCES to equipment users
- Recommended change of device inspection program category based on historical data review and risk assessment
- Recommendations for removal or replacement of aging or problematic (e.g., end of support) patient care technology
- Verification of technical service staff training and competencies, based on a sampling of work performed, service training received, certifications received, and statements of qualifications from outsourced (original equipment manufacturer [OEM] or International Organization for Standardization [ISO]) vendor labor sources

Now the Test: Recent Inspections

During November 2014, two of our hospitals were inspected: one by The Joint Commission (TJC) and another by the Healthcare Facilities Accreditation Program (HFAP; of the American Osteopathic Association).

HFAP inspection

The HFAP inspection was slightly more problematic for us, as the inspector (in our opinion) was overly concerned with the fact that we do not use dated PM inspection stickers, with some devices not having any stickers attached. Specifically, the inspector noted: “During the document review session it was noted that the medical equipment plan does not enable the staff to recognize whether the equipment they are using has been inspected or is due for inspection.”

In response, we outlined why we did not use dated PM inspection stickers. (Of note, we have not used dated stickers for the past 10 years, so we did not understand why this issue was being raised now.) In lieu of the stickers, we have been using a CMMS system with online access that provides all equipment inspection status data and have been providing written reports. We explained that just because a device was inspected at some point in the past, this *does not* mean that the device is currently working properly. In my opinion, teaching equipment users that “as long as a device has a dated safety inspection sticker, the device must be safe to use” is dangerous. Instead, *educating clinical staff of their roles and responsibilities* in using medical equipment is always better. Appendix A provides an example of an instructional document on equipment user responsibilities that is circulated on a regular basis.

Further, the inspector noted: “Therefore the plan does not alert staff to potentially unsafe equipment. The plan includes a yellow sticker that alerts staff to original inspection only. Subsequent inspections and/or due dates for future inspections are not included. Therefore, end user staff have no way of knowing that the equipment is currently operating safely and effectively.”

As mentioned above, the only way that staff would have an indication that a device may be potentially unsafe is by their own observation, self-test, and assessment. To reiterate, PM stickers cannot notify staff whether devices are safe or unsafe to use. Also, clinical staff are not responsible for knowing when a device was last inspected, or due for a subsequent inspection, as this is the responsibility of clinical engineering.

Teaching equipment users that “as long as a device has a dated safety inspection sticker, the device must be safe to use” is dangerous. Instead, educating clinical staff of their roles and responsibilities in using medical equipment is always better.

Ultimately, the dated PM sticker issue was dropped after the inspector received verification from CMS that the stickers were not required. The inspector also indicated that HFAP may need to reconsider its assessment of hospitals' MEMP programs in light of the fact that CMS does not require stickers.

At the request of the HFAP inspector, we produced two lists: one for critical equipment and the other for devices on an AEM program. The inspector recommended that we remove the details of our AEM program from our MEMP document and create a separate AEM program policy.

Last, the inspector pointed out that our MEMP document needed to clearly state who has the authority (and the educational and experiential basis for that authority) for making program decisions and equipment assessments. We revised our MEMP policy to specifically address these needs.

TJC inspection

The inspection by TJC was a bit less eventful, perhaps because the inspector had been to our hospital in the past and was somewhat familiar with our program. Per the usual routine, he selected a few devices at random (e.g., infant scale, fetal monitor, intravenous pump, defibrillator) and asked to see our maintenance records, which we produced. Although he did not specifically question the details of our AEM program, he did ask why we only tested a certain model of defibrillator annually, as opposed to every six months. We produced the OEM manual, which described an annual inspection procedure for the model that has a CO₂ module. However, the manual did not state a recommended PM frequency for the base defibrillator, which was confirmed by calling the OEM. Also, this same defibrillator model is on our ambulance units. Due to the environment, we noted that the ambulance defibrillators are inspected twice a year, but we saw no value in doing this for the stationary units, especially because the clinical users discharge the defibrillator daily into a test load, which is documented. Although the inspector still wanted us to reconsider this policy, it was not considered an element of program performance deficiency.

The TJC inspector requested to see our critical equipment list but did not specifically ask to see the list of equipment on an AEM program. However, he asked to see our scoring process for determining whether equipment should be put on an AEM program. This presented the opportunity to review our new scoring/equipment assessment model, with which the inspector seemed to be impressed.

Just like with the HFAP inspector, the inspector from TJC also asked about PM stickers. Again, we explained why we use a computer and reports, citing reasons such as stickers can fall off or be difficult to read and many devices (e.g., rigid scope, flex scopes, surgical cameras) do not have adequate space for affixing stickers. Following this discussion, the inspector understood.

However, the TJC inspector also asked, "How do the equipment users know that maintenance is being done properly?" This question caused us a bit of confusion, because unless the clinical equipment user has a service or technical background, he/she could not know the answer, and the sticker itself certainly would not be informative. Along this same line of thinking: How does a patient or family member know that the nurse, therapist, or physician is delivering patient care properly? Both answers likely will involve describing the background of the professional, such as his/her education, training, experience, professional judgment, and access to experts for advanced knowledge. To gain a true assessment of whether maintenance is being done properly, one would have to ask, for example, about the service providers' education and experience, test equipment used, calibration dates, sources for parts, troubleshooting skills, performance tests completed, and access to manuals.

CMS inspection

Following the HFAP and TJC inspections, CMS sent six inspectors to our hospital for a three-day survey. One inspector asked for equipment records on standard clinical equipment, including a fume hood (i.e., requested more details on filter changes), an automated external defibrillator (i.e., asked specific questions on battery status and testing), a few sterilizers, and anesthesia

machines. Of note, although the revised CMS regulations do allow anesthesia machines to be on an AEM program, our scoring program puts this device type into a maintenance category that prevents an AEM option, which the inspector liked. We explained that we service anesthesia machines in-house, following OEM recommendations. The inspector then asked specific questions on where and how we deviate from OEM recommendations, whereby we shared our new AEM assessment scoring methodology. He seemed to be impressed with this method and asked to take a hardcopy with him.

A few weeks after the survey was complete, we followed up with an email to this inspector, and he responded saying that our MEMP policy was good and covered all requirements of the revised CMS regulation as related to medical equipment. Also, CMS had no more questions or concerns about PM stickers, which we took as a final confirmation that dated stickers are not a requirement. Last, the inspector asked questions about our critical alarm program, and we were able to discuss our corporate policy on this initiative, which is currently being implemented at all McLaren hospitals.

Conclusion

Satisfying the revised CMS guidelines related to MEMPs would not have been a simple task had we not been proactively reducing our PM workloads by changing frequencies of inspection and modifying or developing our own procedures during the past 10 or more years. Remember the days when we checked every device, twice a year (and chased microamps)? As a profession, we knew that many, if not most, of those scheduled inspections were inefficient and did not add value.

Now, formally justifying or validating current PM program practice models to demonstrate compliance with the newly defined CMS AEM definitions likely will require a substantial amount of work for many hospital clinical engineering (CE)/healthcare technology management (HTM) departments. This will require verifying the existence (or lack) of OEM service manuals for every device in your inventory, documenting where you deviate from the

OEM-recommended inspection frequency and procedure, and developing new equipment maintenance (risk) management strategies. Simultaneously, you will need to develop an assessment process to evaluate the impact of your AEM program and to quantify the impact, if any, on equipment performance and reliability. If you are fortunate enough to have unlimited resources (staff, time, and money), you could obtain every service manual pertaining to all clinical equipment being used, purchase all required specialty test equipment and OEM training, and then simply perform all scheduled inspections on all devices “by the book, procedure, and frequency,” thereby eliminating any concern for the AEM program components. If you don’t have the internal resources to do this, your only alternative may be to contract with the OEM or with qualified ISO companies to have them perform selected equipment inspection and maintenance activities “by the book.” However, regardless of who is doing the maintenance work (OEM, ISO, or in-house HTM/CE staff), the hospital, per CMS regulation, remains ultimately responsible for managing the entire program and documenting its effectiveness.

Depending on the features and reporting capabilities of your CMMS, you will need to determine how best to use it to help you in managing and documenting all requirements of the revised CMS guidelines. If you feel that your current CMMS product is lacking required features, now is the time to work with your vendor to ensure that needed operational features, reports, and data analysis tools are forthcoming in future software releases.

Lastly, the best answer to the question on the effectiveness of an MEMP may lie in one key fact: At least for our program, we have not had a patient injury that was caused by, or had a contribution from, any component of our MEMP. Perhaps this should be the focus of questions asked by the next set of inspectors that visit our hospitals. ■

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Appendix A. Medical equipment safety: Equipment user responsibilities

Safe use of medical equipment is everyone's responsibility, as is the identification of devices that may not be operating correctly. All equipment users shall be trained in the use of the equipment that they use to provide patient care. Generally, when using any medical device, the following guidelines and precautions should be observed:

1. If uncertain how to use any patient care device assigned for use in your area (or on your patients), please contact your supervisor for instruction.
2. When inserting or removing an AC plug from an AC receptacle, be careful not to pull on the power cord itself, as this may damage the wiring near or inside the plug, potentially causing a short circuit. If the plug, power cord, or any accessory cabling looks defective or feels hot to the touch, do not use the device and notify MCES at once.
3. If the device has a self-test that is initiated when the device is first turned on, take note of any error messages or alarms that may indicate a malfunction and, if so, do not use the device. Tag the device as defective and notify MCES at once.
4. Perform a visual inspection prior to using the equipment. If the device looks like it had been dropped, looks damaged, or performs erratically, discontinue using the device and take precautionary measures to ensure patient safety, following procedures established by your departmental supervisor. Tag the equipment as defective and notify MCES immediately.
5. If a device is involved with a patient incident, injury, or other unplanned event, immediately discontinue using the device and obtain an alternate unit, if needed. Tag the affected device as defective and notify your supervisor of the occurrence. Do not change any of the device settings, and do not discard any used accessories. Call MCES or your risk management department for detailed handling instructions.
6. All devices* that have been previously inspected by MCES will have a tag that states, "Approved by MCES for patient use. For service or information call 810-342-XXXX." Also, you can contact your supervisor to review reports delivered annually by MCES. Since inspection intervals may change throughout the course of any given year, reinspection dates are not shown on the equipment tag but are kept on the MCES computer system database. Should a direct patient care device not have an approval sticker, notify MCES. (*Note: Physically attaching stickers on some devices may not be practical, due to the size of the device size or impact on sterilization; therefore, stickers may not be present on all devices. Call MCES if you have questions or concerns about a particular device.)
7. Leased, patient-owned, and rental equipment should be visually inspected by the equipment user prior to use. With some rental equipment suppliers, copies of safety inspections are provided with each device and, if so, should be forwarded to clinical engineering for review and filing. If equipment is to stay in the facility for longer than six months, it will be added to the inventory for tracking purposes.
8. On a periodic basis, each department is supplied with an updated equipment inventory and inspection status schedule listing all active equipment within their cost center. Should you need to review or consult this document, contact your unit manager.
9. Keep all battery-operated devices plugged into an active electrical outlet (emergency power, when available) , so that batteries can remain charged.