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Guidance for the use of medical equipment maintenance strategies and procedures

AAMI
Advancing Safety in Health Technology

Guidance for the use of medical equipment maintenance strategies and procedures

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Association for the Advancement of Medical Instrumentation

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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

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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:

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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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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.