FINAL WORD

Manufacturer-Recommended PM Intervals: Is It Time for a Change?

Malcolm G. Ridgway

A robust debate is under way on various listservs and in professional journals about the standard requirement advanced by some regulating agencies and accreditation organizations that preventive maintenance (PM) intervals follow the equipment manufacturer's recommendations. The most influential of these is the language contained in the Interpretive Guidelines accompanying the regulations of the Center for Medicare and Medicaid Services (CMS).

- Section 482.41(c) (2)—*Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.* The CMS guideline reads: *A qualified individual such as a clinical or biomedical engineer … must monitor, test, calibrate, and maintain the equipment periodically in accordance with the manufacturer's recommendations. …*

A similar reference is contained in the federal regulations embodied in the Clinical Laboratory Improvement Amendments (CLIA).

- Section 493.1254(c) *Standard: Maintenance and function checks.* The CLIA regulation reads: *(a) Unmodified manufacturer's equipment, instruments, or test systems. The laboratory must perform and document the following: (1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. (2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. …*

As a result of these longstanding federal precedents, there are—not surprisingly—similar requirements to follow the manufacturer's recommendations in a number of state regulations and in some of the standards of voluntary organizations accrediting certain healthcare sectors.

What seems to irk the critics of these powerful and far-reaching mandates is the seemingly arbitrary nature of the recommended intervals. Some devices that appear to be very similar in function and design have manufacturer-recommended intervals that vary by a factor of two or more. Questions have been raised as to whether these recommended intervals are based on meaningful test data. And if they are, would manufacturers share that information? If there are no test data, or no willingness to share, and no other credible rationale is provided, then it is easy to understand the concern about the validity of these recommended values.

Setting PM Intervals

According to Reliability Centered Maintenance (RCM) theory[1] two factors should be considered when determining optimum PM intervals. The first is the so-called "useful life" of components that are not designed to last for the device's intended lifetime. This will set a maximum for the point in time before which the non-durable components will need to be restored or replaced. Although it is somewhat idealized, the curve shown in Figure 1 illustrates the way in which this "useful life" interval is defined and the nature of the data needed to establish what that interval should be. This information is available for more common non-durable components, such as rechargeable batteries that are likely to wear out and need to be replaced. We expect nothing less than this kind of information when we are shopping in the wider world for non-durable parts such as rechargeable batteries and automobile tires. For medical devices that have similar non-durable parts, it is the "useful life" of the component that will begin to wear out first that will generally set the maximum PM interval. In these situations—particularly when it is vital to minimize device failures—it is both logical and perfectly reasonable to follow the manufacturer's recommendations—provided they are consistent with "useful life" data available from the manufacturer of the non-durable components in question, or they are based on some other statistically meaningful set of test data. In some instances, where it is appropriate and practical, the overhaul or parts replacement interval may be specified in terms of device

usage (e.g. metered hours for some ventilators or metered usage for some x-ray tubes) rather than as a simple time interval.

How Often to Test?

The second factor that needs to be considered, particularly for devices that have no non-durable parts, is how often do we need to conduct periodic functional testing to confirm that the device is still performing within the manufacturer's performance and safety specifications, and has not already (at the time of testing) degenerated into a hidden failed state. This is, of course, particularly important if the consequences of this substandard performance are potentially life-threatening or otherwise very serious. According to RCM theory,[1, 2] the frequency at which these periodic confirmations should be conducted (frequency being the inverse of the testing interval = TI) relative to the average frequency with which these serious degradations are usually found (usually expressed as the mean time between failures or MTBF) provides us with a theoretical level of confidence that the device is safe. Quantitatively this can be expressed as a percentage probability or level of confidence (LOC) where:

LOC(%) = 100 – HFS(%) and

HFS(%) = 50 x TI (in years) / MTBF (in years)

(where HFS(%) represents the probability the device is in a hidden failed state).

It makes good intuitive sense that, for the same level of confidence, a device that exhibits a high level of reliability (by showing a relatively low "yield" of failures when it is tested) will need to be tested for this reassurance less often than one that yields more failures when tested. For example, suppose that PM testing data shows that the most commonly reported hidden failure of a particular brand and model of infusion pump that is potentially life-threatening is a defective line cord, and that this particular defect has a MTBF of 100 years. Then the probability that this type of pump will have this defect when the testing is done annually, will be (50 x 1/100 =) 0.5% If the testing interval is reduced to six months, the probability will be reduced to (50 x 0.5/ 100 =) 0.25%. Reducing the test interval increases the LOC from 99.5% to 99.75%. If the PM testing data had shown an MTBF of 1,000 years, the LOC numbers would be 99.95% for annual testing and 99.975% for semiannual testing. And if the data had showed an MTBF of only 10 years, the LOC numbers would be reduced to 95% and 97.5% respectively. Many current PM procedures for medical equipment do incorporate performance verification and safety testing tasks that are intended to detect potential hidden failures, particularly when those failures could result in a serious safety hazard.

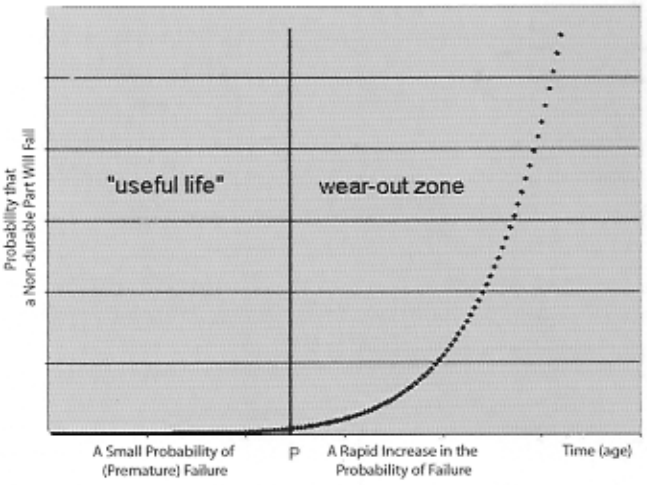

Figure 1. Idealized Reliability Centered Maintenance (RCM) Type B Failure Pattern; obtained from component failure data by plotting the number of failures that occur at successively longer time or usage intervals. For components that are vulnerable to wearing out (such as mechanical bearings) or otherwise deteriorating with time or with use (such as rechargeable batteries and door gaskets), the number of failures typically begins to increase quite rapidly after a certain point (P). The time or usage period prior to this point is known as the component's "useful life."

Data Collection

Finding the appropriate PM interval for procedures that consist of only performance verification and/or safety testing is more challenging than setting the optimum intervals for maintaining devices that have one or more non-durable parts, because it requires access to empirical data on the MTBF of those hidden failures. Because these hidden failures are essentially random there is a need for fairly extensive, statistically meaningful data collected in a real-world, or simulated real-world, environment. Considering the time and probable cost of simulating a real-world environment, it's unlikely that manufacturers will generate this data. A practical source for this data is the findings of routine PM testing now performed in hospitals. One minor complication here lies in the lack of an established consensus on what should be the minimum acceptable LOC that the device is safe when the consequence is potentially life-threatening. Professional risk managers have wrestled with this issue for some time and have come up with only relatively broad guidelines.[1]

Our tolerance for life-threatening risk varies according to the nature of the risk (exposure to a fatal traffic accident, to ionizing radiation, or to an unsafe medical device, etc.) and the circumstances of the exposure (whether we expose ourselves willingly—for example by driving—or whether we are exposed involuntarily). Using an analysis of PM findings from existing devices to document the current levels of exposure to potentially life-threatening failures would give us a good place to start the discussion.

Managing Risk

Given existing regulatory mandates, it seems the driving concern is patient safety. For the vast majority of medical devices, however, the consequences of device failure are not potentially life-threatening, and in most instances the failures cannot even be classified as serious. Out of a total of more than 1,500 different medical devices, only a few—probably less than 25—are classifiable as having potentially life-threatening failure modes. However, it is this important subset that needs special attention.

All devices fail, and they do so for a variety of reasons other than the deterioration of a non-durable part. Even a perfectly executed PM program cannot and does not ensure that a device will not fail. In fact, allowing non-durable parts to run-to-failure will, in most cases, have only a minor impact on the device's overall reliability. It is also well worth emphasizing that only failures that are the result of the deterioration of a non-durable part (a part that exhibits a failure pattern similar to that shown in Figure 1) are predictable and preventable. All other types of device failure are random (i.e., not predictable and not preventable). The average rate at which devices fail varies and can depend on:

- The design of the device itself.
- The quality of the device's components.
- The construction and assembly of the device.

In addition to intrinsic reliability factors, there are a number of other external contributors to device reliability, such as heavy use and misuse, that can, and in the real world do, further increase a device's failure rate. There is no way that medical devices—even those with serious or life-threatening consequences of failure—can be mandated not to fail.[3]

Devices that have failure modes that are potentially life-threatening need to be identified and subjected to special measures aimed at providing the patient with some kind of prompt alternate support when these critical devices do fail. Devices in the critical (life-support) category that have non-durable parts needing timely restoration or replacement (i.e., that are PM-critical, life-support devices) must be given high priority for timely PM completion. The intervals for this high priority PM need to be set on the conservative side of the empirically determined "useful life" of the vulnerable components. This is an efficient and well-focused, risk-based maintenance strategy.

For devices that do not fall into this PM-critical, life-support category, there is no safety imperative and they should be allowed to run to failure unless there are good economic reasons to do otherwise.

Call for Action

The vast majority of medical devices benefit little from preventive maintenance and they should be allowed to run to failure unless (a) they have life-threatening or very serious PM-preventable failure modes, or (b) proactively replacing the non-durable parts will be more cost-effective than simply repairing the device when it breaks. Failures resulting from not replacing parts subject to wear or progressive deterioration reduce overall equipment reliability by a relatively small amount, and streamlining our PM programs to focus on the devices with high consequence PM-related failures would free up a substantial fraction of the valuable technical manpower devoted to medical equipment maintenance. These technical resources could then be redeployed to perform more important and more productive tasks. An intensive focus on devices that have high consequence PM-related failure modes will also help ensure the highest levels of patient safety.

However, two questions remain: How should we gather the empirical MTBF and parts failure data required to implement this alternative approach? Who should be tasked with performing the analyses required to specify which devices should be classified as PM-critical, life-supporting devices?

Resolution of these important issues is long overdue. ■

References

1. **Moubray J.** *Reliability-centered Maintenance,* 2nd ed. Industrial Press Inc., New York, 1992.
2. **Ridgway M.** Optimizing Our PM Programs, *Biomed Instrum Technol.* 43(3): 244-254.
3. **Ridgway M. Atles L., Subhan A.** Reducing Equipment Downtime: A New Line of attack. *J Clin Eng.* 34(4) 200-204.

Malcolm G. Ridgway, PhD, CCE, is senior vice president for technology management at Masterplan Inc.