DOCUMENT: Future ANSI/AAMI EQ89, Guidance for the use of medical equipment maintenance strategies and procedures

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Guidance for the use of medical equipment maintenance strategies and procedures

Abstract: This standard is intended to provide basic information to health care technology management professionals by identifying and describing in general various maintenance strategies and methods for efficient, effective, and timely maintenance of medical equipment in health care facilities. The standard neither mandates nor requires that any of these specific strategies be used, but instead discusses in general the uses of these methods and their potential advantages and disadvantages.

Keywords: medical equipment, maintenance, testing.
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Glossary of equivalent standards

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Committee representation

Association for the Advancement of Medical Instrumentation

Medical Equipment Management Committee

This recommended practice was developed by the AAMI Medical Equipment Management Committee. Approval of the recommended practice does not necessarily mean that all committee members voted for its approval.

At the time this recommended practice was published, the AAMI Medical Equipment Management Committee had the following members:

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.
Foreword

The overall goal of medical equipment maintenance is to ensure that the equipment functions as intended in a safe and effective manner, and to ensure that the equipment is available for use when needed. Health care technology management (HTM) professionals can employ a variety of strategies to meet this goal. This standard outlines some of the commonly used maintenance strategies. This standard is not a maintenance plan, but rather provides guidance around which HTM professionals can apply maintenance strategies and procedures.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the AAMI EQ89/CDV-1, Guidance for the use of medical equipment maintenance strategies and procedures (AAMI EQ89/CDV-1), but it does provide important information about the development and intended use of the document.
Guidance for use of medical equipment maintenance strategies and procedures

Introduction

Sometimes health care technology management (HTM) professionals need to create or modify maintenance strategies and procedures for medical devices or device systems. While the procedures and schedule may vary from facility to facility, the process by which they are developed should be consistent throughout the HTM industry. This document is intended to create the framework for this process.

There are a variety of reasons for creating a maintenance strategy or procedure, including, but not limited to:

a) Maintenance guidelines for the device are not available (e.g., end-of-support for the device).

b) Test equipment specified in the existing procedure is no longer available, or there are new devices that accomplish the same outcome in a different but equivalent manner.

c) Technology of testing equipment has evolved and a different but equivalent method to accomplish the same outcome is available.

d) The procedure needs to be updated.

e) The existing procedure has steps that have been deemed unnecessary or insufficient (e.g., following a step on a device in a given setting may prove through experience to have no impact on maintaining or increasing reliability).

f) The existing procedure may be written for a worst-case scenario or environment that is not appropriate for the device in question (e.g., a device inspection procedure made with the assumption that the device is being used by ambulance crews and is subject to significant wear and tear, but the device in question is in a low-risk area in a health care facility).

g) The existing procedure may include steps that could be performed more efficiently if they were combined or performed in a different order than currently stated.

While there are many accepted maintenance strategies for medical devices, HTM professionals should select the method(s) that work best for their program. Regardless of the method(s) used, HTM professionals should provide documentation of methodologies used for establishing procedures.

Regulatory agencies or other authorities having jurisdiction (AHJ) (whether national, state, or local), may proscribe maintenance requirements that differ than the strategies and procedures presented in this standard. HTM professionals must follow all applicable AHJ guidelines.

1 Scope

This standard is intended to provide basic information to health care technology management (HTM) professionals by identifying and describing in general various maintenance strategies and methods for efficient, effective, and timely maintenance of medical equipment in health care facilities. The standard neither mandates nor requires that any of these specific strategies be used, but instead discusses in general the uses of these methods and their potential advantages and disadvantages.

1.1 Inclusions

This standard identifies general maintenance strategies and procedures that might be incorporated into a medical equipment management plan.
1.2 Exclusions

This standard does not cover other components of a medical equipment management plan (see ANSI/AAMI EQ56). It does not identify device-specific maintenance strategies, nor does it address all applicable regulations from national, state, or local AHJs that must be followed.

2 Definitions and abbreviations

2.1 acceptance testing: Interaction with medical equipment designed to determine whether newly received equipment is in good operating condition, prior to being placed into service for its intended use.

2.2 authority having jurisdiction (AHJ): A department, individual, or group that has the delegated authority to determine, mandate, and enforce code requirements established by jurisdictional governing bodies.

2.3 benchmarking: The measurement of any aspect of performance against a known metric, such as a budget, technical specification, regulatory standard, or the performance level of peers.

2.4 corrective-only maintenance: any maintenance activity required to correct a failure that has occurred or is in the process of occurring.

2.5 critical device: a device that might cause or result in patient death or serious injury if it fails.

2.6 end-of-support: The last date that a product will be supported by its manufacturer.

2.7 fail safe: A feature that automatically counteracts the effect of an anticipated, potential source of failure.

2.8 health care organization: Organization that provides medical, dental, psychiatric, nursing, obstetrical, or surgical care.

NOTE—Health care organizations include, but are not limited to, hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory care centers, whether permanent or movable.

2.9 health care technology management (HTM) professional: A professional who works in the field responsible for managing the selection, maintenance, and safe and effective use of medical equipment and systems. This field includes biomedical equipment technicians (BMETs), clinical engineers, imaging equipment specialists, laboratory equipment specialists, and others who protect patient safety and reduce health care costs related to technology.

2.10 inspection: Interaction with medical equipment designed to detect unsuspected equipment problems, or to perform planned maintenance.

2.11 life-support equipment: Any device used for the purpose of sustaining life and whose failure to perform its primary function, when used according to manufacturer’s instructions and clinical protocol, will lead to patient death in the absence of immediate intervention.

2.12 maintenance: Interaction with medical equipment designed to identify and correct suspected equipment problems, or to perform activities designed to prevent the future occurrence of problems.

NOTE—Maintenance may be initiated on either an unscheduled basis (usually repairs) or on a scheduled basis (usually planned maintenance).

2.12 maintenance strategy: a systematic approach to keep medical devices in safe and good working condition.

2.13 medical equipment: Medical devices that have been cleared by the FDA that are intended to be used for diagnostic, therapeutic, or monitoring care provided to a patient by a health care organization.

NOTE 1—Medical equipment includes devices such as monitoring equipment, life support equipment, imaging equipment, laboratory equipment, mechanical equipment, transport equipment, as well as any other equipment supporting the care of a patient, whether or not it is in the immediate vicinity of a patient. In addition, this category includes other devices, such as computers, that support the care of a patient when in a health care organization, but are generally not specifically manufactured for use in a health care organization. As used in this recommended practice, the term “equipment” refers to medical equipment.

NOTE 2—Embedded software is covered by the medical device manufacturer; standalone software is covered by ANSI/AAMI/IEC 80001-1:2010, Application of risk management for IT networks incorporating medical devices—Part 1: Roles, responsibilities, and activities.

2.15 non-critical device: a device that would not cause or result in patient death or serious injury if it fails.
2.16 **non-life-support equipment:** Any medical device that is not used for the purpose of sustaining life, and whose failure to perform its primary function will not lead to patient death or serious injury.

2.17 **planned maintenance:** Any maintenance activity that takes place before a device experiences a loss of function.

2.18 **predictive maintenance:** Maintenance performed based on the known and expected behavior, condition, and history of the device.

2.19 **preventive maintenance:** An equipment maintenance strategy based on replacing, overhauling or remanufacturing an item at a fixed interval, regardless of its condition at the time.

2.20 **reliability:** The probability that equipment, machinery, or systems will perform their required functions satisfactorily under specific conditions within a certain time period.

2.21 **training:** Interaction with medical equipment designed to provide instruction to an equipment operator or a service agent about the proper method for operating or maintaining the equipment.

2.22 **use:** Operation of the medical equipment in conjunction with the medical treatment provided to a patient.

**NOTE**—Use does not include operation of the medical equipment during acceptance testing, inspection, maintenance, or training activities.

3  **Developing a maintenance strategy**

At all times the goal of the HTM professional is to ensure that the medical equipment they are responsible for is safe and performs as specified by the manufacturer. A maintenance strategy is not a one-size-fits-all approach. HTM departments should develop a plan that will keep the devices maintained without expending resources unnecessarily.

**NOTE**—It would be unsafe and impractical to have all devices in the corrective-only maintenance strategy, or to have everything on an overly aggressive schedule.

Before any changes to maintenance strategies are considered, the original equipment manufacturer’s (OEM) maintenance procedures should be consulted whenever they are available.

The HTM professional should also consider the following when determining a maintenance strategy for a device:

a) the process used to determine the maintenance strategy for similar devices.

b) fail-safes.

c) the availability of back-up critical devices, as well as the clinical nature of a device. The availability of a back-up device does not mitigate the failure, but it can help mitigate the impact of that failure on patients.

d) available evidence and rationale:
   - available data (e.g., a peer HTM department’s data for a given device if the sample size is small or the device is relatively new).
   - maintenance history over time and before and after any procedure modifications.
   - documentation regarding what has changed, why it was changed, when it was changed, and who made the change.

4  **Creating alternative maintenance procedures**

4.1 **General considerations**

When evaluating any potential change to a maintenance procedure, whether for an individual device or within broader device categories, types, or models, the HTM professional should consider the factors outlined in this section.

4.2 **Failure modes and failure effects**

4.2.1 **General considerations**

The factors that may contribute to equipment failure, or otherwise affect equipment reliability, should be considered when selecting the most effective maintenance strategies intended to reduce failure. This might include determining
devices that might fail catastrophically (evident failure mode) and the impact that failure might have on patient or
operator safety (failure effects).

4.2.2 Evidence of equipment failure

HTM professionals should consider the potential types of failure. Device failures can fall into two broad categories:

a) An evident failure is a failure where the device ceases to perform as expected. The operator would normally
report the malfunction.

b) A hidden failure is a failure where the device appears to be working but has a defect that the operator may
not notice.

4.2.3 Functional failures

HTM professionals should consider whether a failure affects a primary function or a secondary function of the device,
which is determined by the context in which the device is used. In some operating contexts, secondary functions may
be as critical as the primary functions.

a) A primary function is one that the equipment operator has determined to be critical to their clinical
operations.

b) A secondary function may be a non-critical function, but is included for convenience, safety, or efficiency.

4.2.4 Risk

4.2.4.1 General considerations

HTM professionals should consider the impact (consequence) of a device failure. In reliability standards, a higher
priority is given to failures that have safety or environmental consequences—that is, where there is a potential harm
for either an individual operator or the public at large. In health care, the analogous concepts would be medical
devices that provide life support functions; devices that are reasonably likely to injure or kill a patient if they abruptly
fail; or mission critical devices where a primary failure may significantly disrupt delivery of urgent health care
services.

NOTE—Delay in treatment or diagnosis is often identified as a contributing factor in the root cause analysis of the sentinel events
reported to health care accrediting organizations. Failure of a mission critical type device is one that has the possibility of creating a
delay in treatment.

4.2.4.2 Risk assessment

Before implementing or revising a maintenance procedure for a specific set of equipment, risk should be assessed
by considering:

a) The possible impact of the proposed change.

b) The probability of that impact.

c) The history of incidents from like devices.

HTM departments should consult with their appropriate committees or departments (e.g., risk management, safety,
environment of care). Other resources include the FDA’s Manufacturer and User Facility Device Experience
(MAUSA) database and ECRI Institute data.

4.3 Clinical environment

The clinical environment in which the device is operating can impact the maintenance requirements for the device.

NOTE—A portable defibrillator used by paramedics in an ambulance may be subjected to frequent mechanical abuse from rough
service. An identical unit may remain relatively undisturbed for months on a crash cart on a med-surg unit and suffer very little
mechanical abuse. Therefore, the paramedics might need to check their equipment several times a day for functional failures,
whereas the unit on a crash cart might need to be checked much less frequently.

HTM professionals should identify significant features in the operating context and determine if they affect the
maintenance requirements for that equipment. Some factors to consider include:

a) Clinical requirements. Identical devices may be used in several different areas (units) of the hospital.
NOTE 2—A digital scale may have different requirements if used in the pharmacy to weigh drugs (ug), in the nursery to weigh neonates (g), or in med-surg to weigh bariatric patients (kg). If the requirements are significantly different, the maintenance strategy may also be different.

b) Operators. The device may be used by a limited number of highly proficient operators, or numerous operators with a wide range of experience in a multitude of settings. Some equipment may leave the hospital environment and be operated by patients.

c) Redundancy. In certain contexts, there may be multiple devices that could provide the equivalent required clinical function. Providing redundancy may redefine the planned maintenance requirements.

d) Back-ups. The availability of back-up equipment may affect the urgency and intensity of planned maintenance activities.

e) Spares. If an entire device cannot be available for a backup, selected high-failure parts or sub-assemblies could be available in reserve to quickly restore functionality of critical equipment.

f) Restoration: How quickly the clinical function can be restored may affect the maintenance strategy.

4.4 Physical environment

HTM professionals should consider the impact of the physical environment on the device. Factors to consider include, but are not limited to:

a) Dusty environments (including heavy use of surgical drapes and linens that create dust).

b) Frequency of use (stored on a cart or used in transport daily).

c) Elements (is the device subjected to weather).

d) Temperature/humidity.

e) Contact with fluids (near wet locations such as hydrotherapy or swimming pools, cleaning solutions).

f) Portable versus fixed location.

4.5 Reliability

HTM professionals should consider the reliability of a device, which should be available in the device history:

a) Frequency and types of failures: How often is the device failing?

b) Downtime during repairs: How long does it take to accomplish the needed repairs? How long is the device out of service?

c) Repair trends (by type, operator group, etc.).

In addition to the device history, reliability information may be available from other sources.

4.6 Performance verification testing/inspection

HTM professionals should consider performance verification testing/inspection of the device:

a) Does the operator conduct performance verification before use?

b) Is there an inspection checklist for operators before use?

c) Do maintainers have a performance verification procedure?

d) Is there an inspection checklist for maintainers?

4.7 Built-in self-testing

HTM professionals should determine if the device has a built in self-test that runs when the device is powered on and/or periodically thereafter.

4.8 Calibration

HTM professionals should determine whether a device requires an actual calibration per manufacturer's specifications or a calibration verification.
NOTE—Some, typically older devices have adjustments that need to be made to keep a device within the specified tolerances, while most newer devices are self-calibrating or have built-in calibration routines.

4.9 Training

HTM professionals should consider the amount of training on a given device, for both operators (clinicians) and maintainers. The better the operators and maintainers understand the proper function and limitations of the device, the more proficient they will be with the equipment. This may reduce use errors and improve operator satisfaction of the device. Considerations include, but are not limited to:

a) Can the operator detect a failure with the equipment?

b) How is the device used?

c) Are there training media available to operators and maintainers?

See also ANSI/AAMI/IEC 62366.

4.10 Batteries

HTM professionals should, if applicable, evaluate battery maintenance strategies:

a) Replacement on a fixed schedule per manufacturer’s recommendations.

b) Replacement on a fixed schedule based on device maintenance evidence.

c) Replacement based on testing criteria.

d) Replacement upon failure.

Rationale: Devices that are used for portable functions need to have a reliable battery. Some items are portable and life support. Battery technology is ever evolving, with newer, faster charging batteries being introduced frequently.

4.11 Accessories

HTM professionals should evaluate accessories for testing and/or replacement as part of any testing/inspection procedure.

4.12 Mitigation

Mitigation is the act of making a condition or consequence less severe. HTM professionals should consider applicable mitigation strategies for reducing the impact of equipment malfunction. Mitigation strategies include:

a) Having sufficient back-up devices available.

b) Having well-trained clinical and technical staff.

c) Keeping devices in safe working condition.

4.13 Utilization

HTM professionals should consider how frequently a device is used.

4.14 Parts availability

As part of the process of adjusting a procedure, HTM professionals should consider the availability of replacement parts.

4.15 Age of equipment

HTM professionals should consider the age of the equipment, as wear and tear of use and deterioration of components could affect the frequency of testing and planned maintenance.

4.16 Time to repair/downtime

HTM professionals should evaluate the time to repair a device in terms of the steps required and possible impediments to completing this repair.

After reviewing the possible impediments, the evaluation result should state a best-case, probable-case, and worst-case scenario for repairing the device. These time-to-repair metrics should then be compared to the acceptable
downtime for the medical device in the environment in which it is used. Devices whose repair times fall above the acceptable timeframe for downtime should have their maintenance and inspection procedures reviewed to ensure the risk of unacceptable downtime is minimized. Possible impediments to consider include:

Availability of:

a) needed parts.
b) expertise required to perform the repair.
c) testing and/or calibration equipment.
d) staff authorized to approve the purchase of parts and/or services.
e) metrics to determine whether a device should be repaired or replaced.
f) the device to be repaired. As more medical devices migrate outside the standard hospital/medical office building locations to patient’s homes, new maintenance and inspection procedures may be required to ensure patient safety. Ambulances present a challenge and potential increase in patient risk. There is a high probability of ambulance-based devices being used when there is an immediate danger to life and/or health and in a harsh environment that might stress medical staff and devices.

Workflow:

g) The level, timeliness, and accuracy of intra- and inter-departmental communication on device and process failure.
h) Applicable staff’s knowledge of device failure identification and appropriate responses to these failures.
i) An efficient and timely inter-departmental process to identify:
   - failure to the appropriate departments.
   - the current location of the device.
   - the required priority of addressing the failure.
j) Whether the device is currently being used in patient treatment and whether the failure compromises the treatment or the patient’s life or health.

4.17 Cost of planned maintenance versus repair or replacement

HTM professionals should consider the cost of performing planned maintenance on an item versus replacing it when it fails, or making the necessary repairs.

4.18 Regulatory requirements

Requirements necessary to maintain compliance with any governing bodies should be taken into account. There may be some regulatory bodies that require a certain schedule of device inspection, testing, and documentation for a particular device or group of devices. HTM professionals should be aware of these requirements and structure their maintenance procedures accordingly.

Regulatory agencies or other AHJs (whether national, state, or local), may proscribe maintenance requirements that differ than the strategies and procedures presented in this standard. HTM professionals must follow all applicable AHJ guidelines.

5 Maintenance strategies

5.1 General considerations

This section reviews the most common maintenance models currently utilized in the health care technology industry with a very general selection guideline. Maintenance, within the context of this document, is defined as the combination of technical and associated administrative actions intended to retain an item or system in, or restore it to, a state in which it can perform its required function.

The description of maintenance strategies and selection methodology that follows is not intended to be:
a) A complete inventory of all existing maintenance strategies. Many maintenance strategies currently utilized in various industries and/or groups of equipment are not included due to their specialized nature and/or impractical application in the health care environment.

b) A complete analysis of all the maintenance strategy selection methods. There are many multi-criteria decision-making approaches requiring extensive data collection, advanced mathematical tools, and time consuming analysis that are outside the capabilities of the typical HTM operation.

Maintenance strategy is defined as a systematic approach to keep medical devices in safe and good working condition, taking into consideration multiple factors such as the manufacturers’ recommendations (if/when available), the types of devices, their working environment, their importance to the organization’s operations (mission-criticality), their locations, and the resources available to the maintainers (human, financial, material, etc.). The most effective maintenance strategy for any given device may vary from facility to facility or even within the same organization, depending on the determinant combination of factors.

When selecting the best approach to ensure medical equipment function (safety, availability, and quality), HTM professionals should consider three basic questions:

c) Which strategy will be the most effective for each type of equipment in the environment where it will perform its function?

d) What is the minimum frequency that will produce acceptable results?

e) How will the selected strategy or procedure be implemented considering the organization’s resources and priorities?

Once a maintenance strategy has been selected and implemented, the next critical step is implementing effective monitoring that can assist with further process refining and improvement. The organization should determine, collect, and analyze appropriate data regularly to demonstrate the effectiveness of testing procedures and frequency and to evaluate the need for adjustment. Data analysis should provide information relating to preventative maintenance modifications.

5.2 Corrective-only maintenance

Corrective-only maintenance is also known as run-to-replace maintenance, run-to-failure maintenance, breakdown maintenance, failure-based maintenance, and other similar terms. When this strategy is selected, a medical device is used until it fails or the operator notices early signs of malfunctioning. At this point corrective maintenance is initiated and one of two actions is typically selected to restore the equipment function: repair or replace.

NOTE—Corrective maintenance is sometimes used interchangeably with “repair” but in the context of this document “repair” is one of the actions that can be selected to restore the equipment function within the broader corrective maintenance concept. In that sense, “repair” is the term that describes the technical steps necessary to solve only one equipment malfunction. Consistent with ISO 14224, a corrective maintenance will include a repair (or repairs if there were multiple malfunctions) plus other associated actions such as calibration (if required), documentation, etc.

In evaluating this maintenance strategy, the HTM professional should consider:

a) Total cost of repair (parts cost + labor cost + travel cost) compared to total cost of replacement.

b) Age of the device. If a device is at the end of its useful life it may be preferable to replace it.

c) Timing (i.e., which option can be implemented faster and result in less disruption to clinical operations).

d) Resource availability. A device could initially be replaced with a spare unit and repaired later under more favorable conditions.

HTM professionals should make the decision to use this strategy in consultation with clinical operators and considering the organizational resources available.

This strategy alone may be appropriate when the device’s failure (total or partial) will not compromise the patient’s or the operator’s safety, its consequences will not have a major impact on the organization’s ability to continue operating effectively, and the device falls in one or more of the following categories:

e) Failures don’t occur at repeatable time intervals.

f) There is no practical or cost effective means to detect failures before they occur.

g) The device has a low replacement cost compared to other associated costs such as downtime and/or repair costs.
h) The device can be easily replaced with a readily available spare unit and returned to service at a later date.

i) The cost of corrective maintenance is less than implementing any form of planned maintenance.

Each organization should decide which types of equipment meet the criteria for this maintenance strategy based on its particular situation and resources.

5.3 Planned maintenance

5.3.1 General considerations

Planned maintenance is a general term that is applied to maintenance strategies that take place before a device experiences a loss of function. Selection of any planned maintenance strategy should be considered if:

a) the device’s failure (total or partial) could compromise the patient’s or the operator’s safety;

b) its consequences could have a major impact on the organization’s ability to continue operating effectively; and

c) the device falls in one or more of the following categories:

- Failures are likely to occur at repeatable time intervals.
- The maintainers have practical and/or cost-effective means to detect conditions that might lead to either evident or hidden failures.
- The device has a high replacement cost compared to repair cost.
- There is a high downtime cost due to high fixed costs, loss of revenue, reputation damage, negative impact on patient satisfaction, significant clinical impact, etc.
- The device cannot be easily replaced with another unit.

5.3.2 Preventive maintenance

The goal of preventive maintenance (called interval-based maintenance by The Joint Commission) is to prevent failures by disassembling the device (when required), cleaning, lubricating, adjusting, and automatically replacing non-durable parts (see Note) at specified time intervals (annually, semiannually, quarterly, etc.). It assumes that components have a repeatable rate of degradation and the selected replacement intervals are shorter than the times to failure.

NOTE—Non-durable parts are those components of the device that have been identified by either the device manufacturer or general industry experience as needing periodic attention, or being subject to functional deterioration and having a useful lifetime less than that of the complete device (Ridgway, 2009).

HTM professionals might consider a preventive maintenance strategy for medical devices that have parts with known and repeatable degradation rates. The OEM usually provides this information. If it is not available, other sources such as the intervals adopted successfully by the general industry can be selected initially. As the organization develops its own experience with the device, intervals may be increased or decreased until an acceptable level of corrective maintenance associated with components reaching the failure point before they are replaced or repaired is reached.

This strategy has two main disadvantages:

a) Components are replaced independently of their condition—potentially resulting in unnecessary and wasteful practices if the wear-out period is significantly greater than the replacement frequency.

b) There are variations in the time-to-failure distribution and occasionally the replacement interval exceeds it, resulting in potentially avoidable corrective maintenance.

A variation of this strategy (called metered maintenance by The Joint Commission) is to measure the equipment’s run time and base the preventive maintenance on when it reaches a certain number of utilization units (hours, cycles, etc.). This approach is not always practical or feasible if the medical device doesn’t have a mechanism to measure run time or utilization.

5.3.3 Predictive maintenance

Predictive maintenance is sometimes referred as condition-based maintenance because parts are replaced only when they are out of prescribed limits or predefined conditions. Predictive maintenance is similar to preventive
maintenance except that it does not involve the automatic replacement of parts. Instead, components showing excessive wear and tear are identified and replaced on as-needed basis. It has similar disadvantages as preventive maintenance concerning variations in selecting the optimal time to measure conditions that would drive replacement of components. However, by using a run-time-based schedule, maintenance may be more effective provided that maintainers can reliably collect the necessary data and manage the workload fluctuations. Sensors to measure wear, vibration, heat, etc., may also signal optimal timeframes for parts replacement.

5.3.4 Diagnostic or detective maintenance
Currently, the vast majority of planned maintenance activities for medical equipment are intended to verify operation within acceptable parameters, detect incidental damage, or verify secondary functions (including protective functions). Intentional parts replacement, refurbishing, or other corrective maintenance is rarely anticipated in the scheduling. The purpose of this planned event is detection of abnormal conditions, and it is also known as a fault-finding default task.

Performance verification tasks for medical equipment may also encompass calibration verification, electrical safety checks, and software version control. If deficiencies of any type are found it is common to issue a corrective work request to remediate.

Since the activity is not based on part replacement or age, setting an appropriate interval for fault-finding activities does not necessarily follow the same schedule as preventive or predictive maintenance. Activities might be based on:

a) Criticality of the equipment.
b) Failure modes (random or predictable).
c) Potential for hidden failures (calibration, silent protective systems).
d) Presence (or absence) of other fault-finding diagnostics or activities such as operator functional checks, equipment self-check, on-board diagnostics, and self-calibrating circuitry.
e) Commissioning inspections. Since most failures statistically occur just after installation, a fault-finding inspection after installation might be prudent.
f) Post-repair inspection. Since a repair or refurbishment is similar to a new installation, a performance verification activity immediately after a major repair might also be appropriate.

5.4 Evidence-based maintenance
An evidence-based maintenance strategy relies on the experience of other devices to predict the performance (or lack thereof) of similar equipment. The implementation of evidence-based maintenance may lead to appreciable reductions in labor and parts costs without compromising the equipment safety and availability. Limitations in the quality and accuracy of performance data may reduce its effectiveness.

Evidence-based maintenance relies not only on the observed history of failures, but the theoretical probability of certain types of failures. This second type of analysis is typically beyond the capabilities of most service organizations, but the conclusions or general recommendations for certain device types can be applied directionally in maintenance decisions.

6 Documenting maintenance findings and repairs
6.1 General considerations
Records of maintenance inspections should be maintained. Appropriate data may consist of, but is not limited to trends identified by repair histories and reflective of:

a) Clinical environment
b) Device type
c) Manufacturer model and serial number
d) Failure type

6.2 Documentation from maintenance activities
The HTM professional should document maintenance activities, including results of preventive maintenance inspections and disposition of equipment failing preventive maintenance inspections.
6.3 Documentation from outside sources

The HTM professional should document information obtained from outside sources, including changes recommended or required by the OEM; new or amended regulatory requirements; and changes recommended by national or international standards.
Annex A

(informative)

Benchmarking

Benchmarking identifies opportunities for improvement. Whenever any aspect of performance is measured against a performance standard—a budget, a technical specification, a regulatory standard, the performance level of peers—that is benchmarking. The idea is to compare the various aspects of performance of health care technology management programs to those of other programs and identify opportunities for improvement. Aspects of performance that fall short of what is achievable reveal potential opportunities for improvement and an area in which focused efforts are likely to produce significant gains in performance.

There are three critical components of benchmarking. The first is performance measurement, including agreeing on definitions of what is being measured, and methods for making these measurements. Three broad categories of performance measures are productivity (or time to accomplish a task), quality, and cost. Within each of these categories are dozens of measures that can be made in a consistent manner so that performance can be objectively compared. For example, productivity measures include how long it takes to inspect a particular make and model of equipment, quality measures include how frequently repairs are repeated on the same piece of equipment, and cost measures include the maintenance cost of a type of equipment as a percent of its acquisition cost.

The second critical concept is best practices: the things—policies, procedures, practices—that lead to high performance. Best practices include determining not only what performance is best, but how it was attained and how one's own performance compares. One important resource is the professional literature, including descriptions of what works in health care technology management and in related professions. Health care technology management has its own extensive literature, but there is much to learn from other professions that manage sophisticated technologies in high-risk settings. Another important resource for identifying best practices is professional experience—that of individuals, original equipment manufacturers, and the collective knowledge-base of colleagues—typically shared through informal networks and formal professional associations.

The third is performance improvement: applying best practices and getting better at whatever it is being done. In the context of health care technology management, performance improvement is about getting better at managing technology. Every aspect of performance—financial, technical, regulatory compliance, and so on—can be improved. Ongoing performance improvement is essential for health care technology management and is the ultimate objective of benchmarking.

The key to effective benchmarking is to find a reference group whose characteristics match those of the program being reviewed. Organizational characteristics that are important to match might include size, type of service, geographical location, and other demographic factors. Critical characteristics of the program might include the scope of services, mix of equipment, type of accreditation, and so on. The objective is to find a reference group that is comparable with regard to factors that can be expected to influence key aspects of performance. The reference group also needs to measure performance using the same definitions and methods of measurement.

When comparing the performance of one health care technology management program to the performance of an appropriate reference group, any differences in performance are more likely to be based on different practices rather than different environments. As a result, an aspect of performance in which one program falls short is likely to represent an achievable opportunity for improvement, an opportunity that can be capitalized on by adopting best practices associated with high performance in that area of health care technology management.

There are many practical applications of benchmarking. For example, it can be used as a communication tool to help justify requests for organizational resources. It can show that staffing and budgeting for a program are in line with comparable organizations. It can show that programs that have invested in a particular capability have higher levels of performance. An effective benchmarking process can also help the health care technology management program comply with accreditation requirements for performance monitoring and performance improvement.

A number of management tools are available to support benchmarking in health care technology management. Technical performance data can be generated by computerized maintenance management system (CMMS) software. Financial performance data are available within the organization. There are also comprehensive benchmarking systems that include a database of performance measures from other health care technology management programs.

The guidelines contained in this standard should be incorporated into a comprehensive program of benchmarking and identification of opportunities for improvement, adoption of best practices, and continuous performance

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improvement. The result will be health care technology management programs that are more cost-effective and more supportive of high-quality patient care.
Annex B
(informative)

Regulatory requirements

Listed below are some regulatory requirements from authorities having jurisdiction (AHJs) that may be applicable to health care facilities. This is not intended to be an exhaustive list; there are many applicable state and local regulations that must be followed as well.

Regulatory agencies or other AHJs (whether national, state, or local), may proscribe maintenance requirements that differ than the strategies and options presented in this standard. HTM professionals must follow all applicable AHJ guidelines.

- U.S. Food and Drug Administration. Medical Devices; Reports of Corrections and Removals. Code of Federal Regulations, Title 21, Part 806.
- The Joint Commission
- Det Norske Veritas
- Healthcare Facility Accreditation Program
- Center for Improvement in Healthcare Quality
References


10. Wang, B; Furst, E; Cohen, T; Keil, O; Ridgway, M; Steifel, R. "Medical equipment management strategies." Biomedical Instrumentation & Technology, 40(3):2006.