American National Standard

ANSI/AAMI EQ89:2015

Guidance for the use of medical equipment maintenance strategies and procedures

AAMI
Advancing Safety in Healthcare Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

Guidance for the use of medical equipment maintenance strategies and procedures

Approved 6 February 2015 by
Association for the Advancement of Medical Instrumentation

Approved 12 February 2015 by
American National Standards Institute

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

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Dr., Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 1-57020-580-9

Contents

Page

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Medical Equipment Management Committee

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

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

Chairs:
Michael Angel, GE Healthcare
Paul W. Kelley, CBET, Washington Hospital

Members:
Stuart Albert, MBA CBET-E CHSP, Independent Expert
Michael Angel, GE Healthcare
Chester Arnold, Harris County Hospital District
Bruce H. Barkalow, CCE PhD PE, BH Barkalow P.C.
Britton E. Berek, MBA CCE CHFM CPMM, Sodexo Healthcare
John M. Brown, Steris Corporation
Scott A. Colburn, MS, BSN, RN, FDA/CDRH
John T. Collins, MSEE, American Hospital Association
Robert M. Dondelinger, CBET-E MS, US Military Entrance Processing Command
Thad Flood, JD, Medical Imaging & Technology Alliance a Division of NEMA
Jonathan A. Gaev, MSE, HEM, CCE, PMP, ECRI Institute
Hudson Garrett, Jr., Nice-Pak Products Inc
Elisabeth George, Philips Electronics North America
Stephen L. Grimes, FACCE FHIMSS FAIMBE, ABM Health
Ethan Hertz, PE CCE MAS MS, Duke University Health System - Clinical Engineering
Julio A. Huerta, EE MPH, University of North Carolina Hospitals
John G Knapp, LifeBridge Health
Ilir Kullolli, Kaiser Permanente (US)
Lane McCarthy, CCHT, Hortense & Louis Rubin Dialysis Center
Kenneth Aaron McMahon, American Renal Associates
George Mills, MBA FASHE CEM CHF, The Joint Commission
Mark Newell
Ray P. Silkaitis, PhD, Amgen Inc
James W. Smith, EQ2 LLC
Randall Snelling, DNV GL Healthcare USA, Inc.
Robert H. Stiefel, MS CCE
Lynne A. Thomas, Integrated Medical Systems
Steven C. Vanderzee, CBET AA, Advocate Health Care
Karen F. Waninger, CBET, Community Hospital @ Indianapolis
Patrick B. Weixel, FDA/CDRH
Rex H.L. Young, CBET, St Patrick Hospital & Health Sciences Center
Daidi Zhong, PhD, Chongqing University

Alternate:
Shawn Kimmel, Medical Imaging & Technology Alliance a Division of NEMA

NOTE—Participation by federal agency representatives in the development of this standard 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.

As used within the context of this document, “shall” indicates requirements strictly to be followed in order to conform to the standard; “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; “may” indicates that a course of action is permissible within the limits of the standard; and “can” is used as a statement of possibility and capability. “Must” is used only to describe unavoidable situations, including those mandated by government regulation.

The provisions of this standard should be reviewed by department managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with the appropriate hospital committees (e.g., safety and hazardous materials).

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.

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 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).

e) 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).

f) 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 from 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.

NOTE—For example, at the time this standard was approved, hospitals and critical access hospitals participating in Medicare or Medicaid were required by CMS to adhere to manufacturer's recommendations for all imaging and radiologic equipment; for medical laser devices; and for new equipment for which insufficient maintenance history is available.

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 or staff 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 high-risk equipment: Equipment that might cause or result in patient or staff death or serious injury if it fails.

NOTE—High-risk equipment includes life support equipment.

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

2.12 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.

2.13 maintainer: One who participates in maintenance activities.

2.14 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 unscheduled (usually repairs) or scheduled (usually planned maintenance)

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

2.16 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 standard, 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.*

2.17 non-critical device: A device that is not likely to cause or result in patient death or serious injury if it fails.

2.18 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.

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

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

2.21 preventive maintenance: An equipment maintenance strategy based on replacing, overhauling, or remanufacturing an item, regardless of its condition at the time.

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

2.23 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.

2.24 use: Operation of the medical equipment in conjunction with patient diagnosis, therapy or monitoring.

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