AEM Program Guide

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ACTION: Include the names of additional reviewers.

Foreword

QUESTION: Is this needed? If so, who will write it?

Disclaimer

This document represents only the opinion of its author and does not represent an official AAMI position on the subject.

There is a lot of confusion in the HTM community about AEMs. The confusion starts with inconsistent use of AEM-related terminology by regulatory and accreditation entities. The Centers for Medicare and Medicaid Services (the originator of the AEM concept) says that AEM is an abbreviation for "Alternate Equipment Management"; the Joint Commission (which is a major focus of this document) says it stands for "Alternative Equipment Maintenance." Two words of disagreement in a three-word phrase! And that's just the beginning.

What is an AEM program? Why might we want to implement an AEM program? How do we remain compliant with applicable standards and regulations while achieving the benefits of an AEM program? The purpose of the *AEM Program Guide* is to help answer questions like these. Along the way, the document addresses AEM-related terminology and spells out the requirements of an AEM program. More importantly, it offers some ideas for practical implementation of an AEM program, drawing on the good work by many HTM professionals.

Let's jump right in and review the key players:

- **CMS: Centers for Medicare and Medicaid Services**. To receive Medicare and Medicaid funds, which most healthcare organizations in the United States rely heavily upon, we have to comply with Medicare Conditions of Participation. One way to demonstrate compliance is be surveyed by CMS, a process that CMS typically delegates to the state department of health.

  The far more common way to demonstrate compliance is to be surveyed by an accrediting organization with "deeming authority." When we achieve accreditation, we are "deemed" to be in compliance with the Conditions of Participation. Accrediting organizations with deeming authority include The Joint Commission (TJC), the Healthcare Facilities Accreditation Program (HFAP), and DNV GL Healthcare (DNV).

  In the Code of Federal Regulations, the Condition of Participation that addresses medical equipment maintenance, §482.41(c)(2), is surprisingly brief: "Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality." Where the rubber meets the road is Appendix A of the State Operations Manual [1], an irregularly updated document that tells CMS surveyors how to assess compliance.

  With regard to medical equipment maintenance, CMS starts with the belief that manufacturer recommendations are the "gold standard." Who should know better than the manufacturer what's necessary to keep their equipment working safely and effectively? However, within very specific

limitations, CMS allows healthcare organizations to carry out medical equipment maintenance in ways that differ from what the manufacturer recommends. This is the concept of Alternate Equipment Management and the subject of the *AEM Program Guide*.

- **TJC: The Joint Commission.** In the *AEM Program Guide*, I am going to focus on the TJC implementation of the CMS requirements. Why TJC? First, because all the accrediting organizations with deeming authority base their standards on CMS requirements, their AEM rules are equivalent. Second, because most healthcare organizations use TJC for accreditation, the TJC rules are the most widely familiar. However, as needed, I will provide a crosswalk between CMS and TJC requirements. If you use HFAP or DNV, double-check their AEM rules and adjust as needed.

  Specifically, I'm going to focus on the TJC requirements as laid out in the *2017 Environment of Care Essentials for Health Care* [2]. This is an annually-updated publication that, in my opinion, TJC-accredited HTM programs should buy every year. In my consulting work, I still find healthcare organizations that are running their HTM programs on outdated standards. Don't be one of them!

  Even more specifically:

  - TJC has several different accreditation programs. The AEM concept applies only to the Hospital Accreditation Program (HAP) and the Critical Access Hospital (CAH) program. I will be quoting the HAP material exclusively, but the CAH material is nearly identical. If you are in a critical access hospital (you know who you are), double check your standards manual.
  - At some places within the HAP standards you will find the phrase, "For hospitals that use Joint Commission accreditation for deemed status purposes." That (probably) means you and that's the material I will be quoting. The most prominent exceptions are Veterans Administration and Department of Defense hospitals that voluntarily pursue TJC accreditation but do not receive Medicare and Medicaid funds from CMS.

  TJC says that AEM stands for "Alternative Equipment Maintenance," but it is identical to the CMS phrase "Alternate Equipment Management." Throughout the *AEM Program Guide*, I use "AEM."

Unfortunately, we in the HTM community have also been guilty of inconsistency in terminology. However, when it comes to AEM program implementation, terminology matters. Here are some of the terms I use in the *AEM Program Guide*:

- **PM: Planned Maintenance**. In this document, when I write "PM" I mean "planned maintenance," which is maintenance work we do on some sort of schedule. CMS [1] says all equipment must be

"inspected, tested, and maintained." TJC [2] calls for "maintaining, inspecting, and testing." The *AEM Program Guide* is all about PM.

- **PM Activity and PM Frequency**. TJC [2] and CMS [1] both emphasize that PM encompasses both "activities and associated frequencies." In the *AEM Program Guide*, I use "PM Activity" to refer to *what* we do during PM and "PM Frequency" to refer to *when* we do it.

  Note that CMS and TJC give us a lot of leeway on the concept of "PM Frequency," including interval-based maintenance (PM performed at fixed time intervals), metered maintenance (PM performed after a specified number of uses, hours of usage, etc.), predictive (condition-based) maintenance (PM performed before performance degradation, as indicated by periodic or continuous assessment of equipment condition), reactive (corrective, breakdown, "run to failure") maintenance (PM performed upon equipment failure), and reliability-centered maintenance (a multi-factorial elaboration of condition-based maintenance).

- **Device Restoration and Safety Verification**. Here I am borrowing liberally (with permission) from AAMI's Maintenance Procedures Task Force (Sidebar 1), which divides PM activities into two categories:

  - **Device Restoration**. DR activities restore parts that need periodic attention improve reliability and reduce the likelihood of failure. This is genuine *preventive* maintenance that is intended to *prevent* equipment failures. DR activities are useful for moving parts that are subject to wear and need to be cleaned, lubricated, refurbished, or replaced (such as bearings, drive belts, or pulleys) and non-moving parts that are subject to some other kind of deterioration over time and need to be refurbished or replaced during the working lifetime of the device (such as gaskets, filters, flexible tubing and batteries). For medical equipment, batteries are the most common focus for DR activities, but there are other examples as well.

  - **Safety Verification**. SV activities determine if performance and safety characteristics are within specified limits. This corresponds to the "inspecting and testing" activities referred to by CMS [1] and TJC [2]. SV activities are intended to discover deterioration of performance or safety that is not obvious to the equipment user, sometimes referred to as hidden failures. Typically, this requires specialized knowledge or test equipment not available to the user. Examples include defibrillator output testing (performance characteristic) and electrical safety testing (safety characteristic), among many others.

----------Sidebar 1 *about here*----------

- **PM Procedure**. The PM procedure for a particular type of medical equipment specifies all the planned maintenance activities and associated frequencies required to maintain the equipment. This typically includes several activities that are performed together. Generally speaking, out CMMS software keeps track of when to carry out the PM procedure and generates a list of activities that the front-line maintenance technician carries out.
- **PM^{OEM} and PM^{AEM}**. To reduce my typing workload, I use "PM^{OEM}" to refer to planned maintenance that follows the manufacturer recommended procedure and "PM^{AEM}" for planned maintenance that follows an AEM procedure.

To practice all this AEM-related jargon, let's consider the imaginary Acme model 123 medical device as an example. The Acme 123 service manual calls for the following PM activities and frequencies:

Step 1. Replace the beaucoup-bucks widget every 24 months. (By the way, this is a DR activity.)

Step 2. Verify the function of the doohickey sensor every 12 months. (And this is an SV activity.)

Step 3. Give three cheers to the manufacturer every 12 months. (A silly activity.)

That's the PM^{OEM} procedure for the Acme 123.

Suppose we decide to put our Acme 123 devices into our AEM program. Our PM^{AEM} procedure might consist of the following activities and frequencies:

Step 1. Take a look at the widget every 24 months and replace it only if it doesn't look right.

Step 2. Verify the doohickey function every 18 months instead of every 12 months.

Step 3. Never give three cheers to the manufacturer.

These changes might be good ideas (reducing maintenance costs without reducing safety) or bad ideas (reducing the safety of the Acme 123). How do we separate the good ideas from the bad ideas? How do we decide if it's safe to streamline (or eliminate) PM activities? How do we decide if it's safe to reduce PM frequencies? The *AEM Program Guide* is intended to help answer those questions.

Unfortunately, there is not yet a consensus on exactly how to create an AEM program. Fortunately, there is a lot of creative activity in the published literature, at professional conferences, and among thought leaders in the HTM community. I have done my best to incorporate the best of these ideas into

the *AEM Program Guide*, which has benefited from generous input by the reviewers listed at the beginning of this document.

Importantly, as this is being written, AAMI has up a committee to develop a formal AEM standard for the profession. That effort will take a while to reach fruition, but it will give us detailed guidance for compliance activities that (it is devoutly to be hoped) should be recognized by CMS and by the various accrediting organizations. In my not-so-humble opinion, It's high time for the HTM community to move from a reactive stance on regulation (struggling to comply with regulations developed independent of the HTM community) to a proactive stance (participating in the development of cost-effective regulations). So stay tuned for more information about the standard and plan to participate in its development. In the meantime, here are some ideas to think about while designing an AEM program today.

Why consider implementing an AEM program?

The answer to that question is simple: to save time or money or both. When we can reduce our costs while achieving the same level of safety, we should do it. Adopting an AEM procedure is not an academic exercise; it's good business [3].

So how do we identify good candidates for the AEM program? One approach is to look at where we're spending our PM hours and dollars. PM^{OEM} procedures for some types of medical equipment are lengthy and time-consuming. Even if we have only a few of these devices in your inventory, we may be able to save a significant amount of money by shifting from PM^{OEM} to PM^{AEM}.

On the other hand, there are many types of medical equipment that don't require much PM individually but, because there are so many of them, even a small reduction in PM time can add up to substantial savings. If we have 500 Acme 123 devices in our inventory, and can save 5 minutes each year on each PM, we've saved more than 40 hours of work.

Check your CMMS (Computerized Maintenance Management System) records for the last year or two. Which device types, by make and model, took the most PM time or money? That's your initial list of device types to look at for shifting from PM^{OEM} to PM^{AEM}. By the way, while you're making your plans, be sure to take a look at Sidebar 2.

----------Sidebar 2 *about here*----------

What are the rules?

In our quest to save money on PM, we need to follow some rules, all of which are based on CMS [1] requirements and incorporated into TJC [2] standards. There is actually only one TJC standard that addresses AEMs: HAP EC.02.04.01. Under that standard there are four Elements of Performance in which the AEM rules are spelled out. The EPs that apply to AEM program are detailed in the following tables:

Table 1. HAP EC.02.04.01 EP 4.

Table 2. HAP EC.02.04.01 EP 5.

Table 3. HAP EC.02.04.01 EP 6.

Table 4. HAP EC.02.04.01 EP 7.

In each table, the first column (blue background) has the official TJC text. The second column (green background) contains my unofficial comments and, as appropriate, a crosswalk to CMS requirements. You might think of these columns as the "packed" and "unpacked" versions of the requirements.

As we work through Tables 1-4, there are a couple of symbols that might need explanation. One is the Ⓓ, by which TJC signals that written documentation of compliance is required. You'd think that could go without saying. When thinking about TJC compliance and documentation, Ⓓ stands for Duh!

The other symbol we will encounter is R, which indicates "an identified risk" in TJC-speak. Don't worry about this symbol; just comply with the EP.

One other thing to note at the outset is that AEM programs apply only to *medical* equipment. (Well, to be precise, CMS and TJC do allow hospitals to adopt AEM programs for utility systems. What I mean is that, for the purposes of this *AEM Program Guide*, we need to consider only medical equipment and not computer equipment, communication equipment, test equipment, and all the other odds and ends of non-medical items that might be in our HTM inventory.)

CMS [1] defines medical equipment as "devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient." TJC [2] defines the term as "fixed and portable equipment used for the diagnosis, treatment, monitoring, and direct care of individuals." Either definition is fine, although TJC-accredited hospitals probably ought to use the TJC definition. Choose one and include it somewhere in the MEMP.

HAP EC.02.04.01 EP 4 (Table 1) says, basically, that every item in the medical equipment inventory must be covered by either a PM^{OEM} procedure or an PM^{AEM} procedure. Whichever type of procedure is adopted, the PM activities and PM frequencies need to be spelled out, in writing.

---------- Table 1 *about here* ----------

Where and how you spell out the activities and frequencies is up to you. PM frequencies are typically entered into the hospital's CMMS work order scheduling module [4]. Some hospitals build the PM activities into the CMMS database so that each PM work order specifies the tasks to be done. Others rely on printed or online descriptions of PM activities that maintenance personnel can refer to as needed. In my experience, the first method produces better compliance and is more impressive to surveyors, but your mileage may differ.

There are two fundamental principles embedded in Note 1 of EP 4. The first is that AEM procedures "must not reduce the safety of equipment." That entails a couple of questions:

- How do we measure equipment safety? The HTM community has long lived by the watchwords, "safety" and "effectiveness." My (simple-minded) definitions are that "effectiveness" means the equipment does what it should (achieve a clinical objective) and "safety" means it doesn't do what it shouldn't (hurt someone).

  So, one approach would be to measure how often some type of equipment hurts someone. The good news (for the patient) and the bad news (for statistical analysis) is that the answer is "only rarely." And if we consider only the subset of adverse events that might have been averted by PM (which, after all, is the only thing relevant to AEM planning), the number of events available for statistical analysis in a particular hospital is mighty small (but take a look at Sidebar 1 for a long-term effort to address this issue).

  As a result, at least in the short term, we need to use proxy metrics to measure medical equipment safety. Metrics that have been suggested include failure rate (failures per device per year), MTBF (mean time between failures), downtime (hours per device per year, relative to required uptime), and so on. Although these metrics are only proxies for equipment safety, good CMMS software can automate their calculation and make it easy to identify trends early [4].

---------- Sidebar 3 *about here* ----------

- How do we make sure equipment safety does not deteriorate under an PM^{AEM} procedure? Ideally, we should have before and after data. Some hospitals have been carefully collecting data (proxy

measures of safety) for years and, therefore, have a good baseline. Other hospitals have not been so careful in the past and have opted to run PM^{OEM} procedures exclusively for a period of time to establish their baseline. Still other hospitals are moving ahead without a baseline in place and implicitly or explicitly setting a limit for their equipment safety metric that they believe will allow them to identify PM-related problems (see Sidebar 2).

Another approach is to track "PM-preventable" equipment failures. The idea is that discovery of a failure that could have been prevented by "better" PM should raise a red flag about equipment safety. The response to the red flag is to review the existing PM procedure for opportunities to improve it. Although this approach has promise, its implementation is problematic (Sidebar 3). To yield reliable data, the term "PM-preventable failure" must be defined in a way that allows front-line maintenance technicians to readily recognize the failure and consistently record it in the CMMS database.

I think any of these methodologies can work if the hospital is clear about its rationale and bases its decisions on sound reasoning (and puts all this in writing). Whatever methodology your hospital chooses, be sure to track the metric regularly and take action when the metric hits whatever limit you have set for it (and document all this). Are you tired of me telling you to document it in writing?

The second fundamental principle in Note 1 of EP 4 is that AEM procedures "must be based on accepted standards of practice." The note cites "ANSI/AAMI EQ56: 2013" [5] as an example of an accepted standard of practice; however, EQ56 has very little information that we can actually use for designing an AEM procedure. Take a look at Sidebar 4 for more thoughts along these lines.

----------Sidebar 4 about here----------

In the (hopefully very temporary) absence of a *formal* standard that focuses on AEM programs, we can look to *de facto* standards of practice as described in the published literature. Not everything that gets into print is worth relying on, but there's good stuff out there that can be regarded as representing the professional consensus and standard of practice. However, *caveat emptor*. Some of the proposed AEM policies I have seen are, in my opinion, simply not compliant with CMS and TJC requirements. That's why the *AEM Program Guide* goes into such (excruciating?) detail about those requirements.

As we encounter a new AEM-related idea, we should ask ourselves three questions:

- Does it save time or money?
- Does it reduce safety?

- Does it comply with the rules?

EP 4 also sets requirements for the "on-schedule completion of PM" metric for equipment covered by PM^{OEM} procedures (Note 2 of the EP) and PM^{AEM} procedures (Note 3 of the EP). After some back-and-forth between TJC and CMS, the requirement for both PM^{OEM} and PM^{AEM} procedures is now 100% on-schedule completion of PM (www.jointcommission.org/assets/1/6/NCC_LSC_July2017_Prepub.pdf). And that's all I have to say about that.

HAP EC.02.04.01 EP 5 (Table 2) is the taboo list, the list of equipment types that are not eligible for PM^{AEM} procedures. The first taboo item is basically a disclaimer regarding anything that federal law, state law, or Medicare Conditions of Participation say must use PM^{OEM} procedures. In other words, if the law says to do something, do it. As this is being written, I am not aware of any federal laws that apply to medical equipment in this regard. However, check your state laws, especially if you're in a state that likes to go above and beyond the feds.

---------- Table 2 about here ----------

Also not eligible for inclusion in an AEM program are "medical laser devices" and "imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)." What's the rationale for these taboos? Darned if I know, but bewilderment should not deter us from following the rules.

Identifying medical laser devices is pretty straightforward. The FDA (which CMS cites) defines medical lasers as "medical devices that use precisely focused light sources to treat or remove tissues (www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/surgicalandtherapeutic/ucm115910.htm#ip). Don't overthink this; for example, don't put something on your hospital's taboo list just because it's got a laser somewhere in it.

Interpretation of the "imaging and radiologic equipment" taboo has led to some controversy in the HTM community, especially with regard to the phrase "diagnostic or therapeutic." CMS [1] specifically points to §482.26(b)(2), which refers to "devices used to deliver diagnostic or therapeutic radiologic services." Following the rabbit hole a bit further underground leads to the introductory material for §482.26, which states that "radiologic services encompass many different modalities used for the purpose of diagnostic or therapeutic medical imaging and radiation therapy." It also says that "some of these modalities (radiography, computer tomography, fluoroscopy) utilize ionizing radiation ... while others

(ultrasound, magnetic resonance imaging) use other forms of non-ionizing radiation ... to diagnose, monitor, or treat medical condition."

With that background information in mind, I don't think we need to look too far and wide for items to put on the taboo list. Are ultrasound therapy machines (ultrasound + therapeutic) taboo? Are simple doppler blood flow detectors (ultrasound + diagnostic) taboo? I say it's over the top to consider those devices as taboo. Stick to the core intent of the CMS requirements. When you hear hoofbeats outside your window, look for horses, not zebras (at least in the western hemisphere).

The final taboo is "new medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies." As shown toward the bottom of the first column in Table 2, the term "maintenance history" is construed rather generously, including the experience of the hospital and its contractors (maintenance service providers, presumably) and information from recognized sources. Refer to Sidebar 1 for information about the national database that AAMI's Maintenance Practices Task Force is developing.

It's also important to understand what "new medical equipment" actually refers to. If you have fifty of the Acme 123 devices in your medical equipment inventory, it's unreasonable to regard the fifty-first as "new" to your hospital. So "new medical equipment" really refers to a new *type* of medical equipment. Extending that principle leads to the idea that "new medical equipment" refers only to equipment based on technology that is unfamiliar to your hospital. As you write your AEM policy you need to decide where on that continuum you want to be (see Sidebar 5 for further commentary on the role of professional judgment).

----------Sidebar 5 about here----------

Another way to define "new" is to calculate device-years for equipment in your inventory. If you have had ten of some type of equipment for five years, that's 50 device-years. There is some uncertainty about how to do the calculation in practice, but the Maintenance Practices Task Force (Sidebar 1) is working on it and has tentatively suggested 50 device-years as sufficient for purposes of compliance with EP 5.

Whatever approach you take, your AEM policy should include your own list of taboo items, the specific types of medical equipment that your hospital regards as ineligible for AEM procedures. My recommendation for the list is that rather than simply repeating the CMS or TJC language (e.g., "Imaging and Radiological Equipment") you should use whatever nomenclature your CMMS uses for devices types

(e.g., “16260 Scanning Systems, Magnetic Resonance Imaging,” and so on). ECRI Institute’s Universal Medical Device Nomenclature System (UMDNS) can be cumbersome, but it’s comprehensive and standardized [4]. Then load the taboo list into your CMMS. A well-designed CMMS will flag any attempts to put a taboo item into your AEM program.

The good news: Your list of taboo items will very probably include only a small fraction of all medical equipment in your inventory. That means the large majority of device types will be eligible for inclusion in the AEM program, giving you many opportunities to reduce your PM workload.

HAP EC.02.04.01 EP 5 (Table 3) addresses a couple issues, one small and one large. The small issue is about the qualifications required of the person making AEM-related decisions. The short answer, as discussed in the upper-right-hand cell of Table 3, is “most HTM professionals, at least for most types of medical equipment.” However, keep in mind the comments of Sidebar 5 as you ponder this issue.

---------- Table 3 about here ----------

The big issue in HAP EC.02.04.01 EP 5 (Table 3) is about how to decide if it’s safe to use a PM^{AEM} procedure for a particular type of equipment and to modify one or more PM activities or PM frequencies that are recommended by the equipment manufacturer.

TJC says the decision must be based on written criteria that include several factors (each of which is “unpacked” in in the right-hand column of Table 3):

- How the equipment is used.
- Likely consequences of equipment failure or malfunction.
- Availability of alternative or backup equipment.
- Incident history of identical or similar equipment.
- Maintenance requirements of the equipment.

I think a reasonable way to comply with this EP is to put into your AEM policy your own “unpacked” version of these factors. You can also add other factors that you want to consider in your AEM-related decision-making. Some examples I’ve seen: knowledge level of clinical users, the presence of self-test capabilities.

The challenge is how to weigh the various factors and reach a decision about putting the equipment into the AEM program. I can imagine some sort of algorithm that combines the ratings on each of the

factors, but that strikes me as rather artificial and only superficially scientific. What evidence or engineering principles would the algorithm be based on? But people do love "plug and crank" processes, so don't let me stand in your way.

Before we go further down this road, take a look at Sidebar 6. It's time for straight talk about risk. Go ahead, I'll wait ...

----------Sidebar 6 about here----------

HAP EC.02.04.01 EP 5 (Table 3) is an engraved invitation to apply a genuine risk assessment methodology at the level of medical equipment types. What I mean is that we can do a risk assessment of Acme 123 devices as a particular type of medical equipment. (Later we will apply the risk assessment process to PM activities and PM frequencies as recommended by the manufacturer of the Acme 123.)

Suppose (referring to Figure 1) that we rate failures of the Acme 123 (using, for example, data in our CMMS) at Probability 2 and Severity 2. That means that there is a low risk of failure from whatever causes. I wouldn't hesitate to evaluate it for inclusion it our AEM program and see if we can save some time or money on PM.

Alternatively, suppose that we rate failures of the Acme 123 at Probability 3 and Severity 3. That puts it in the high-risk category for failure from any cause. Does that mean we should exclude it from our AEM program? I don't think so, especially if there is a substantial opportunity to save time or money on PM. What I do think is that I'm going to be very cautious in adopting a PM^{AEM} procedure for the Acme 123. How cautious, decide for yourself how risk averse your hospital is (and, of course, document how you implement that preference in your AEM policy).

In these examples, I have talked about risk assessment for failure *from any cause*. That's how CMS [1] and TJC [2] talk about it. However, a reasonable alternative might be to do the risk assessment for *PM-preventable* failures, even though that's technically not how the CMS [1] and TJC [2] rules are written. I am sympathetic to this alternative and it is part of some of the best thinking on the topic. However, as described in Sidebar 3, I think we should be proceed with caution.

Why in the world would we consider adopting a PM^{AEM} procedure for a high-risk device? Remember that an AEM policy does not necessarily throw out *all* of the manufacturer's PM recommendations. Suppose we have a high-risk device for which the manufacturer recommends annual electrical safety testing, which was typical practice until CMS and TJC adopted the 2012 edition of NFPA 99 (Health Care Facilities Code) [7]. There is simply no longer a requirement to do routine electrical safety testing for most

medical equipment [10]. Why not implement a PM^{AEM} procedure that drops annual electrical safety testing but leaves all other PM activities and PM frequencies at manufacturer-recommended levels? You may be one of those people who loves electrical safety testing. If so, keep doing it. If, on the other hand, you prefer to rely on a consensus-based standard that both CMS and TJC have adopted, implement the abbreviated PM^{AEM} procedure and save yourself some time without adversely impacting equipment safety.

Compliance with HAP EC.02.04.01 EP 7 (Table 4) is easy. Configure a field in the CMMS asset table (let's call it "AEM Status," but let your creativity run wild) that indicates whether or not a particular asset is being maintained under an AEM procedure. For example:

---------- Table 4 *about here* ----------

AEM Status = 1	Medical equipment maintained under manufacturer recommendations; *not eligible* for AEM. (This is for the "taboo" items described in Table 2.)
AEM Status = 2	Medical equipment maintained under manufacturer recommendations; *eligible* for AEM.
AEM Status = 3	Medical equipment maintained under AEM procedure.
AEM Status = 4	Non-medical equipment. (This is for other types of equipment you maybe carrying in your CMMS database.)

When you configure the CMMS, make sure that the AEM Status codes are "exhaustive" (covering all possible situations) and "mutually exclusive" (with clear, non-overlapping definitions) [4] so that every asset has an accurate entry for AEM Status.

How to create an AEM procedure

Let's say we have identified a type of medical equipment that we might want to create a PM^{AEM} procedure for. That means (a) it's not on our taboo list, (b) it meets our decision-making criteria for inclusion in our AEM program, and (c) we think we have a chance to save time and money on its PM. Where do we go from here?

The first thing to do is to get ready to document (in writing) everything we do (preferably in a computer-readable format; who wants to file more paper?). Then we make a list of the PM activities and associated PM frequencies that the manufacturer recommends (or at least the ones that we think we might want to modify).

Examine each manufacturer-recommended PM activity and see which of them are really needed. Some of these are no-brainers. We have already talked about routine electrical safety testing. How about turning on the otoscope/ophthalmoscope to see if the light comes on? How does that improve safety or effectiveness? Why does it take a skilled maintenance technician to do that? It's time for us to stop doing dumb stuff!

Let's put this into "risk assessment" terminology. What is the severity of an otoscope/ophthalmoscope lamp failure? Not much. The user is immediately aware of the failure. The patient is not harmed. A substitute unit is typically nearby.

What is the probability of an otoscope/ophthalmoscope lamp failure? Not much. And, in any case, turning it on and off to test it increases (however marginally) the probability of failure, rather than decreasing it.

Are there ways to mitigate the already very low risk of lamp failure? Show users how to replace lamps and give them a box of spares? Switch from incandescent lamps to LEDs? Maybe, but *more PM is a waste of time and money*. Adopt a PM^{AEM} procedure that drops lamp testing.

For some equipment, we'll find that there are no other PM activities worth doing. If so, switch to a "run to failure" strategy with, at most, a quick visual inspection (for obvious physical damage) when we're in the area doing genuinely useful PM work.

Now let's consider a DR (Device Restoration) activity that a device manufacturer calls for. The majority of medical equipment is electrical rather than mechanical and so the number of DR activities is relatively low. There are filter changes, pneumatic device overhauls, and so. Perhaps the most common is battery replacement, so we can use that as an example. Do our CMMS records show that batteries don't have to be replaced as often as the manufacturer recommends? Do we believe (on the basis of experience or a literature review or some other source) that it's less expensive to replace batteries on a fixed schedule than to do battery testing and conditioning? If a risk assessment says that's reasonable, adopt a PM^{AEM} procedure that modifies the manufacturer's PM activity and/or PM frequency. If you wish, can retain all other manufacturer-recommended PM activities and PM frequencies.

Modifying SV (Safety Verification) activities and frequencies can be somewhat more challenging (except, perhaps, for routine electrical safety testing). Recall that SV activities are intended to discover deterioration of performance or safety that is not obvious to the equipment user, often requiring specialized knowledge or test equipment.

The phrase “not obvious to the equipment user” is important. Respiratory Therapy and Anesthesia technicians routinely (at least daily) check the calibration of their oxygen analyzers. Is it necessary for HTM personnel to duplicate these checks during PM?

Let’s take as an example, flow rate testing for infusion pumps. This is, of course, a critical parameter for infusion pump functionality. And flow rate errors can go unnoticed by the infusion pump operator if the rate is not dramatically out of specification. Should we stop doing flow rate testing? I would be reluctant to do that because my incident investigation experience tells me that flow rate errors are quite common (probability) and my knowledge of intravenous medication delivery tells me that both under-infusion and over-infusion can cause serious harm (severity). I could also factor in my observation that reported infusion rate errors are most often the result of programming errors, or failures of disposables and accessories, rather than PM-preventable equipment failure (see Sidebar 3). But my initial, subjective, back-of-the-envelope risk assessment is not good enough. Do a genuine risk assessment before proceeding.

And keep in mind that there are alternatives to completely dropping flow rate testing. We could test less often. We could adopt a less complicated testing procedure (e.g., testing for shorter times at fewer different flow rates). I’m a firm believer that we’re in the business of screening for problems rather than duplicating the manufacturer’s quality control procedures. When we go to the health fair, we get speedy but approximate values for blood lipids using a finger prick; only if the numbers are questionable do we go in for full-scale (accurate, slow, expensive) blood work. I think that’s the way to think about our SV activities.

So here are the basic steps for creating a PM^{AEM} procedure. Each step can be elaborated as appropriate for you individual HTM program. And after you have worked out the details you can, assuming you have better graphic-design skills than I do, turn these steps into a flow chart.

Step 1 Select a type of medical equipment that might benefit from inclusion your AEM program; that it, you think you can save time or money by switching from PM^{OEM} to PM^{AEM} without reducing safety. Let’s say, the Acme 123.

Is it on your taboo list? If so, you can’t put it in your AEM program. Do not pass Go. Do not collect $PM savings.

Does the manufacturer say no PM is needed? Adopt a PM^{AEM} strategy of corrective-maintenance-only (run to failure) with, at most, periodic visual inspection during area sweeps. Skip to Step 3.

Does the manufacturer not provide PM recommendations? You're free to develop a PM^{AEM} procedure that makes good sense. This is where you might use a resource like ECRI Institute's *BiomedicalBenchmark* for guidance.

Does the manufacturer say that only the manufacturer can do PM? First, don't buy any more stuff from that manufacturer. Second, you're free to develop a PM^{AEM} procedure, but be sure you understand the manufacturer's rationale.

Run the Acme 123 through a risk assessment process for (1) the probability and severity of equipment failure from any cause and/or (2) the probability and severity of PM-preventable equipment failure. Use this information to temper your AEM enthusiasm: Higher levels of risk require greater caution and wider margins of safety.

Step 2. List the manufacturer's recommendation for PM activities and PM frequencies (or at least those that you think might worth modifying). What does the Acme company recommend for the Acme 123?

Are there PM activities that can safely be modified or eliminated?

Are there PM frequencies that can safely be extended?

Are there other maintenance strategies, such as moving from interval-based maintenance to RCM, that can safely reduce maintenance costs?

For each of these questions, base your answers on good evidence and good professional judgment. You can also run each proposed modification of a PM activity and associated PM frequency through a risk assessment for (a) the probability that the proposed modification will reduce equipment safety and (b) the severity of the potential reduction in equipment safety. If the risk is low, proceed.

Thoroughly document your decision-making process.

Step 3. Create and implement the new PM^{AEM} procedure.

If there are no PM activities worth doing, the new PM^{AEM} procedure is corrective-maintenance-only (run to failure) with, at most, periodic visual inspection during area sweeps.

For the PMOEM activities or frequencies you have decided to modify, spell them out in the new PM^{AEM} procedure.

If there are some PM^{OEM} activities and frequencies that you have decided *not* to modify, simply cut-and-paste them into the new PM^{AEM} procedure.

Follow whatever approval process you have specified in your AEM policy (e.g., notification of the EOC Committee), communicate the new PM^{AEM} for the Acme 123 to front-line maintenance technicians, and update your CMMS.

And (you knew this was coming) thoroughly document your actions.

How to write an AEM policy

There is no consensus about the best way to write an AEM policy. So far, TJC seems to be pretty open to a variety of approaches. The key is to write a reasonable policy that follows the rules (with plenty of documentation built in). However, TJC leniency could decline over time, with surveyors increasingly expecting hospitals to justify the policy choices they have made and to provide definitive evidence that equipment safety has not been eroded.

How are CMS surveyors dealing with AEM programs? There's less information on this because only a small minority of hospitals undergo CMS survey. There's also more variability with CMS surveys because they are typically conducted by state health department staff who follow, with limited training and experience, the State Operations Manual [1]. Again, the best advice is to follow the rules and document that you've done so.

Sometimes I am asked whether the AEM policy should be a stand-alone policy that is referred to in the Medical Equipment Management Plan or a section of the MEMP itself. Either way is fine with me (and, more importantly, with CMS and TJC), but if pressed I would lean toward the first option. I think the MEMP works best if it's short, serving as a sort of "executive summary" [11]. And, because our AEM policies are likely to evolve over time, it's probably easier to leave the MEMP intact while modifying only the AEM policy.

So I can't provide a cut-and-paste AEM policy template. Instead, I offer Table 5, which I'm calling an AEM policy skeleton; the bare bones for you to put some meat on. The purpose of the skeleton is to identify the essential components (the bones) of an AEM policy. How you flesh out the bones is up to you.

Let me know how it goes!

— Matt Baretich
Fort Collins, Colorado

---------- Table 5 *about here* ----------

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Sidebar 1. AAMI Maintenance Practices Task Force.

In 2015, AAMI established the Maintenance Practices Task Force "to begin exploring whether an approach known as reliability-centered maintenance (RCM) should be adopted on a wider scale throughout the field of healthcare technology management."

One of the Task Force's objectives is to develop "a scientifically sound, RCM-based methodology for determining which types of medical devices are actually made safer by periodic planned maintenance (PM)." That clearly has implications for AEM program design.

There are two aspects of the Task Force's work that I have incorporated into the *AEM Program Guide*:

1. The well-crafted terminology that divides Planned Maintenance (PM) into Device Restoration (DR) and Safety Verification (SV). This lets us converse more precisely about these conceptually distinct types of activities.
2. The careful use of standard methodologies for risk assessment. As discussed in Sidebar 6, the HTM literature is filled with muddled thinking about the idea of "risk." It's time to clean up our conversations regarding this foundational concept.

For more information on RCM and the Task Force's activities, check out www.htmcommunitydb.org. And, to continue their evidence-based work, they need real-world maintenance data. Please consider contributing to their growing database.

Sidebar 2. Do the right thing.

For the most part, the *AEM Program Guide* assumes that you have been carefully following PM^{OEM} procedures for a good while. I'm not going to point any fingers, but my HTM consulting work tells me that there are (gasp!) HTM programs that have been using for many years for some or all of their medical equipment.

If these non-PM^{OEM} procedures were based on sound principles, and if you have the data to show that these procedures have not reduced equipment safety, then that's fine. Demonstrating that safety has not been reduced could be difficult if you don't have a baseline of PM^{AEM} data. However, for very low risk equipment (e.g. otoscope/ophthalmoscope units) that are maintained under a corrective-maintenance-only (run to failure) strategy, safety of the PM^{AEM} is self-evident. Be sure to roll these into your AEM program.

On the other hand, if you've been using the classic "stuff we've been doing for a long time because that's the way we've always done it and it's probably OK" methodology, it's past time to clean up your act. Write the policy for your AEM program and start examining your past practices. If you can't justify what you've been doing to maintain a particular type of equipment, either implement the PM^{OEM} procedure or develop a genuine PM^{AEM} procedure as described in the *AEM Program Guide*.

Does that sound like a lot of work? Keep in mind that CMS [1] tells its surveyors to focus their review of a hospital's AEM program on "Critical Equipment" (see Sidebar for an explanation of the terminology), so that's a good place to start. Be sure to write up a performance improvement plan (and share it with the EOC Committee) so that surveyors will know you're working on it. Then get to work!

Sidebar 3. PM-preventable failures.

CMS [1] and TJC [2] talk a lot about equipment failure. The objective, of course, is to reduce the impact of equipment failure on patient safety.

Equipment failure can be thought of as a subset of "use error." A use error event occurs when a clinician attempts to achieve a clinical objective (diagnosis, treatment, monitoring, and so on) that requires the use of medical equipment, but is not successful.

There are many possible causes for use error. And, as RCA (Root Cause Analysis) and HTM experience tell us, there are many causes of use error. Indeed, a single use error event may have multiple, interacting causes of various types. As HTM professionals, we need to be prepared to participate effectively in medical device-related incident investigations and formal RCA processes.

On a day-to-day basis, however, HTM professionals focus on actual and reported equipment failures. How do we learn about apparent equipment failures? Here are the most common ways:

- Service calls. HTM receives a report that a medical device has failed. Sometimes the report includes details about the apparent failure; sometimes a device just shows up with a "BROKEN" sign on it. We check out the equipment and, if necessary, repair it.
- PM procedures. While carrying out a PM procedure, we discover a failure. It could be that an SV (safety verification) PM activity did not meet specifications (the defibrillator output was low, for example). It could be that a DR (device restoration) PM activity identified a problem (an O-ring that was to be replaced had already failed, for example). Or it could be physical damage that was found during visual inspection. Depending on our HTM policies, we may repair the equipment under the PM work order or open a CM (corrective maintenance) work order.

Regardless of how we learn about the equipment failure, the follow-up question is this: Could the identified failure have been prevented (or made less likely) by "better" PM? If the answer is Yes, a PM-preventable failure has been identified. That triggers a review of the existing PM procedure for possible modification. That might involve adding a PM activity, making an existing PM activity more thorough, increasing the PM frequency for a PM activity, adopting a different PM approach (e.g., calendar-based or condition-based), or combinations of these.

To trigger the review, we need to have a very practical, working definition of "PM-preventable failure." Our definition needs to meet the following criteria:

- Easily applied by front-line maintenance technicians. The definition should capture essentially all occurrences of PM-preventable failures without capturing other types of failures. Recognition of a PM-preventable failure needs to be consistent from one technician to another within the HTM program. And, in the long run, the HTM community should work toward a definition that is consistent from one HTM program to another.
- Easily documented in the CMMS. Most CMMS databases have one or more fields for recording key characteristics of a work order. For example, there might be a Failure Code field with allowed values of Use Error, Random Electronic Failure, Abuse, Failed Critical Task, No Problem Found, and so on [4]. It might be possible to use one of the existing fields if it is configured properly. However, in my experience, such fields often are not configured to have a set of allowed values that are exhaustive and mutually-exclusive, which makes them problematic for AEM program quality assurances purposes. My recommendation is to have a separate "PM-Preventable" field on all work orders (PM and CM), with allowed values of Yes and No. Ideally, this should be a required field; alternatively, blank values in this field should audited periodically by HTM supervisory staff.

I have seen some definitions for PM-preventable failure, but I am not yet convinced they fully meet these two criteria. My recommendation is to take care in crafting your definition and associated policies, because high-quality data are essential for high-quality decision-making about medical equipment maintenance.

On a more philosophical note, we need to be careful about the distinction between "equipment failure" from all causes and "PM-preventable equipment failure." In some contexts, the broader term is more appropriate. For example, CMS [1] asks us to consider "the timely availability of alternate devices or backup systems in the event of equipment failure or malfunction." That's about equipment failure in general, not about PM-preventable failure.

Elsewhere, CMS [1] asks us to describe "how incidents of equipment malfunction are investigated, including whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and how a determinization is made whether or not the malfunction resulted from the use of an AEM strategy." That's clearly about PM-preventable failure.

Sidebar 4. Standards of practice.

Many of the AEM-related issues that we're thinking about as HTM professionals also apply in the parallel universe of Healthcare Facility Management (HFM). Just as CMS and TJC refer to EQ56 [5] as an "accepted standard of practice" for HTM, they also refer in the same way to the ASHE (American Society for Healthcare Engineering) publication, *Maintenance Management for Health Care Facilities* [6]. (For those of us who are sticklers for detail, CMS [1] cites the 2009 edition, even though the current edition is 2014.)

The ASHE [6] document is more of a guideline rather than a standard, and consists primarily of generic maintenance procedures for HFM equipment. In many ways, it is similar to the IPM (Inspection and Preventive Maintenance) component of ECRI Institute's *BiomedicalBenchmark* program, which contains generic maintenance procedures for HTM equipment (www.ecri.org/biomedicalbenchmark).

That raises some interesting questions in my mind:

- Can we simply take the generic ECRI Institute IPM tasks and schedules and call them our AEM procedures? I think that's a big stretch, even though ECRI Institute is unquestionably a recognized source of credible HTM-related information. To the best of my knowledge, ECRI Institute does not represent their IPM guidelines as compliant with CMS and TJC requirements for AEM procedures (but then neither does ASHE represent their HFM maintenance guidelines in those terms).
- Can our AEM procedures be "based on" the ECRI Institute PM guidelines? I think puts us on firmer ground. When we are reviewing the PM^{OEM} procedure for a particular type of medical equipment, it makes sense to compare them to the ECRI Institute guidelines, as one (but not the only) factor to consider when we design our PM^{AEM} procedure.

Sidebar 5. Professional judgment.

In this sidebar, I want to make a pitch for the role of professional judgment in AEM-related decision-making. Basing our decisions on solid evidence is the gold standard, but in the day-to-day practice of HTM we have to make good decisions without complete evidence.

In the medical literature, there are discussions about the roles of evidence-based medicine versus science-based medicine. Medical decision-making that is based on solid evidence (e.g., randomized controlled clinical trials) is ideal, but not always possible. Medical decision-making based on solid science (e.g., reasoning from established scientific principles) may be the best available alternative.

The analogy I would draw is that evidence-based maintenance should be supplemented by engineering-based reasoning. Basing AEM-related decisions on reasoning from solid engineering principles seems to me to be appropriate in the absence of complete evidence.

When I say *engineering*-based reasoning, I don't mean to exclude professional judgments made by non-engineers. All qualified HTM professionals, including clinical engineers and biomedical equipment technicians, can apply professional judgment to AEM-related questions. The key is to base our judgments on sound engineering principles, clearly stated reasoning, and relevant professional experience.

I believe there is a role for professional judgment in AEM-related decision-making. However, before exercising it I should ask myself if I'm confident enough to say (to the EOC Committee, to the surveyor, to myself in the middle of the night) that I know better than the manufacturer what's necessary to keep the device working safely and effectively. When in doubt, give yourself a wider margin for error.

How do we build professional judgment into our AEM programs? By documenting how we make our AEM-related decisions. Use recognized analytical techniques like FMEA (Failure Modes and Effects Analysis). Include references from the HTM (and related) literature. Cite applicable standards. Make your reasoning explicit. Spell out how you came to your conclusions. Leave a trail that others can follow.

Sidebar 6. The right way and the wrong way to talk about risk.

Here's the right way: "The concept of risk has two components: (a) the probability of occurrence of harm and (b) the consequences of that harm, that is, how severe it might be" [8].

Something that happens rarely (low probability), and is no big deal when it happens (low severity), is a low-risk event. Think, a moderate rain storm in Tucson. Something that happens often (high probability), and actually is a big deal when it does (high severity), is a high-risk event. Consider a major blizzard in Minneapolis. In between these extremes are intermediate levels of risk.

One way to illustrate this is shown in Figure 1 [9]. Green indicates low risk, red indicates high risk, and yellow indicates an intermediate level of risk.

----------Figure 1 about here ----------

Here's how we might use the standard risk assessment process in medical equipment maintenance:

Step 1. List the failure modes. How can a particular type of medical device fail to work safely and effectively? Examples: The power supply stops working. The infusion rate is too high. The image is distorted.

Step 2. Evaluate the probability of each failure mode. Sometimes we have precise data. Sometimes we have to make do with good estimates.

Step 3. Evaluate the severity of each failure mode. What are the consequences of the potential failures?

Step 4. Evaluate the risk of each failure mode. Multiply the probability by the severity. Is the risk low, high, or intermediate?

Now what? Rank the failure modes and try to mitigate those with the highest risk levels. Risk mitigation is accomplished by reducing the probability or the severity (or both) of each failure mode. There are many options for risk mitigation. Sometimes (but not always) better maintenance can reduce the probability of failure. Sometimes having backup equipment available can reduce the severity of failure (because the equipment user can grab a spare and achieve the desired clinical objective). To do good risk mitigation for medical equipment, you have to know the equipment and how it's used in your hospital.

To learn more about the *right* way to talk about risk, read Grimes [9] and check out the website of the Maintenance Practices Task Force (Sidebar 1). To learn more about the *wrong* (or perhaps I should say the non-standard or idiosyncratic) way to talk about it, consider the following:

- CMS [1] defines “Critical Equipment” as “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.”
- TJC [2] defines “High-Risk Equipment” as “medical equipment for which there is a risk of serious injury or even death to a patient or staff member should it fail, which includes life-support equipment.”

Both definitions ignore probability and consider only severity. A wooden tongue depressor can break, potentially leading to laceration of the tongue and exsanguination of the patient. The severity of the event is high which, by CMS and TJC definitions, means the risk is high. However, the probability is vanishingly low, and so is the risk. Use the terminology correctly to avoid faulty risk assessments.

Nevertheless, CMS and TJC require hospitals to identify those items in the medical equipment inventory that the hospital regards as “Critical Equipment’ or “High-Risk Equipment,” respectively. Make a list, put the list in your MEMP, and use the list to populate a field in the asset records of your CMMS. Don’t ask why; just do it.

However, and here’s the important thing, keep in mind that the terms “Critical Equipment’ and “High-Risk Equipment” have absolutely nothing to do with your AEM program. An AEM procedure can be created for any type of medical equipment that’s not on the taboo list (Table 2). Beware any publication that says otherwise.

Figure 1. Sample risk assessment matrix.

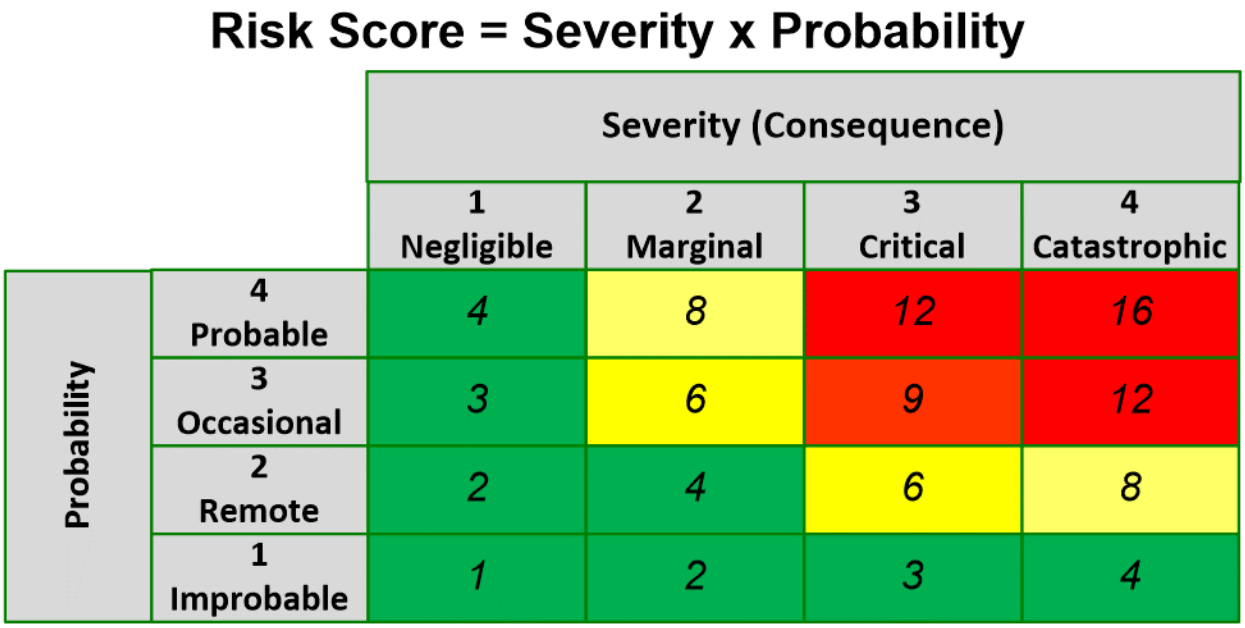

Table 1. HAP EC.02.04.01 EP 4.

Packed: Official TJC Text	Unpacked: Unofficial Commentary
The hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program. Ⓓ R	This EP is the heart of the AEM concept. Medical equipment must be maintained according to manufacturer recommendations or according to an AEM procedure that complies with EP 4 through EP 7. The Ⓓ means you need to provide written documentation, something you can hand to the TJC surveyor as soon as he or she walks in the door. Don't worry about the R.
Note 1: The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice, such as the American National Standards Institute/Association for the Advancement of Medical Instrumentation handbook ANSI/AAMI EQ56: 2013, Recommended Practice for a Medical Equipment Management Program.	By the way, although not specifically mentioned in the TJC elements of performance, it's OK to do *more* than the manufacturer recommends. CMS [1] says "hospitals may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases." Presumably, you could also *add* any PM activities that make sense in your organization.
Note 2: Medical equipment with activities and associated frequencies in accordance with manufacturers' recommendations must have a 100% completion rate.	Be sure your MEMP specifies how you calculate this metric.
Note 3: Scheduled maintenance activities for high-risk medical equipment in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. Scheduled maintenance activities for non-high-risk medical equipment in an alternative maintenance (AEM) program inventory may be deferred as defined by organization policy, provided the completion rate is not less than 90%.	CAUTION: After publication of the latest Environment of Care Essentials for Health Care [2], CMS made TJC change the 90% target to 100%. Bottom line: OEM or AEM, "high-risk" or "non-high-risk," the requirement is now 100% on-schedule completion of PM. Get over it and get smart about how to calculate the metric.

Table 2: HAP EC.02.04.01 EP 5.

Packed: Official TJC Text	Unpacked: Unofficial Commentary
The hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations: Ⓓ	This is the taboo list, equipment types that cannot use an AEM strategy.
• Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining must be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements	See the text for discussion of this taboo. CMS [1] provides an example from the Life Safety Code (NFPA 101) regarding maintenance of some fire safety equipment. However, at present, this bullet point does not seem to entail any *federal* requirements regarding medical equipment but be sure to check for requirements in your state.
• Medical laser devices	This is straight out of CMS [1] …
• Imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)	… and so is this. See the text for further discussion.
• New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies	See the text for discussion about how to deal with this taboo.
Note: Maintenance history includes any of the following documented evidence: • Records provided by the hospital's contractors • Information made public by nationally recognized sources • Records of the hospital's experience over time	The good news is that both TJC [2] and CMS [1] interpret "maintenance history" rather broadly to include information from a range of legitimate sources.

Table 3. HAP EC.02.04.01 EP 6.

Packed: Official TJC Text	Unpacked: Unofficial Commentary
A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternate manner that includes the following: Ⓓ	What individual(s) are qualified to do this? TJC is not prescriptive in this regard. Standard HR.01.02.01 (mentioned in the last row of this table) doesn't help much. CMS [1] says: In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program. It seems safe to say that most HTM professionals would be considered qualified for AEM decisions about most types of medical equipment. However, CMS also says: The hospital must maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM program, and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.
• How the equipment is used, including the seriousness and prevalence of harm during normal use.	This bullet point seems to correspond to the following CMS [1] material: 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.
• Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm	This is an invitation to use a standard risk assessment methodology as discussed in Sidebar 6. CMS [1] uses nearly identical terminology, but includes some interesting examples that are worth a look.
• Availability of alternative or backup equipment in the event the equipment fails or malfunctions	You can think of this as risk mitigation, which means reducing risk by reducing the severity of an event, or the probability, or both. Availability of backup equipment can reduce the severity of an event. For example, failure or your one-and-only Acme 123 may be a big deal, but if you've got a several of them nearby (or similar devices that do the same thing) it's not as bad.

• Incident history of identical or similar equipment	More risk assessment (Sidebar 6). For example, if you have evidence (in your maintenance records or another legitimate resource) that an equipment type is especially reliable, then the probability (and, therefore, the risk) of failure is lower.
• Maintenance requirements of the equipment	CMS [1] adds some questions that the surveyor might ask regarding maintenance requirements: 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. I think it's interesting that CMS seems to acknowledge the well-known fact that some manufacturers are not very forthcoming about their PM recommendations.
For more information on defining staff qualifications, refer to Standard HR.01.02.01.	Don't bother looking this up. It just says that people should be qualified to do their jobs. I should hope so.

Table 4. HAP EC.02.04.01 EP 7.

Packed: Official TJC Text	Unpacked: Unofficial Commentary
HAP EC.02.04.01 EP 7. The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program. Ⓓ	Not much to unpack here, but there's that Ⓓ one more time.

Table 5. AEM program skeleton.

Policy Skeleton	Policy Commentary
Policy ABC Medical Center allows medical equipment to be placed in an AEM (Alternative Equipment Maintenance) program as described in this policy.	You can be as plain or fancy as you want here. I recommend following the style of other policies at your hospital.
Objectives • Reduce the cost of medical equipment maintenance, consistent with the following objectives. • Continue to provide a level of safety equivalent to that provided by manufacturer recommendations for medical equipment maintenance. • Continue to comply fully with CMS and Joint Commission requirements.	Some people like to go on at great length here, making sure to praise motherhood, apple pie, and the American flag. Perhaps you should say "optimize the deployment of maintenance resources" rather than "reduce the cost." My advice is to follow your heart and match the style of other policies at your hospital.
Definitions • AEM (Alternative Equipment Maintenance) ... • PM (Planned Maintenance) ... • PM activity ... • PM frequency ... • Device restoration (DR) ... • Safety verification (SV) ... • Medical equipment ...	Include whatever terms you think will be helpful to readers. You can pull the definitions from the text of the *AEM Program Guide* or other sources. Define any terms you use that might be unfamiliar to your readers. The objective is to be understood. As you're imagining who might be reading this policy, think of surveyors, EOC Committee members, HTM staff, your boss, and (if you're starting to run out of memory bandwidth, as I am) yourself.
Procedure 1. Within the limitations described in this policy, medical equipment can be placed in the AEM program and can have planned maintenance (PM) activities and associated frequencies modified relative to manufacturer recommendations. Modified PM activities and frequencies are recorded in the HTM department's CMMS (Computerized Maintenance Management System) database.	Advice: Use the formal name of your department (i.e., don't use something lame like "BioMed"). Use the formal name of your CMMS software. Be serious (but it's OK to brag a little). Specify how you record the PM activities (e.g., incorporated into the CMMS and printed/displayed with each PM work order). This tells readers, especially surveyors, where to look if they want to learn more about how the policy is implemented.

2. The following types of medical equipment are not eligible for inclusion in the AEM program: a. Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining must be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements b. Medical laser devices: All surgical laser devices used in ABC Medical Center. c. Imaging and radiologic equipment: Fixed and mobile x-ray equipment; CT equipment; MRI equipment; ultrasound imaging equipment; and nuclear medicine equipment. d. New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies	This is your taboo list. Keep it as short as possible, while complying with CMS and TJC requirements. You want to be able to apply PM^{AEM} procedures to as many devices types as you're allowed. 2a. If you are aware of any taboo equipment types that fall into this category, include them in your taboo list. If not (which is likely), say so. You want the reader to know that you checked. 2b. & 2c. Purely in the interest of keeping Table 5 short, the text to the left uses generic terminology for taboo device types. A better practice, in my opinion, is to use here the terminology you use in your CMMS. In other words, there should be a one-to-one correspondence between this list and the CMMS. That makes it easier to keep everything in sync. 2d. Here you should describe exactly what you mean by "new" medical equipment and how you identify it. You could incorporate this into your procedure for handling incoming equipment. More importantly, you should spell out what you mean by "insufficient maintenance history" and how you deal with it.
3. The Director of HTM determines which medical equipment types are eligible for inclusion in the AEM program. As appropriate, the Director solicits input from internal and external consultants. The determination is based on the following factors: • How the equipment is used, including the seriousness and prevalence of harm during normal use. • Likely consequences of equipment failure or malfunction, including seriousness and prevalence of harm. • Availability of alternative or backup equipment in the event the equipment fails or malfunctions. • Incident history of identical or similar equipment, • Maintenance requirements of the equipment.	You could spell out the qualifications (and limitations) of the "decider," but I'd say keep it more general. I don't think TJC and CMS are making this into a big deal. In the list of factors you consider, include all of these required factors (of course) plus any others (e.g., financial impact of downtime for revenue-generating equipment). More importantly, describe how you take these factors into consideration. Do you use an algorithm? Do you carry out a risk assessment process? If so, spell it out. However you weigh these factors, be sure to document your decision-making process. You might create a form that includes at least the following: • Description of the type of equipment you're considering. • Your assessment of each of the factors. • Your decision on eligibility.

4. The Director of HTM develops AEM procedures ... Proposed AEM procedures are sent to the EOC Committee for review and approval. Accompanying documentation includes the following: • How it was determined that the type of medical equipment covered by a proposed AEM procedure is eligible for inclusion in the AEM program. • How it was determined that a proposed AEM procedure maintains a level of safety equivalent to manufacturer recommendations for PM.	Because there are many ways to create an AEM procedure for a particular type of medical equipment, I am leaving it up to you to specify how you have chosen to do it. Be sure to spell it out in enough detail so that (a) it can serve as a consistent process for you to use when creating AEM procedures and (b) it lets the reader understand your process. You'll probably want to develop a form for documentation of the process, either a stand-alone form or a continuation of the form described above. The critical elements would be the following: • The manufacturer's recommendation for each PM activity and the associated PM frequency. • The proposed modifications to manufacturer recommendations for PM activities and/or PM frequencies. • The justification for each proposed modification. For purposes of compliance with CMS and TJC requirements, the key consideration would be avoidance of a deterioration in equipment safety. It might also be worthwhile to include an estimate of the annual saving in hours or dollars. Approval by the EOC Committee is not a requirement, but I think it's a good idea. It provides multi-disciplinary oversight of the process. It provides a layer of documentation (EOC Committee minutes) that surveyors often turn to. And it forces us to write clearly enough to convince colleagues who are not HTM professionals.
5. The Director of HTM monitors the safety and effectiveness of the AEM program ... The Director of HTM takes action in response to identified issues regarding the safety and effectiveness of the AEM program ...	Here's where you specify how you define and measure equipment safety, what baseline level you use (if you do), how often you measure the level of safety for equipment in the AEM program, how you identify and respond to deterioration in safety, and so on. If you choose to track "PM-preventable" failures, which I think is the way forward, be sure to define your terms, spell out your procedures, and (this is my last chance to make this admonition) document it. And, by the way, it's a good idea to keep the EOC Committee in the loop.

6. The CMMS database includes an AEM Status asset field with the following values: AEM Status = 1 Medical equipment maintained per manufacturer recommendations; not eligible for AEM. AEM Status = 2 Medical equipment maintained per manufacturer recommendations; eligible for AEM. AEM Status = 3 Medical equipment included in the AEM Program. AEM Status = 4 Non-medical equipment.	The only requirement for compliance is to record which medical devices in your inventory are maintained under an AEM procedure. This is one way to do it, but there are obviously other ways, too.
References • Joint Commission. Hospital Accreditation Program. 2017 Standard EC.02.04.01 EP 4. • Joint Commission. Hospital Accreditation Program. 2017 Standard EC.02.04.01 EP 5. • Joint Commission. Hospital Accreditation Program. 2017 Standard EC.02.04.01 EP 6. • Joint Commission. Hospital Accreditation Program. 2017 Standard EC.02.04.01 EP 7. • Association for the Advancement of Medical Instrumentation. AEM Program Guide. 2017.	References are not essential, but they add to the validity of the policy. Include whatever resources you rely on.