Reliability-Centered Maintenance: A Tool for Optimizing Medical Device Maintenance

Malcolm Ridgway, Matthew Clark, and Cheryl Bettinardi

About the Authors

Malcolm Ridgway, PhD, CCE, is a retired clinical engineer who has been a leader in several initiatives aimed at elevating the HTM field and advancing the works of its professionals. Email: malcolmr36@gmail.com

Matthew Clark, MBA, CBET, is a clinical engineer at Advocate Health in Downers Grove, IL. Email: matthew.clark@advocatehealth.com

Cheryl Bettinardi, BMET, is a biomedical equipment technician at Advocate Health in Downers Grove, IL. Email: cheryl.bettinardi@advocatehealth.com

Accessing the HTMC Website

The website of the Healthcare Technology Management Community (HTMC) Maintenance Practices Task Force can be found at **www.htmcommunitydb.org**. The site is in the process of being updated to eliminate the need to log in. Currently, materials on the site can be accessed by using "view" as both the username and password.

After many years of inconclusive discussions about the role of planned (or what has traditionally been referred to as preventive) maintenance (PM) in keeping medical equipment safe, the Association for the Advancement of Medical Instrumentation (AAMI) announced its support for a new project in October 2015. The association stated that it would 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 (HTM).

RCM was pioneered in the 1950s by the civil aviation industry as a way to reduce the cost of maintaining aircraft. The approach found success, playing a key role in making it economically feasible to bring the first jumbo jets into successful commercial service. Although the original motivation for this new approach was business economics, it was soon discovered that these new maintenance strategies had a considerable and unexpectedly positive effect on the reliability of aircraft.[1] Consequently, during the latter part of the last century, virtually all of the nation's high-reliability industries, including NASA, the military, the aerospace industry, nuclear submarine industry, and nuclear power industry, among others, switched over to these new, very effective, and highly efficient practices. Although healthcare technology is now regarded as part of the high-reliability sector, the embryonic HTM community at that time did not adopt any of these changes. It is disappointing to report that we will almost certainly be the last of the high-reliability technology sectors to adopt RCM's modern scientific methods. It is way past time for us to move on and abandon the outdated maintenance practices of the last century.

Getting Started

An excellent place to begin this exploration of RCM is by drawing on its basic principles to investigate our current rationale for performing PM. There has been a long period of contentious debate about the shortcomings in efficiency and effectiveness of the traditional methods still being used to maintain medical devices. After many years in the business of providing medical equipment maintenance services to hospitals, one of the authors (M.R.)

is convinced that at least half of all the PM work currently being performed in the name of regulatory compliance provides little or no value and does virtually nothing to improve the overall safety of the equipment. At this time of an ever-increasing desire to apply modern technology to healthcare, combined with a very limited pool of technical resources, there are endless opportunities to redeploy the technical manpower that is currently being wasted performing valueless PM on the nation's medical equipment. Many HTM areas are experiencing technical challenges where these scarce resources could be put to much better use.

A volunteer Healthcare Technology Management Community (HTMC) Maintenance Practices Task Force has been formed and the project is underway. It has three broad objectives:

1. Disseminate as widely as possible a concise body of information clearly describing why routine PM fails to improve the safety of a majority of medical devices
2. Develop guidelines and tools to facilitate a rational optimization of PM programs
3. Create a communitywide database to provide a substantial body of quantitative evidence to support this rational optimization

Periodic PM can prevent medical equipment failures in only two ways. This becomes immediately obvious when we examine the PM procedure of a typical medical device. Figure 1 is a good example; it is the generic PM procedure for a critical care ventilator. Like all of the PM procedures in use throughout the industry, it contains only two kinds of tasks:

1. **Device restoration (DR) tasks,** which restore the device to like-new condition by reconditioning or replacing parts such as batteries, cables, fasteners, gaskets, and flexible tubing. These parts are not usually intended to last for the entire working lifetime of the device. DR tasks improve the device's reliability (but usually only to a minor degree) by preventing failures that would otherwise result from the deterioration of these so-called nondurable components. Sometimes the parts are reconditioned, and other times they are replaced. But this improved reliability increases the device's level of safety only if a complete failure of the device is likely to result in an adverse outcome that could harm the patient or a member of the staff treating the patient. In the generic PM procedure, DR tasks that could result in an adverse outcome if they are found to be worn out are labeled according to the potential worst case level of severity of the outcome.
2. **Safety verification (SV) tasks,** which consist of visual inspections or tests to confirm that the device is still performing within its original functional and safety specifications. In the generic PM procedure, SV tasks that could result in an adverse outcome if they fail the performance/safety verification are labeled according to the potential worst-case level of severity of the outcome.

In a case where the generally accepted PM procedure for the device contains no DR tasks (because the device has no parts needing periodic restoration) and the procedure has no SV tasks with potentially significant adverse outcomes because the device has no potential to deteriorate in a way that could conceivably cause patient injury, then there is no way that performing this procedure can make the device any safer.

In cases where the PM procedure does have one or more DR tasks (that would prevent the device from failing), but failure to perform the DR tasks is not considered to have the potential to cause a patient injury, then this periodic PM will improve the device's reliability (usually by only a small amount) but will not make the device any safer.

Devices that fit into either of these two categories (i.e., have no PM tasks with an adverse outcome, or the device presents no risk to the patient if it fails) are considered to be *non–PM critical* or, more simply, *noncritical* devices. There is no way they can be made any safer by any kind of periodic PM. Figure 2 provides a good example of this; it is the generic PM procedure for a patient scale, which is a noncritical device.

Contrary to general belief within the healthcare industry, and in particular by the authors of the current regulations governing equipment maintenance in the nation's hospitals promulgated by the Centers for Medicare & Medicaid Services (CMS), the great majority of medical devices in use in today's modern healthcare facilities are noncritical devices that cannot be made any safer by periodic PM.

Direct evidence from the field also seems to confirm that PM plays only a minor role in both preventing equipment failures and in improving equipment safety. In spite of its traditional and potentially misleading name (i.e., preventive maintenance) planned maintenance (PM) currently has a very minor impact in preventing medical equipment failures. A study from 2009 showed that maintenance issues are the root causes of less than 3–4% of all medical device failures.[2] The overwhelming balance of equipment failures (96–97%) are attributable in about equal parts to inherent device problems (e.g., random failures or malfunctions of a component part of the device) and to process-related failures (e.g., incorrect setup or operation of the device by the user). If PM-related device failures are so rare, then the possibility of patient injuries resulting from PM-related failures must be even more rare. Statistics from at least one nationwide database appear to confirm that this is the case.[3]

The simple questionnaire shown below provides a quick and easy way of identifying which of the hospital's devices are noncritical.

Questionnaire for Determining Which Devices Are Noncritical

Question 1. Is it reasonably possible that there could be some kind of adverse patient outcome if this device, without reasonable warning, stops working while being used on a patient?
Response: yes or no

Question 2. Is it reasonably possible that the device will stop working if one (or more) of the device restoration tasks included in the manufacturer's PM procedure (or the corresponding HTMC PM procedure*) is not completed in a timely manner? **Response:** yes or no

Question 3. If the responses to questions 1 and 2 are both "yes," briefly describe the nature of the worst-case possible adverse outcome. **Response:** [see examples in column 6 of Table 2 at **www.htmcommunitydb.org**]

Question 4. Identify possible mitigating factors that might reduce the severity of the expected outcome. **Response:** [see examples in column 8 of Table 2 at **www.htmcommunitydb.org**]

Question 5. After considering the possible mitigating factors listed in response to Q4 above, project the worst-case level of severity (LOS) of the outcome of the failure; where LOS 3 represents a potentially life-threatening situation, LOS 2 represents the possibility of a non–life-threatening patient injury, and LOS 1 represents a possible disruption of patient care (e.g., significant delay in obtaining diagnostic information, significant delay in treating the patient, increasing the patient's length of stay in some other way). **Response:** LOS 1, LOS 2, or LOS 3

Question 6. If the manufacturer's recommended PM procedure (or the corresponding HTMC PM procedure*) includes any functional performance or safety tests, is it reasonably possible that some kind of adverse patient outcome could result if the device falls out of spec and fails one or more of those tests? **Response:** yes or no

Question 7. If the response to question 6 is "yes," briefly describe the nature of the worst-case outcome. **Response:** [see examples in column 5 of Table 3 at **www.htmcommunitydb.org**]

Question 8. Identify possible mitigating factors that might reduce the severity of the expected outcome. **Response:** [see examples in column 7 of Table 3 at **www.htmcommunitydb.org**]

Question 9. On the same scale of 1 to 3 described in question 5, project the worst-case LOS of the anticipated adverse outcome. **Response:** LOS 1, LOS 2, or LOS 3

Noncritical device. If the analysis results in response 6 being "no" and one or both of responses 1 and 2 also being "no," then this type of device should be classified as not potentially PM critical or, more simply, as noncritical.

Device is potentially PM Priority 1. If the analysis results in any other combination of responses, then this type of device should be classified as PM-critical at a severity/Priority level representing the combined LOS levels of the DR- and SV-related failure modes (Table 1). The definition of the term PM-critical will be addressed below.

*The HTMC Maintenance Practices Task Force is currently creating a set of standardized generic PM procedures for each separate type of medical device. These procedures are designed to be functionally equivalent to each of the manufacturer-recommended PM procedures, and for the purpose of this analysis, they can be used instead of the manufacturer's recommended procedure. The proposed format for these standardized generic procedures is shown in Figures 1 and 2. To view some of the task force's other model generic PM procedures, go to **www.htmcommunitydb.org** (see Table of contents, select Page 2 ["The database Tables"], then Table 4, and click on one of the active links in column 6).

The key parts of the questionnaire are questions 1, 2, and 6. The other questions help categorize the worst-case severity of the patient harm that could result (in the case of a potentially PM Priority 1 device) if the PM is not performed and whether mitigating factors could reduce or change this.

Preliminary Findings

Many relatively simple devices, such as patient scales (Figure 2), have no critical nondurable parts needing periodic attention and no critical safety verification tasks needing to be performed. We estimate that between 750 and 1,500 different types of healthcare-related devices are in use in today's facilities. An unknown number of these are nonclinical devices, such as printers or other accessories that do not even fall into the formal category of a medical device that is regulated by the Food and Drug Administration. The task force believes that these nonclinical devices are very likely to also be noncritical devices.

At the other end of the scale, initial work performed by the task force (as described in the documents on its website) has identified at least 20 of the 71 device types listed in Table 1 as having potential LOS 3 outcomes. More details on this tentative categorization can be found in Table 1, and supporting Tables 2 and 3, on the website. (For convenience, Table 4 from the website is reproduced here as Table 1.) The task force believes that a large percentage of the remaining balance, representing at least 700 and perhaps as many as 1,400 different device types, will prove to be noncritical when they are analyzed using the questionnaire.

Immediate Workload Relief

This first step—using the questionnaire to separate devices from the inventory that are noncritical—provides a rational justification (regulatory constraints permitting) for a considerable amount of immediate workload relief. This is because all of the device types that are found to be noncritical are legitimate candidates for the so-called *light maintenance* strategy, which allows the device to be used (regulatory constraints permitting) without any periodic maintenance.[1] In some cases an argument might be made for periodic PM interventions on the grounds that they would reduce the net cost of maintaining the device, but as of this time, we are not aware of any studies that have documented such a finding for any type of medical device.

C.VEN-01

HTMC PM Procedure no. **C.VEN–01 rev 1: CRITICAL CARE VENTILATOR**

Scope: This procedure is to be used for To Be Completed (TBC) **Time required:** TBC person-hours

Test equipment and supplies required: (TBC)

Special precautions: If there is evidence of blood or body fluid contamination, make sure the device is cleaned and decontaminated before attempting to work on it.

This is considered to be a **potentially PM Priority 1 device** because 1) it has one or more device restoration tasks that could cause the device to fail while in use, with potentially **high-severity/life-threatening** consequences, if they are not performed in a timely manner). 2) it has the potential to develop one or more hidden, but discoverable, performance or safety deficiencies that could have **high-severity/life-threatening** consequences if not corrected in a timely manner.

Verify whether the device appears to be working. If it is not, **check the box on the right, at the end of this line,** and **open a repair work order.** [ ]

> **Device restoration (DR) tasks:** Restoration, reconditioning, or replacement of the device's nondurable parts (for specific "how to" instructions, refer to the manufacturer's PM procedure)

[ ]DR1. With power off, **inspect** the exterior housing especially any moving parts, including any user-accessible areas that are under covers. Clean as needed. Adjust or replace any loose or damaged parts. Lubricate as required (if applicable). Rate your finding for this task using the **PHYSICAL CONDITION** finding scale described below and note your rating for this task (1, 5, or 9) here: __

[ ] DR2. Confirm that all **markings and labeling** are legible. Clean or replace, as required. Note your rating for this task (1, 5, or 9) here: __

[ ] DR3. Check the **battery**, and replace it if so scheduled. (If not scheduled and the battery is found to be no longer capable of holding a charge, rate this finding as a 9). Note your rating for this task (1, 5, or 9) here: __ **(A rating of 9 here could result in a high-severity/life-threatening outcome)**

[ ] DR4. Inspect all **cables, electrodes and transducers** to confirm their integrity and proper function. Note your rating for this task (1, 5, or 9) here:__ **(A rating of 9 here could result in a high-severity/life-threatening outcome)**

[ ] DR5. Verify the integrity of the **patient circuit**. Inspect/clean all **gas filters**, as required. Inspect/adjust **all other elements in the gas supply chain**, as required. Note your rating for this task (1, 5, or 9) here:__ **(A rating of 9 here could result in a high-severity/life-threatening outcome)**

[ ] DR6. Perform a **leak test**. Note your rating for the finding from this task (1, 5, or 9) here:__

> **Safety verification (SV) tasks:** To detect and correct any **hidden** performance/safety degradations (for specific "how to" instructions, refer to the manufacturer's PM procedure)

[ ] SV1. Check that the physical condition of the **power cord and cap**, including the strain relief, is OK. Check the auxiliary receptacles (if applicable). Check the **circuit breaker/fuse**. Rate your finding from this task using the **PERFORMANCE/SAFETY** finding scale described below (A, B, or F), and note your rating here: __

[ ] SV2. If there is exposed metal that could conceivably become energized, check the **continuity to ground**. (< 0.5 ohm). Note your finding from this task (A, B, or F) here:__ **(A finding rated at F here could result in a low-moderate severity outcome [e.g., a minor electric shock])**

[ ] SV3. Verify that the **battery charging system** is operating within specifications. Note your finding from this task (A, B, or F) here:__

[ ] SV4. Verify that the **time/date** indication (if applicable) is correct. Note your finding from this task (A, B, or F) here:__

[ ] SV5. Review the on-board **error log/event history** for any unusual indications. Note your finding from this task (A, B, or F) here:__

[ ] SV6. Verify the functional performance of all **controls**, switches, latches, clamps, soft touch keys, etc. Note your finding from this task (A, B, or F) here:__ **(A finding rated at F here could result in a high-severity/life-threatening outcome)**

[ ] SV7. Verify proper performance of all **indicators and displays**, in all modes. Note your finding from this task (A, B, or F) here:__ **(A finding rated at F here could result in a high-severity/life-threatening outcome)**

[ ] SV8. Verify that the **output gas concentrations** are within spec. Note your finding from this task (A, B, or F) here:__ **(A finding rated at F here could result in a high-severity/life-threatening outcome)**

[ ] **SV9**. Verify that all **alarms** and any **interlocks** operate correctly, in all modes. Note your finding from this task (A, B, or F) here:__ (**A finding rated at F here could result in a high-severity/life-threatening outcome**)

FINDINGS

Rate the device's **PHYSICAL CONDITION** by giving the finding for each DR task a numerical code (1, 5, or 9), where **1** = <u>Still good/better than expected</u>; **5** = <u>About as expected</u>; and **9** = <u>Worn out/serious physical deterioration</u>.

Write in the numbers of any DR tasks with a possible high-severity outcome where an out-of-spec (OOS) **"9"** condition was found: _____ and provide details in the **Notes** field below

Rate the **PERFORMANCE/SAFETY** of the device by coding the finding for each SV task as an **A, B, or F**, where **A** = <u>Passed</u>; **B** = <u>Minor OOS condition(s) was found</u>; and **F** = <u>Failed</u>.

Write in the numbers of any SV tasks with a possible high-severity outcome where an out-of-spec (OOS) **B** or **F** condition was found: _____. Provide details in the **Notes** field below.

Notes:

PM FINDINGS REPORT

[ ] **Device PASSED PM** (if all PM tasks **with a possible high-severity outcome** are rated 1, 5, A, or B)

When done, attach a **new PM sticker** indicating the <u>next PM due date</u>. **PM interval:** ___months.
Make sure all controls are set at normal positions and place a **CAUTION tag** in a prominent position asking the next user to verify the control settings and proper device set up before its next use.

[ ] **Device FAILED PM** (if one or more PM Tasks with a possible high-severity outcome are rated 9 or F)

This is a **potentially PM Priority 1 device**; **if it is** and if it DID NOT PASS **it should be** <u>removed from service immediately</u>.

[ ] Check here if <u>all</u> DR Tasks were coded **1** (**an indicator that the PM interval may be TOO SHORT**)

[ ] Check here if <u>any</u> DR Tasks were coded **9** (**an indicator that the PM interval may be TOO LONG**)

[ ] Check here if <u>any</u> SV Tasks were coded **B** (**an indicator that these tasks should be considered for a future WATCH LIST**)

HTMC PM Procedure No. **C.VEN – 01 rev 1** .... **Date:** _____ Initials: _____

Disclaimer: This PM procedure may not reference all of the maintenance tasks specified by the manufacturer's technical or user manual. In many instances, the manufacturer suggests a number of user-level tasks, such as cleaning or replacing consumables, which need to be completed. These are considered to be outside the scope of this technician-level procedure.

Figure 1. Planned maintenance (PM) procedure for a critical care ventilator (C.VEN-01)

PA.SC-01

HTMC PM Procedure no. **PA.SC–01 rev 1: PATIENT SCALE**

Scope: This procedure is to be used for mechanical and electronic scales that are used to measure the weight of patients, including under-bed and wheelchair scales. It can be customized for scales incorporated into patient lifts and patient beds. It is not to be used for infant scales (see separate PM Procedure no. **IN.SC**). **Time required:** 0.5 person-hours

Test equipment and supplies required: Three 25-kg calibration weights

Special precautions: If there is evidence of blood or body fluid contamination, submit the device for cleaning and decontamination before attempting to work on it.

This is considered to be a **noncritical device** because it has **no** PM tasks that could have potentially adverse consequences if they are not performed in a timely manner. There would be no significant adverse outcome if this device stopped working while it is being used on a patient. The device also is unlikely to develop any hidden performance or safety deficiencies that could have serious consequences, and that could be discovered by periodic testing.

Verify whether the device appears to be working. If it is not, **check the box on the right, at the end of this line,** and **open a repair work order.** [ ]

> **Device restoration (DR) tasks:** Restoration, reconditioning, or replacement of the device's nondurable parts (for specific "how to" instructions, refer to the manufacturer's PM procedure)

[ ] DR1. With power off, **inspect** the exterior housing especially any moving parts. Clean as needed. Adjust or replace any loose or damaged parts. Lubricate as required (if applicable). Rate your finding for this task using the **PHYSICAL CONDITION** finding scale described below and note your rating for this task (1, 5, or 9) here: __

[ ] DR2. Confirm that all **markings and labeling** are legible. Clean or replace as required. Note your rating for this task (1, 5, or 9) here: __

[ ] DR3. Check the **battery** (if applicable) and replace it if so scheduled. (If not scheduled and the battery is found to be no longer capable of holding a charge, rate this finding as a 9.) Note your rating for this task (1, 5, 9, or NA [not applicable]) here: __

> **Safety verification (SV) tasks:** To detect and correct any **hidden** performance/ safety degradations (for specific "how to" instructions, refer to the manufacturer's PM procedure)

[ ] SV1. Check that the physical condition of the **power cord and cap** (if applicable), including the strain relief, is OK. Check the auxiliary receptacles (if applicable). Check the **circuit breaker/ fuse** (if applicable). Rate your finding from this task using the **PERFORMANCE/ SAFETY** finding scale described below (A, B, F, or NA) and note your rating here: __

[ ] SV2. Verify that the **battery charging system** (if applicable) is operating within specifications. Note your finding from this task (A, B, F, or NA) here:__

[ ] SV3. Check that the **zero calibration** is within the acceptable limit. Reset as required. Note your finding from this task (A, B, or F) here: __

[ ] SV4. Use the calibration weights to verify that the **weight accuracy** is within the acceptable limit (±2%). Recalibrate as required. Note your finding from this task (A, B, or F) here: __

[ ] SV5. Verify that the "**display-locked**" control makes the display read in metric units (grams, kilograms), if applicable. Note your finding from this task (A, B, F, or NA) here: __

[ ] SV6. Verify the functional performance of all other **controls**. Note your finding from this task (A, B, or F) here:__

FINDINGS

Rate the device's **PHYSICAL CONDITION** by giving the finding for each DR task a numerical code (1, 5, or 9), where **1** = Still good/ better than expected; **5** = About as expected; and **9** = Worn out/ serious physical deterioration.

Write in the numbers of any DR tasks where an out-of-spec **"9"** condition was found: _____ and provide details in the **Note** field below

Rate the **PERFORMANCE/ SAFETY** of the device by coding the finding for each SV task as an **A, B,** or **F**, where **A** = Passed; **B** = Minor OOS condition(s) was found; and **F** = Failed.

Write in the numbers of any SV tasks where an out-of-spec **B** or **F** condition was found: _____. Provide details in the **Notes** field below.

PM FINDINGS REPORT
      [ ] **Device PASSED PM** (if all PM tasks are rated 1, 5, A, or B)

When done, attach a **new PM sticker** indicating the <u>next PM due date</u>. **PM interval:** ___months.
Make sure all controls are set at normal positions and place a <u>**CAUTION tag**</u> in a prominent position asking the next user to verify the control settings and proper device set up before its next use.
      [ ] **Device FAILED PM** (if one or more PM Tasks are rated 9 or F)

      [ ] Check here if <u>all</u> DR Tasks were coded **1** (**an indicator that the PM interval may be TOO SHORT**)
      [ ] Check here if <u>any</u> DR Tasks were coded **9** (**an indicator that the PM interval may be TOO LONG**)

HTMC PM Procedure No. **PA.SC – 01 rev 1** .... **Date:** _____ Initials: _____

Disclaimer: This PM procedure may not reference all of the maintenance tasks specified by the manufacturer's technical or user manual. In many instances the manufacturer suggests a number of user-level tasks, such as cleaning or replacing consumables, which need to be completed. These are considered to be outside the scope of this technician-level procedure.

Figure 2. Planned maintenance (PM) procedure for a patient scale (PA.SC-01)

Risk-Based PM Prioritization

Now that we have described a way of identifying those noncritical medical devices that cannot be made any safer by subjecting them to periodic PM, the next step is to perform a risk assessment to determine which of the potentially PM Priority 1 devices should be given the highest priority (PM Priority 1) because they are the most likely to become hazardous if they are not given timely attention. As we shall see, different device types that are categorized as potentially PM Priority 1 devices can be expected to present different levels of risk. Those with the potential to present the greatest risk of injuring a patient should be given a correspondingly higher priority for attention and timely PM.

The Joint Commission uses the term "high-risk device" in its standards, but the criteria they use for this term do not necessarily coincide with the criteria described here. In its regulations, CMS uses the term "critical" in a similar way. In the current work, we have chosen to use the alternative term "PM Priority 1 device" to label devices that present the highest level of potential risk. Similarly, we have adopted the terms PM Priority 2, 3, 4, and 5 to describe devices with progressively lower levels of risk (Table 2). These can be considered to represent moderate-high, moderate, low, and very low levels of risk, respectively.

A New RCM-Based Risk Assessment

According to modern reliability and risk management theory, risk has two components: 1) the severity of the outcome of the event (in this context, a PM-preventable device failure) and 2) the likelihood that the event (the PM-preventable device failure) will occur.

Requiring this combination of two factors means that devices for which a manufacturer-recommended PM procedure exists will not necessarily become hazardous if the manufacturer's recommendations for periodic PM are not followed exactly to the letter. If the likelihood of a PM-related failure actually occurring (even if the failure potentially has a high-severity outcome) is found to be very low, with a probability equivalent to a mean time between failures (MTBF) of (for example) 100 years, then the corresponding risk of harming the patient also is relatively low. This is why travelling on a commercial airliner is considered to be safe. Although a theoretical possibility exists of a high-severity outcome if the plane should crash, the likelihood that this will actually happen is very low, meaning that the risk of flying on a commercial airliner is also very low.

This two-factor requirement also can be illustrated by an example from the mid-1980s. At that time, there were many practical, hands-on people who seemed to intuitively recognize that a failure with a very low probability of actually occurring did not represent a very serious risk, even if the outcome of that failure could be a high severity event. Following the great electrical safety scare of 1968, which was widely publicized by Ralph Nader, the Joint Commission had urged that all line-powered devices be checked at fairly frequent intervals for excessive leakage current. However, after a period of time, many in-house programs discontinued the practice, usually rationalizing their action by stating that

they never found any high levels of leakage current. A conventional RCM risk assessment requires the identification of all possible ways in which a device could fail. In RCM jargon, these ways are called the device's failure modes. There are failure modes associated with inherent failures (e.g., random failures in the device's electronics), process-related failures (e.g., an operator setting one of the controls incorrectly), and maintenance-related failures (e.g., the device being out of calibration). However, for the purpose of the current work, we can ignore the process-related and inherent failure modes and take a legitimate shortcut by simply conducting a maintenance-focused risk assessment.[1]

Step 1: Projecting the Worst-Case LOS of the Outcomes of the Failures

As noted in the earlier questionnaire, there are two kinds of PM-related failures: device restoration-related failures and safety verification-related failures. Consulting the aggregated findings in response to questions 5 and 9 will allow us to project the worst-case LOSs for the potential outcomes, thus fulfilling this first step in our maintenance-focused risk assessment.

The second step of the risk assessment is addressed below. After actual risk levels have been projected, the final step will be determining to what degree the actual PM-related failure rates of the potentially PM Priority 1 devices are higher than the tentative levels that the task force has set for acceptable safety (Table 2).

Step 2: Estimating the Likelihood that the Theoretical Failures Will Occur

Rather than attempt to make educated guesses at typical failure rates, the task force has decided, for credibility reasons, to initiate a communitywide effort to gather real-world data. In an ideal world, the data needed to determine each device's PM-related failure rates would be obtainable from the equipment maintenance records, which are required at every accredited healthcare facility. In an ideal world, the format and content of those records would have some degree of consistency. Unfortunately this is not the case, and if members of the HTM community are willing to respond to this call to action and collaborate with the task force in addressing this very important issue, we will have to appeal for some voluntary standardization.

Guidelines for Standardizing Maintenance, Testing, and Reporting

- The maintenance entity must use the manufacturer's recommended PM procedure or one that includes, as a minimum, all of the device restoration and safety verification tasks listed in the relevant HTMC PM procedure (which is functionally equivalent to the manufacturer's recommended procedure) for each manufacturer model version of the various potentially

Failure Rates Expressed as MTBFs

It is generally more convenient to express device failure rates in the form of their equivalent mean time between failures (MTBF). The MTBF is simply the inverse of the failure rate. For example, a device that failed twice in 9 years has an MTBF of 4.5 years. It can also be expressed as the number of device-years of device experience divided by the total number of device failures occurring during the observation period. The greater the number of devices in the sample and the longer the period of the observations, the closer the observed failure rate will be to the device's true failure rate.[4]

PM-critical device types. (Figures 1 and 2). This will ensure that all of the device restoration tasks and safety verification tasks identified by device manufacturers in their recommended PM procedures are addressed by each maintenance entity.

- Although some regulatory constraints currently exist, for the purpose of this proposed project, it is not necessary for the maintenance entity to perform the PM restoration and verification tasks at the same interval as that recommended by the manufacturer. Indeed, in the absence of any regulatory mandates, some diversity would be welcome since one of the goals of the project is to compare the levels of device reliability and safety that are achieved at different maintenance intervals.
- The maintenance entity must use some form of coding for repair calls that allows a separate count of the failures that are attributable to inadequate PM (similar to the Category 7 coding described by Ridgway et al.[2]).
- The maintenance entity also must use some form of coding for the PM findings, similar to that described below in "Documenting Important PM Findings." This allows a separate count of the number of times that a hidden failure was detected (PM Code F), as well as the number of times that a nondurable part was found to have deteriorated too far (PM Code 9).

Documenting Important PM Findings

A helpful feature of the standardized generic PM procedures (Figures 1 and 2) is a section devoted to documenting key PM findings. At the bottom of the procedure, in a section titled "Findings," the service person is asked to indicate (by circling one of three letters [A, B, or F]) the result of the performance and safety testing of the device:

- **A (passed).** Testing to detect hidden failures found the device to be in complete compliance with the relevant specifications and any other functions tested were all within reasonable expectations.

	2. HTMC device type	3. LOS of effects of device restoration failures	4. LOS of effects of hidden safety failures	5. PM failure severity level (based on potential severity of PM-preventable device failures)	6. HTMC PM procedure code
1	Automated external defibrillator	3	3	A. Highest severity	AED-01
2	Anesthesia unit	3	3	A. Highest severity	ANES-01
3	Critical care ventilator	3	3	A. Highest severity	C.VEN-01
4	Defibrillator/monitor	3	3	A. Highest severity	DEF-01
5	Intra-aortic balloon pump	3	3	A. Highest severity	I.A.B.P-01
6	Transport incubator	3	3	A. Highest severity	T.INC-01
7	Transport ventilator	3	3	A. Highest severity	T.VEN-01
8	Apnea monitor	2	3	B. High severity	APN.M-01
9	Infant incubator	2	3	B. High severity	IN.IN-01
10	Cardiac resuscitator	3	2	B. High severity	C.RES-01
11	External pacemaker	3	2	B. High severity	EX.PA-01
12	Heart-lung bypass unit	3	2	B. High severity	H.L.BY-01
13	Neonatal monitor	2	3	B. High severity	NEO.M-01
14	Oxygen monitor	2	3	B. High severity	OXY.M-01
15	Patient monitoring system	2	3	B. High severity	P.M.S-01
16	Linear accelerator	1	3	C. Moderate-high severity	LN.AC-01
17	Blood pump, extracorporeal	3	0	D. Moderate severity	BL.P.E-01
18	Oxygen analyzer	0	3	D. Moderate severity	OXY.A-01
19	Patient-controlled analgesia pump	0	3	D. Moderate severity	INF.D-03
20	Syringe pump	0	3	D. Moderate severity	INF.D-02
21	Blood bank refrigerator	2	2	E. Moderate-low severity	RE.BB-01
22	Computed tomography (CT) scanner	2	2	E. Moderate-low severity	CT-01
23	Fetal monitor	2	2	E. Moderate-low severity	FET.M-01
24	Surgical guidance unit	2	2	E. Moderate-low severity	S.GUI-01
25	Surgical robot	2	2	E. Moderate-low severity	S.ROB-01
26	Telemetry system	2	2	E. Moderate-low severity	TELE-01
27	Transcutaneous O_2/CO_2 monitor	2	2	E. Moderate-low severity	TRA.M-01
28	Brachytherapy unit	1	2	F. Low severity	BR.TH-03
29	C-arm	1	2	F. Low severity	C.ARM-01
30	Cath lab, SP	1	2	F. Low severity	CATH-01
31	Clinical lab analyzer	1	2	F. Low severity	C.L.A-01
32	Electrocardiogram recorder	1	2	F. Low severity	ECG.R-01
33	Electrophysiology lab	1	2	F. Low severity	EP.LB-01
34	Electrosurgical unit	1	2	F. Low severity	ESU-01
35	Endoscope, specialty	1	2	F. Low severity	ENDO-0x
36	Gamma camera	1	2	F. Low severity	G.CAM-01
37	Hemodialysis unit	1	2	F. Low severity	HEMO-01
38	Hypo/hyperthermia unit	1	2	F. Low severity	HYPO-01
39	Infant warmer	1	2	F. Low severity	IN.WA-01
40	Mammography unit	1	2	F. Low severity	MAMO-01
41	Magnetic resonance imaging (MRI) scanner	1	2	F. Low severity	MRI-01
42	Opthalmic laser	1	2	F. Low severity	O.LAS-01
43	Peritoneal dialysis unit	1	2	F. Low severity	P.DIA-01
44	Positron emission tomography (PET) scanner	1	2	F. Low severity	PET-01
45	PET/CT scanner	1	2	F. Low severity	P.CT-01
46	PET/MRI scanner	1	2	F. Low severity	P.MR-01
47	Special procedures room	1	2	F. Low severity	S.PRO-01
48	Sterilizer	1	2	F. Low severity	STER-01
49	Surgical laser	1	2	F. Low severity	S.LAS-01
50	Thyroid uptake unit	1	2	F. Low severity	TH.UP-01
51	Tomography room	1	2	F. Low severity	TOMO--01

52	Xenon scintigraphy system	1	2	F. Low severity	XE.SC-01
53	Blood gas analyzer	0	2	G. Very low severity	BL.G.A-01
54	Blood pressure monitor (invasive)	0	2	G. Very low severity	BP.M-01
55	Blood warmer	0	2	G. Very low severity	BL.WA-01
56	Bone densitometer	0	2	G. Very low severity	B.DEN-01
57	Electroencephalogram recorder	0	2	G. Very low severity	EEG.R-01
58	Infusion pump	0	2	G. Very low severity	INF.D-01
59	Lab microscope	0	2	G. Very low severity	L.MIC-01
60	Phototherapy light	0	2	G. Very low severity	PH.LI-01
61	Portable X-ray unit	0	2	G. Very low severity	PORT-01
62	Radiography and fluoroscopy room	0	2	G. Very low severity	R&F-01
63	Radiology room	0	2	G. Very low severity	RAD-01
64	Radiation dosimeter	0	2	G. Very low severity	R.DOS-01
65	Radioisotope calibrator	0	2	G. Very low severity	R.CAL-01
66	Ultrasound scanner	0	2	G. Very low severity	ULTR-01
67	Cataract extraction unit	1	0	H. Lowest severity	CAT.X-01
68	Contrast injector	1	0	H. Lowest severity	C.INJ-01
69	Infant scale	0	1	H. Lowest severity	IN.SC-01
70	Operating room light	1	0	H. Lowest severity	OR.LI-01
71	Ventilator	1	0	H. Lowest severity	VENT-01
	Autotransfusion unit	0	0	Noncritical	AU.TR-01
	Hemodialysis blood pump	0	0	Noncritical	HE.B.P.-01
	Patient scale	0	0	Noncritical	PA.SC-01
	Pulse oximeter	0	0	Noncritical	P.OX-01
	Vital signs monitor	0	0	Noncritical	VS.M-01

Table 1. Worst case PM-related failure severity levels for all potentially PM Priority 1 devices

These 71 devices are considered by the task force to be potentially PM-critical, because examination of their generic PM procedures shows that they have PM-related failure modes associated with their device restoration or safety verification tasks that could cause the device to fail while in use, with some significant potential level of severity (LOS). These failure modes are described in Tables 2 and 3 on the task force's website. These potentially PM-critical devices are ranked into eight different worst-case PM-related failure severity level categories (A through H [column 5]), according to the severity of the potential consequences of a PM-related failure, then they are ordered alphabetically within each ranking. The group of device types listed in column 5 as highest severity (A) have the greatest potential for severe consequences, while those listed as lowest severity (H) have the least potential for severe consequences. All other devices (not included in one of the 71 device types listed) are considered non–PM critical (or noncritical) devices.

Device PM priority level	Severity of worst-case outcome of device failure		
	Life-threatening injury (LOS 3)	Possible patient injury (LOS 2)	Disruption of patient care (LOS 1)
PM Priority 1	Poor reliability (MTBF <75 years)	—	—
PM Priority 2	Good reliability (MTBF 75–150 years)	Poor reliability (MTBF <50 years)	—
PM Priority 3	Very good reliability (MTBF >150 years)	Good reliability (MTBF 50–100 years)	Poor reliability (MTBF <25 years)
PM Priority 4	—	Very good reliability (MTBF >100 years)	Good reliability (MTBF 25–50 years)
PM Priority 5	—	—	Very good reliability (MTBF >50 years)

Table 2. Tentative definitions of what should be considered the minimum acceptable levels of planned maintenance (PM)-related reliability/safety

Devices with the most severe potential outcome (level of severity [LOS] 3) and the highest likelihood of failing are classified as having the highest level of risk (PM Priority 1 devices). Devices with a worst-case outcome of a failure that is a somewhat lower level of severity (LOS 2) are classified as PM Priority 2 device, even though there still is a relatively high probability of a PM-related failure occurring. Similarly, devices with the lowest severity outcomes (LOS 1) are considered to be even lower risk (PM Priority 3, 4 or 5 devices), depending on their demonstrated likelihood of failing. MTBF = mean time between failures.

- **B (minor OOS condition[s] found).** One or more of the tests revealed a slightly out-of-spec (OOS) condition. The purpose of this rating is to create a watch list to monitor for future adverse trends, particularly performance or safety failures, even though the discrepancy is not considered to be significant at present. A performance rating of B is considered to be a passing grade.
- **F (failed).** One or more of the tests found that one or more of the device's performance or safety features were significantly OOS. This is a failing grade and, if this is a PM Priority 1 device, it should be removed from service immediately.

The service person also should indicate (by circling one of four numbers [1, 5, 9, or 0]) whether the physical condition of the parts of the device that were rejuvenated by the device restoration tasks called for in the procedure were:

- **1 (still good/better than expected).** Very little or no deterioration.
- **5 (about as expected).** If there was some minor deterioration, it was probably having no adverse effect on the device's function.
- **9 (already worn out/serious physical deterioration).** Considerably worse than expected. The restored part(s) was already worn out and probably having an adverse effect on device function.
- **0 (no physical restoration required).** The device has no parts needing any kind of physical restoration.

Systematically documenting these findings each time a PM is performed, then aggregating the data, will make it possible to obtain the following:

- **An indication of how well the PM interval matches the optimum.** The optimum PM interval is when the parts being restored have slightly deteriorated, but only to the point where the deterioration is just beginning to affect the functioning of the device. The indicators for how close the interval is to this optimum are as follows. A preponderance of:
  – PM Code 1 findings (still very good) is an indicator that the interval is too short.
  – PM Code 5 findings (about as expected) is an indicator that the interval is about right.
  – PM Code 9 findings (already worn out) is an indicator that the interval is too long.
- **A numerical MTBF indicating each device's level of PM-related reliability and safety.** This indicator is the lesser (the one representing the lower level of reliability) of the following two MTBFs:
  – The MTBF based on the total of 1) any overt failures caused by inadequate device restoration (from the repair cause coding) and 2) any PM Code 9 findings (which are immediate precursors of the overt failures caused by inadequate restoration).
  – The MTBF based on the total of any hidden performance and safety degradations detected by the safety verification tasks (PM Code F findings).

For more on this, including a discussion of the benefits of the PM procedure's other important features, see the HTM ComDoc 1 on the website.

Preferred System for Coding Repair Calls

Equipment systems fail for a variety of reasons, and recognizing that only a few of these failures can be preempted by periodic maintenance is important. Ridgway et al.[2] point out that equipment failures can be classified into three general types depending on which part of the equipment system has failed. For a more detailed description of this repair coding system, see section 1.6 ("What causes equipment systems to fail?") in HTM ComDoc 5 on the website.

Compiling the Data into Organized Batches

To streamline the reporting part of the project, the task force will be asking certain organizations to volunteer to act as data-aggregating intermediaries. Organizations that are candidates for this data aggregator role include independent service organizations, national or regional hospital systems with in-house maintenance services, and computerized maintenance management system companies. For additional information, see section 7.5 ("Guidelines for compiling the data into organized batches") in HTM ComDoc 7 on the website.

Why We Need a Communitywide Database

Collecting sufficient data to provide a statistically valid body of evidence to support the use of particular maintenance strategies may prove to be difficult for many individual healthcare facilities, for the following reasons:

- Because they are designed and constructed differently, different manufacturer model versions of devices with LOS 3 outcomes (e.g., defibrillators, critical care ventilators) will very likely display different levels of reliability. This means that each of the different manufacturer model combinations will have to be analyzed separately.
- Devices that have LOS 3 outcomes are presumably designed to be quite reliable, so they will likely demonstrate a correspondingly low failure rate. This reduces the number of failures that an individual facility will be able to document over a reasonable time period.
- Many individual healthcare facilities will have only a small number of the different manufacturer model versions of the device types that have LOS 3 outcomes.

To illustrate this dilemma, suppose that a facility has only three similar (same manufacturer, same model) heart-lung units and only three years of maintenance history for each unit. Because this amounts to an experience base of only 9 device-years, it is unlikely that if the actual MTBF of the units is greater than 9 years (we are hoping to find that the MTBFs for typical high-reliability devices will be at least 75 years), then the facility will not have experienced one failure during the

three-year testing period. In this case, the facility would have to report its finding with respect to the devices' indicated failure rate (zero failures over 9 device-years) as "undetermined."

Even if the devices experienced one or more failures during this relatively short period of time, the indicated MTBF (of up to 9 years) will appear to be unacceptably short for a device that is potentially PM Priority 1. With an indicated MTBF this low, it would obviously be prudent for the facility to look to the findings on the reliability of these specific types of device in the national HTMC database to see whether its particular experience is indeed typical (and that the version of this type of device is in fact not sufficiently reliable). For more on this possible situation, see Ridgway and Fennigkoh[4] and Ridgway and Lipschultz.[5]

The bottom line on these statistical validity considerations is that many individual facilities probably will have difficulty generating enough failure data to get a good indication of each device's true PM-related failure rate and, therefore, the device's true level of maintenance-related safety. To get accurate indications of the true PM-related failure rate of PM Priority 1 devices, it will be necessary to create a pool of maintenance statistics containing a certain minimum number of device-years of experience for each manufacturer model version of each device type (Table 3).

Aggregating the Data

With the recent initiation of this AAMI-supported RCM project, we are appealing to every member of the HTMC to provide the Maintenance Practices Task Force with summaries of the documented findings from their ongoing maintenance on all devices that the task force has classified as potentially PM Priority 1 (Table 1). To allow the findings to be properly aggregated, it also is very important that the maintenance, testing, and reporting be performed in accordance with the guidelines described above.

Proof Tables in the Proposed Community Database

The key part of the website-based community database will be a set of tables that the task force is calling "summary proof tables." These tables will catalog the PM-related failure rates calculated from the aggregated maintenance data submitted for each of the different potentially PM Priority 1 device types. The format of this table is illustrated in Table 4. Note that this particular table contains only hypothetical data. It is provided to illustrate the kind of useful information that this project will make available to the entire community.

The data displayed in the table is relatively simple. The MTBF for the device restoration-related failure rate shown in column C4 is derived by adding together the number of reported PM-related device failures and the number of PM Code 9 Failures found during the reporting period. The MTBF for the safety verification–related failure rate in column C8 is derived from the number of PM Code F

Failures found during the same period.

Table 4 illustrates how this project will enable the HTM community to present solid empirical evidence for which manufacturer model versions of the various potentially PM Priority 1 devices should be designated PM Priority 1. Generally speaking, all devices usually will exhibit different levels of reliability and PM-related risk when they are maintained at different intervals, and a device that exhibits an unacceptably high risk of a serious outcome when it fails from a PM-preventable failure will usually exhibit a lower, more acceptable level of risk when the PM interval is reduced.

Once this information begins to become available, it will no longer be necessary to guess at what the "safe" PM interval should be. The answer will be apparent from the numbers in the summary proof tables. In time, the results will show whether the manufacturer's recommendations are correct or if some require modification.[6]

Other issues, such as the thresholds for acceptability for the size of the experience base (Table 3) and what should be used as the acceptable level of safety (Table 2), require further deliberation. The task force is addressing both of these issues, and their current positions and conclusions can be found in the relevant documents on the website.

Commentary on the Hypothetical Data in Table 4
- According to the illustrative PM findings shown in rows R1 and R2, it appears that the brand A/model 1 critical care ventilator behaves like a PM Priority 1 device when it is maintained at a 12-month interval. As can be seen from the data in row R2, the frequency of device restoration-related (DR) failures is higher than the acceptable limit (with an MTBF of only 13 years) at this interval. However, the data in row R1 show that the frequency of DR-related failures (with an MTBF of 107 years) is comfortably below the acceptable limit (with an MTBF tentatively set at 75 years) when the same devices are maintained at the recommended 6-month interval. This provides good empirical evidence that the recommended PM interval of 6 months provides an adequate level of safety and that the 12-month interval is too long.
- In contrast to this, the PM findings data for the brand B/model 2 ventilator (R3 and R4), show that the device demonstrates an acceptable level of PM-related reliability and safety, even when it is maintained at a longer interval than the manufacturer-recommended 6-month interval.
- Although the brand C/model 3 ventilator (rows R5 and R6) shows acceptable PM-related reliability and safety when it is maintained at a 6-month interval, it shows an unacceptable frequency of performance/safety problems (with an MTBF of only 43 years) when it is maintained at the longer 12-month interval. It also shows an unacceptable frequency of device restoration–related failures (with an MTBF of 23 years). Based on this empirical evidence, this

particular model should be classified as a PM Priority 1 device if it is maintained at the 12-month interval.

- A different and more concerning pattern is seen with the PM findings data for the brand D/model 4 ventilator (rows R7 and R8). The data demonstrate unacceptable levels of PM-related reliability and safety at both maintenance intervals, apparently related to the poor reliability of the device's nondurable parts. As a result, this particular model should be classified as a PM Priority 1 device when maintained at either interval and consideration should be given to using a shorter (maybe 3-month) PM interval.

In Table 5.3HE on the website, clicking on the "active" link in the first field of the table (row R1, column C1) takes users to a detailed proof table (for a brand A/model 1 critical care ventilator, maintained at a 6-month interval), which shows all of the separate (again hypothetical) batches of data that are aggregated into the summary data shown in each row of the illustrative summary proof table.

Periodic Review of the Findings

The project plan calls for the members of the task force to regularly review the aggregated findings as they are posted on the website and to provide their collective informed judgments on 1) the adequacy of the sample size and experience base for each manufacturer model version at each maintenance interval, and 2) whether the indicated levels of PM-related safety are acceptable and truly representative.

Recommendations for Optimizing Periodic Maintenance of Medical Devices

For all PM Priority 1 devices that require periodic restoration. These are potentially hazardous devices with outcomes that could cause a serious, life-threatening patient injury and that have relatively high PM-related failure rates. For these devices, it would be prudent (even in the absence of any regulatory mandates) to follow, at least initially, the manufacturer's recommended PM interval. It is impossible to judge how conservative the manufacturers' recommendations for the device restoration intervals might be for each device. It is also unlikely that there will be any consistency in any included "safety factors" from device to device and from manufacturer to manufacturer. It remains to be seen how the aggregated findings from actual testing will compare with the recommendations. If the device is also found to have hidden failures with serious, life-threatening outcomes that real-world testing reveals to have failure rates with MTBF values less than the thresholds of acceptability (50 years for serious injuries [LOS 2] and 75 years for life-threatening injuries [LOS 3]), then it would be prudent (even in the absence of any regulatory mandates) to perform the safety testing at the manufacturer-recommended interval.

Rating	Amount of data (device-years)
Inadequate	<50
Good	50–200
Very good	200–500
Substantial	>500

Table 3. Tentative characterizations of different amounts of data in the experience base

For all PM Priority 1 devices that do not require periodic restoration. These also are potentially hazardous devices with outcomes that could cause a serious, life-threatening injury and that have relatively high PM-related failure rates. For these kinds of devices, for which the only "maintenance" that the manufacturer recommends is periodic safety testing, it would be prudent (even in the absence of any regulatory mandates) to perform the safety testing at intervals no longer than the manufacturer's recommendation. When testing for possible hidden failures with high-severity outcomes, there is no optimum interval—shorter is always better. However, it has been shown elsewhere[1] that for safety verification–related failures with MTBFs greater than about 50 years, the increase in the time that the patient would be exposed to potentially hazardous hidden failure(s) if the testing interval were increased from 6 months to as long as 5 years is very small.

For all PM Priority 2–5 devices that require periodic restoration. For these lower-risk devices, the logical rule here (in the absence of any regulatory mandates) is to explore extending the interval until there is evidence that it has become too long because the device is breaking down for lack of timely restoration. At this point, if there is a desire to eliminate the failure caused by the lack of device restoration, the interval should be moved back to the last interval where the device is no longer breaking down for lack of attention. For all practical purposes, there is no disadvantage in testing for hidden failures at the same interval as used for the device restoration tasks.

For all PM Priority 2–5 devices that do not require periodic restoration. For these lower-risk devices where the only "maintenance" that the manufacturer may recommend is periodic safety testing, and the PM-related failures have been found to occur relatively infrequently (with MTBFs greater than the respective thresholds of acceptability [75 years for LOS 3 devices, 50 years for LOS 2 devices, and 25 years for LOS 1 devices]), then in the absence of any regulatory mandates, there is no logical justification for performing anything more than occasional safety testing to confirm the previously established level of PM-related reliability.

	C1 Critical care ventilator type/PM interval (in months)	C2 Experience base (no of device-years)	C3 Is size of experience base acceptable? (see Table 3)	C4 MTBF for DR-related reliability	C5 Level of severity of DR-related failure modes	C6 Is level of DR-related reliability/safety acceptable? (see Table 2)	C7 PM priority level (see Table 2)	C8 MTBF for SV-related reliability	C9 Level of severity of SV-related failure modes	C10 Is level of SV-related reliability/safety acceptable? (see Table 2)	C11 PM priority level (see Table 2)
R1	Brand A/ model 1, 6 months: C.VEN/BA-M1/06	1,492 device-years	Yes, >500 device-years = substantial	107 years	LOS 3 (life threatening)	Yes, 75–150 years = acceptable - good reliability	PM Priority 2*	249 years	LOS 3 (life threatening)	Yes, >150 years = acceptable - very good reliability	PM Priority 3
R2	Brand A/ model 1, 12 months: C.VEN/BA-M1/12	80 device-years	Yes, 50–200 device-years = good	**13 years**	LOS 3 (life threatening)	No, <75 years = unacceptable to poor reliability	**PM Priority 1***	80 years	LOS 3 (life threatening)	Yes, 75–150 years = acceptable - good reliability	PM Priority 2
R3	Brand B/ model 2, 6 months: C.VEN/BB-M2/06	600 device-years	Yes, >500 device-years = substantial	100 years	LOS 3 (life threatening)	Yes, 75–150 years = acceptable - good reliability	PM Priority 2*	200 years	LOS 3 (life threatening)	Yes, >150 years = acceptable - very good reliability	PM Priority 3
R4	Brand B/ model 2, 12 months: C.VEN/BB-M2/12	160 device-years	Yes, 50–200 device-years = good	80 years	LOS 3 (life threatening)	Yes, 75–150 years = acceptable - good reliability	PM Priority 2*	80 years	LOS 3 (life threatening)	Yes, 75–150 years = acceptable - good reliability	PM Priority 2*
R5	Brand C/ model 3, 6 months: C.VEN/BC-M3/06	810 device-years	Yes, >500 device-years = substantial	90 years	LOS 3 (life threatening)	Yes, 75–150 years = acceptable - good reliability	PM Priority 2*	270 years	LOS 3 (life threatening)	Yes, >150 years = acceptable - very good reliability	PM Priority 3
R6	Brand C/ model 3, 12 months: C.VEN/BC M3/12	300 device-years	Yes, 200–500 device-years = very good	**23 years**	LOS 3 (life threatening)	No, <75 years = unacceptable - poor reliability	**PM Priority 1***	**43 years**	LOS 3 (life threatening)	No, <75 years = unacceptable - poor reliability	**PM Priority 1***
R7	Brand D/ model 4, 6 months: C.VEN/BD M4/06	400 device-years	Yes, 200–500 device-years = very good	**40 years**	LOS 3 (life threatening)	No, <75 years = unacceptable - poor reliability	**PM Priority 1***	200 years	LOS 3 (life threatening)	Yes, >150 years = acceptable - very good reliability	PM Priority 3
R8	Brand D/ model 4, 12 months: C.VEN/BD M4/12	160 device-years	Yes, 50–200 device-years = good	**53 years**	LOS 3 (life threatening)	No, <75 years = unacceptable - poor reliability	**PM Priority 1***	160 years	LOS 3 (life threatening)	Yes, >150 years = acceptable - very good reliability	PM Priority 3

Table 4. Summary proof table for critical care ventilators

Where there is a conflict between the PM priority levels indicated in columns C7 and C11, the more stringent (indicated by *) categorization should prevail. DR-related failure = device restoration-related failure. A device failure is considered to be a DR-related failure when it can be attributed to inadequate restoration of the device's non-durable parts. SV-related failure = safety verification-related failure. A device failure is considered to be an SV-related failure when it can be attributed to a hidden performance or safety deterioration that was not discovered and repaired during the device's last PM. MTBF = mean time between failures.

For all noncritical devices. By definition, there is absolutely no safety downside to these devices failing and, according to the RCM methodology (and in the absence of any regulatory mandates), unless there is a convincing case that periodic PM can be cost-justified, all noncritical device types are excellent candidates for the very cost-efficient light maintenance (run-to-failure) strategy. By adopting this run-to-failure maintenance strategy, the civil aviation industry was able to reduce maintenance costs by 50%, which also (amazingly) improved the reliability and safety statistics for civilian aircraft by a factor of 200 times.[1]

Regulatory Compliance

We have made no attempt in the current work to address the issue of dovetailing these concepts with the requirements in the current standards and regulations. This would be an excellent topic for a companion article by others with current expertise in regulatory compliance.

Final Cautionary Note

Patient and staff safety has long been the primary justification in the medical device field for performing routine PM on the hospital's frontline patient care equipment. Regular PM also has become a deeply rooted symbol of institutional caution and caring. If the equipment doesn't look well cared for, what does that imply about how well we take care of our patients?

The intent of this article is to address the apparent misunderstanding about how much regular PM contributes to keeping modern medical equipment safe. If this analysis is accepted as supporting a reduction in PM, we urge that careful thought be given to replacing those services with more efficient and less technically intensive alternative routines (such as department rounds) to ensure that the clinical staff still has confidence in the equipment and that it still looks well cared for and ready to do its job.

More detailed discussions of this and all of the other topics mentioned in this article can be found in various documents posted on the task force's website.

References

1. **Ridgway M.** Introduction to reliability-centered maintenance: the modern approach to planned maintenance. In: *A Practicum for Healthcare Technology Management*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2015.

2. **Ridgway M, Atles L, Subhan A.** Reducing equipment downtime: a new line of attack. *Journal of Clinical Engineering*. 2009;34(4):200–4.

3. **Wang B, Rui T, Balar S.** An estimate of patient incidents caused by medical equipment maintenance omissions. *Biomed Instrum Technol*. 2013;47(1):84–91.

4. **Ridgway M, Fennigkoh L.** Metrics for equipment-related patient safety. *Biomed Instrum Technol*. 2014;48(3):199–202.

5. **Ridgway M, Lipschultz A.** Doing it by the numbers. *Biomed Instrum Technol*. 2014;48(1):72.

6. **Ridgway M.** Manufacturer-recommended PM intervals: is it time for a change? *Biomed Instrum Technol*. 2009;43(6):498–500.