On Dec. 20, 2013, the Centers for Medicare & Medicaid Services (CMS) released a document that will affect nearly all healthcare technology management (HTM) organizations in the United States. The guidance document, titled *Hospital Equipment Maintenance Requirements*, is addressed to CMS state directors who survey hospitals for compliance with the agency’s regulations. Other accrediting organizations, such as The Joint Commission (TJC) and DNV Healthcare (DNV), base their accreditation on CMS standards. The new memo involves considerable revisions compared with a Dec. 2, 2011, CMS document on the same subject.

The guidance issued by CMS in 2011 caused a major stir in the HTM community because it specified that hospitals should follow manufacturer preventive maintenance (PM) requirements in caring for hospital facilities and equipment. Many HTM groups, based on their experience and professional judgment, had not been following manufacturer PM recommendations. AAMI and the American Society for Healthcare Engineering jointly developed a response providing evidence that other alternatives to manufacturer PM recommendations have not caused harm to patients and urging CMS to allow more flexibility.

Many hospitals rely on TJC standards as they pertain to management of medical equipment. HTM managers in these hospitals may not realize that TJC bases its standards on the CMS standards. As a result of this CMS directive, TJC recently announced a new Element of Performance, effective 7/1/2014, to bring its standard in compliance. CMS may elect to inspect a healthcare organization independently of TJC. Hospitals that do not rely on TJC are most likely already following CMS standards.

The objective of the current article is to discuss the 2013 CMS document from the standpoint of HTM. HTM professionals are encouraged to focus on Appendix A, which begins on page 6 of the CMS guidance, because it is easier to read and is the actual standard with which hospitals need to comply. Because the current article is meant for those with responsibility for managing healthcare technology, it will focus on medical equipment, which is defined by CMS as “devices intended to be used for diagnostic, therapeutic, or monitoring care provided to a patient by the hospital (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).”

Excerpts from sections of the CMS guidance relevant to HTM professionals are...
provided, followed by commentary from the author. (Note: My commentary is just that; others may have equally valid commentary that may conflict with mine. In the end, what really counts is the actual CMS language and how inspectors interpret that language.)

**Equipment**

Of note, in the following excerpt, the term “equipment” includes both medical and facility equipment.

“All equipment must be inspected, tested, and maintained to ensure their safety, availability, and reliability. The hospital maintains records of hospital personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

“All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules, fall under the purview of the hospital’s clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by hospital leadership.

“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.”

**Commentary**

The term “all equipment” as it pertains to medical equipment includes many types of medical equipment used in hospitals that are not necessarily under the purview of the HTM group but still are “intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the hospital.” Examples could include sterilizers, operating tables, patient beds, stretchers, endoscopes, nurse call systems, and surgical devices. The HTM group should take responsibility for expanding this list and discussing within their organization whether each example meets the definition of a “medical device.” If the device under discussion meets the definition of medical equipment and the HTM group does not have responsibility (either directly or by supervising a contractor), then some other group in the organization needs to assume responsibility. If the consensus is that the device under discussion does not meet the definition, the discussion should be documented and saved for future reference. If a potential for patient harm exists because the medical equipment in question is not maintained properly, then I urge the organization to err on the side of patient safety by including the example under the definition of “medical equipment.”

CMS specifically included “surgical devices” for the first time in the CMS example list of devices that are clearly “medical devices.” This is important and should not be ignored. Many HTM groups do not have any involvement in maintenance programs for surgical devices. Typically, the operating room has assumed responsibility for these devices. I agree with CMS that surgical devices clearly are “medical equipment,” as well as “healthcare technology.” HTM groups need not have direct responsibility for surgical devices, but they should be fully aware of what is happening with these devices in their organizations, even if this involves going outside of their comfort zone.

If a potential for patient harm exists because the medical equipment in question is not maintained properly, then I urge the organization to err on the side of patient safety by including the example under the definition of “medical equipment.”

The requirements for “equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules” clearly fall under the traditional HTM responsibility. Keep this in mind when evaluating existing policies, procedures, and programs for medical equipment not under the purview of HTM (e.g., surgical devices).

Even when outside contractors, including the original manufacturer, have been
columns and departments

contracted to perform the required maintenance, the hospital still is responsible for overseeing and documenting that the needed work was done.

Of note, “manufacturer-recommended maintenance activities and schedule” are the gold standard according to the CMS guidance. Even if hospitals want to increase the frequency of scheduled maintenance, they “must use the manufacturers-recommended maintenance activities.” I disagree with CMS on this particular point. For example, I see no reason why hospitals should not be able to replace batteries more often than recommended by the manufacturer independent of other manufacturer-recommended activities. If this type of situation arises in your organization, I suggest using an alternate equipment management (AEM) program (discussed below) to document an acceptable deviation.

If following TJC standards, EC.02.04.01, EP 4, states: “The hospital identifies the activities, in writing, for maintaining, inspecting, and testing for all medical equipment on the inventory” (also see EC.02.04.03, EPs 2 and 3). Hospitals may use different strategies for different items, as appropriate. For example, strategies such as predictive maintenance, reliability-centered maintenance, interval-based inspections, corrective maintenance, or metered maintenance may be selected to ensure reliable performance.” The “manufacturer-recommended maintenance activities and schedule” are a perfectly valid methodology for fulfilling this requirement. I suggest that hospitals document the rationale for known deviation from “manufacturer-recommended maintenance activities and schedule” using a documented process. The AEM strategy described by CMS is one such process, and the similar process recommended by TJC is equally satisfactory. Both processes should be based on actual data.

AEM Program
“A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. Hospitals that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated with the use of facility or medical equipment. An example of guidelines for a medical equipment maintenance program may be found in the American National Standards Institute/Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:1999/ (R) 2013, 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.”

Commentary
As mentioned previously, the manufacturer-recommended maintenance activities and schedule are the gold standard from a CMS standpoint. Although that seems logical, many issues exist with the maintenance activities specified by manufacturers, as reported by Stiefel.

In my experience, many HTM groups have paid little or only passing attention to manufacturer recommendations. Many HTM groups have routinely used generic inspection procedures to test for device performance, assuming that this will detect actual problems. Some have read manufacturer manuals when the device was first implemented into their system and informally decided on the manufacturer procedures that seemed “reasonable” based on their experience with similar devices. Most HTM groups have not documented who read the manufacturer recommendations, when the recommendations were read, and whether deviations were made.

All of this must change. HTM groups who deviate from manufacturer-recommended maintenance activities and frequencies now are required to document all of these deviations, along with a well-thought-out rationale.
are required to document all of these deviations, along with a well-thought-out rationale. In many cases, existing policies and procedures may not mention deviations from manufacturer recommendations. These policies and procedures need to specify under what circumstances deviations are allowed, who has the authority to make deviations, and the necessary documentation.

When CMS published the 2011 version of this document, some HTM groups publically stated that they always follow manufacturer recommendations. I urge those groups to question their teams to determine whether that actually occurs in practice. I strongly suspect that all HTM groups will want the flexibility and procedure for setting up an AEM for some types of equipment.

I expect that the percentage of devices covered by an AEM will vary greatly among HTM groups. I also expect that the scrutiny caused by the CMS standards will increase the percentage of devices maintained across the industry according to manufacturer recommendations. The burden of an AEM is not a trivial one; thus, some organizations will conclude in many cases that the path of least resistance is to follow what the manufacturer recommends, even if they have not done so in the past.

Notice that the CMS refers to American National Standards Institute/AAMI EQ56:1999, as revised in 2013. If this document is not already in your library, it should be. EQ56 contains many relevant sections that pertain to an AEM. HTM groups should ensure that their AEM program conforms with EQ56.

As HTM groups develop their AEM, both generally and for individual types of equipment, consulting and/or contributing their efforts to the AAMI Healthcare Technology Management Resources web page (www.aami.org/htmconnect/index.html) is strongly encouraged. Readers also are encouraged to check out, and hopefully participate in developing, the Healthcare Community Database Project (www.htmcommunitydb.org/wiki/index.php?title=Main_Page; note: “view” can be used for both the username and password). Malcolm Ridgway started the site in response to the initial CMS requirement to use manufacturer recommendations. Both sites are valuable resources for developing an AEM and are useful for sharing knowledge on this important topic. Not only is it wasteful for each individual HTM group to “reinvent the wheel,” but it also is important that our industry start developing common best practices.

**Decision to Place Equipment In an AEM Program**

“The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are hospital employees or contractors.

“In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the hospital must take into account the typical health and safety risks associated with the equipment’s use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the hospital where it is used.

“A hospital is expected to identify any equipment in its AEM program which is "critical equipment," i.e., 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.

Surveyors must focus their review of a hospital’s AEM program on critical equipment in that program and the hospital’s documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

“Factors for a hospital to consider when
evaluating the risks associated with a particular type of equipment include, but are not limited to:

- How the equipment is used and the likely consequences of equipment failure or malfunction—would failure or malfunction of the equipment hospital-wide or in a particular setting be likely to cause harm to a patient or a staff person?
  - How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.
  - How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.

- Information, if available, on the manufacturer’s equipment maintenance recommendations, including the rationale for the manufacturer’s recommendations;
- Maintenance requirements of the equipment:
  - Are they simple or complex?
  - Are the manufacturer’s instructions and procedures available in the hospital, and if so can the hospital explain how and why it is modifying the manufacturer’s instructions?
  - If the manufacturer’s instructions are not available in the hospital, how does the hospital assess whether the AEM uses appropriate maintenance strategies?
  - How readily can the hospital validate the effectiveness of AEM methods for particular equipment? For example, can the hospital explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?
- The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction; and
- Incident history of identical or very similar equipment— is there documented evidence, based on the experience of the hospital (or its third party contractor), or on evidence publicly reported by credible sources outside the hospital, which:
  - Provides the number, frequency, and nature of previous failures and service requests?
  - Indicates use of an AEM strategy does not result in degraded performance of the equipment?

“Generally multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. 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.”

**Commentary**

This guidance is fairly detailed and straightforward regarding what must be considered and documented as part of an AEM program. I deliberately included the bulk of the guidance in this area because I believe the CMS did an excellent job of absorbing and summarizing the material that was submitted in reaction to the agency’s 2011 statement.

Hospitals that already have TJC documentation on their existing medical equipment management program (MEMP) need not change the structure. However, they should review their program to ensure that it also meets the AEM requirement. The title of your program does not matter to CMS or TJC; however, both care that you are meeting the essential elements of their respective requirements. Ensuring that your program meets both sets of requirements is recommended.

Putting together an AEM justification will not be a trivial exercise. As mentioned earlier, in addition to circumventing the wasted time of everyone trying to develop their own analysis for an AEM, community resources are vital to gaining the wisdom that comes from a shared experience.
TJC currently has specific, more stringent requirements for life-support equipment (LSE). CMS in turn defines critical equipment. Generally speaking, all LSE also is critical equipment but not vice versa. LSE only refers to equipment involving a risk of death to a patient, while critical equipment also involves risk of serious injury to a patient and risk of serious injury/death to a staff person (e.g., electrosurgical units, powered surgical devices, surgical tables, hyperthermia units, infusion pumps, some laboratory analyzers, tracheal suction pumps, radiotherapy units, sterilizers).

To determine what constitutes critical equipment, each hospital will need to consider their individual situation, as well as discussions within the overall HTM profession. The discussion on the definition of critical equipment should include clinicians and should be documented.

Over time, I believe that manufacturers will begin to see the wisdom of designing their recommended maintenance procedures to reflect what makes sense in the real world. I also predict that manufacturers will begin monitoring community websites for postings that pertain to their products and will comment if they have safety concerns about what is being posted. Manufacturers bear some responsibility for knowing how their medical equipment is really being maintained in the field. That responsibility will become hard to ignore after it becomes “reasonable” for manufacturers to be aware of the content on the sites. When an HTM group discovers actual injuries or near-miss events that could have been caused by deviating from manufacturer responsibilities, that group will be responsible for letting the manufacturer and other HTM groups know of its discovery.

Since 2011, some HTM groups have suggested that their primary reason for not following manufacturer recommendations is because of the expense. When asked to explain, these groups said that they don’t have the staff, that the parts are too expensive, or that an inadequate supply of spares will result in unacceptable downtime during scheduled maintenance. My advice has been that reasons such as these are not adequate in and of themselves when justifying the need for an AEM. Patient safety needs to be the primary focus. If a real cost-benefit issue exists, then the HTM group needs to discuss the topic with senior management, risk management, and patient safety.

For example, if more staff would be needed to comply with manufacturer recommendations and a considerable safety risk would result from not doing the maintenance, then clearly more resources (not necessarily more staff) would need to be devoted to the task. In most cases, the risk decisions will not be this clear cut. Cost-benefit ratios are appropriate factors in the discussion, as long as patient safety remains the primary target. For example, if the institution does not have enough spare devices, then the option of obtaining additional equipment or doing the recommended maintenance during off hours needs to be explored. For each deviation from the manufacturer-recommended maintenance, all factors and options should be considered and the rationale documented.

Certain manufacturers do not provide adequate service manuals and/or training to HTM groups to allow them to perform manufacturer-recommended maintenance activities on medical equipment. In particular, if referring to critical equipment, I suspect that most risk management and senior administration teams will be reluctant to allow an AEM without very strong evidence that safety to patients and/or staff can be maintained. Even if the justification is strong, the hospital may have assumed a considerable degree of liability in the event of equipment failure that results in serious injury. The hospital or HTM group always has the option of trying to convince the manufacturer to change their ways or risk loss of future sales.

The CMS requirements allow the use of data from reputable outside sources in justifying an AEM. Taking advantage of those
resources is important. In addition, the manufacturer should be contacted directly if you feel that their existing maintenance recommendations are excessive, and a record of the communications should be kept. You may not get much satisfaction from the manufacturer, but your record of notifying them can become valuable if you decide to implement an AEM.

**Imaging/radiologic equipment.** CMS makes it clear that medical lasers and imaging/radiologic equipment are not eligible for an AEM program.

“Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes” is not allowed to have an AEM because it is governed by CFR-482.26(b)(2). Even though the referenced section of the Code of Federal Regulations only refers to ionizing radiation, CMS has told TJC that the language is intended to include all types of imaging and radiologic equipment, not just those that are radiation-emitting. With this interpretation, ultrasonic imaging equipment, magnetic resonance imaging (MRI), and other imaging equipment are not allowed to be included in an AEM.

For both medical lasers and ionizing radiographic equipment, some HTM groups may want to consider an AEM in spite of the CMS stance. That decision should not be made without thorough discussion with both the risk management group and the group responsible for compliance with CMS. The perceived benefits on the part of the HTM team may be vetoed by one of these groups because of the possibility of major negative consequences.

CMS makes it very clear that the requisite maintenance history for making a decision about an AEM need not come from each individual hospital organization. Even if a specific device type is new to a particular hospital organization, prior history from other sources is acceptable. If a product is new to the market, an AEM is not an option until a sufficient amount of actual experience is acquired.

**Strategies used by maintenance organizations.** The CMS document contains a brief summary of various strategies that maintenance organizations have used as the basis for an AEM. HTM groups often use a variety of these approaches depending on the type of equipment. Wang et al. provide a detailed description of the different strategies.

**AEM Program Documentation**

“For each type of equipment subject to the AEM program, there must be documentation indicating:

- The pertinent types and level of risks to patient or staff health and safety;
- Alternate maintenance activities, and the maintenance strategy and 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;
- Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. 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.
- The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and

For both medical lasers and ionizing radiographic equipment, some HTM groups may want to consider an AEM in spite of the CMS stance. That decision should not be made without thorough discussion with both the risk management group and the group responsible for compliance with CMS.

---

*a* The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the Federal Register by the department and agencies of the federal government.
• Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual. (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the hospital’s required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance 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.”

Commentary
The key phrase in the preceding excerpt is “For each type of equipment subject to the AEM program, there must be documentation indicating.” In my opinion, HTM groups setting up an AEM need to document each manufacturer model combination deviation. In particular, when multiple manufacturers are involved, their maintenance recommendations are based on different risk assessments and design strategies.

Within the same medical equipment type or category (e.g., infusion pumps, electrosurgical units), documentation may be very similar among manufacturers but still have specifics for an individual manufacturer’s model combination. In some cases, several model numbers from the same manufacturer may be similar enough that the AEM documentation can be lumped together. Wherever possible, I recommend that HTM groups use their computerized maintenance management system (CMMS) as the logical repository of this required AEM documentation.

Where to Begin?
HTM groups that have many undocumented deviations from manufacturer recommendations are likely to be overwhelmed by the implications of this ruling. I recommend the following priorities. The order of these priorities is not as important as beginning efforts on all of them as soon as possible.

1. Categorize your CMMS inventory to identify the critical medical equipment. Start with your list of “types” or “categories” within the CMMS. Flag each equipment type as “yes” for those that definitely are “critical” and as “?” for a much larger group of types that bear some discussion with clinicians. Brainstorm with clinicians, particularly from surgery, catheterization labs, and other invasive labs, to supplement your list of types with other equipment types that are potentially critical.

2. Begin the process of identifying in your CMMS the types of equipment (hopefully at the manufacturer/model level) for which you know that you have deviated from manufacturer recommendations. At this point, don’t worry about the details of the deviation, just document that it occurred. If uncertainty exists whether deviation occurred, categorize these types as “not sure” until someone can investigate. If the list of equipment types that need to be researched for this part is overwhelming, start with “critical equipment” types.

3. Understand how existing policies/procedures (both within the HTM group and in the overall organization) mention (or do not mention) the subject of manufacturer maintenance recommendations and deviations from those recommendations. If existing policies/procedures are silent on the subject, decide which ones logically address the overall topic of periodic maintenance of medical equipment or if something new is needed.

4. Have an overall discussion on the topic with administration, the environment of care (or safety) committee, the patient safety committee, and the risk management team about the philosophy and policies that your organization wants to take regarding these issues. I strongly advocate that HTM groups lead the discussion, as they are the ones most knowledgeable about the issues. Be prepared to answer some of the following questions, but don’t worry too much if you don’t know the answers without talking to other stakeholders:
   a. What has been the past practice regarding deviation from manufacturer recommendations?
b. Does documentation exist on deviations that have been done in the past?
c. How big is the gap between current practice and full compliance?
d. Do existing policies/procedures need to be modified or created?
e. What should be the timeline for an action plan?
f. Who will be responsible for coming into compliance with this document? (Hint: it should be HTM.)

5. Develop a methodology for setting up and documenting AEMs in general.
6. Develop an action plan for gaining compliance with these new requirements. Start with the critical equipment, then proceed to equipment deemed important.
7. Review medical devices cared for by third-party vendors (not by the manufacturer) to determine whether they follow manufacturer recommendations.
8. Review types of medical devices in the organization where HTM has no current involvement. Either HTM needs to get involved or the groups in the organization who are responsible need to be part of the assessment and action plan.

Conclusion
Considerable work will be needed by many HTM groups to achieve compliance with this CMS directive. This guidance from CMS represents an opportunity for the HTM field to implement much-needed standardization. Maintenance of medical devices has varied too greatly and often has been based on opinion with little or no real data.

The issues surrounding this CMS directive may be overwhelming for some HTM groups. If so, have a frank discussion with senior leadership as soon as possible. Senior leadership needs to have a full understanding of barriers to compliance and, if necessary, implement an action plan for overcoming these barriers.

This CMS directive has the potential to motivate the HTM industry toward standardizing our practices based on actual data. Let’s get started!

References