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ANSI/AAMI EQ56:2024

Standard for a medical equipment management program

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Advancing Safety in Health Technology

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Standard for a medical equipment management program

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Abstract: Specifies minimum requirements for a management program designed to minimize risks associated with medical equipment that is used during the care of patients in a healthcare delivery organization. The standard addresses the structure of the program, documentation requirements, staffing, resources, relationship/client management, service continuity and availability, change management, and quality management associated with the management of medical equipment.

Keywords: healthcare technology management, maintenance, medical equipment, service, healthcare technology, quality

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Committee representation

Association for the Advancement of Medical Instrumentation

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This AAMI American National Standard (ANS) was developed and approved by the AAMI HTM Program Management Working Group under the auspices of the AAMI Medical Equipment Management Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval.

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Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

— “shall” and “shall not” are used to express requirements;

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— “can” and “cannot” are used as statements of possibility or capability;

— “might” and “might not” are used to express possibility;

— “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall”.

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

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Introduction

This standard has been developed by experts in the field of healthcare technology: clinical engineers, biomedical engineers, biomedical equipment technicians, medical equipment manufacturing engineers, and regulatory experts. This standard specifies the minimum requirements of a medical equipment management program. Many existing programs exceed these standards by very wide margins. This standard will provide a clear understanding of the minimum expectations for a medical equipment management program and the resources necessary to achieve those expectations.

Standard for a medical equipment management program

1 Scope

1.1 General

This standard applies to all entities responsible for the management of medical equipment used as part of the delivery of healthcare to patients, including healthcare delivery organizations (HDOs) as a whole; divisions and departments within HDOs; and outside vendors such as medical equipment manufacturers, shared service providers, and independent service organizations.

Medical equipment is an essential part of healthcare. Appropriate management of equipment maintenance is vital for ensuring that medical equipment remains safe and effective for its intended use, that equipment life is maximized, and that total lifetime costs are minimized. In addition, an equipment management program is required by accrediting and licensing organizations.

NOTE Some examples of accrediting organizations are The Joint Commission (TJC), DNV Healthcare (DNV), Center for Improvement in Healthcare Quality (CIHQ), Accreditation Association for Ambulatory Health Care (AAAHC) and the Accreditation Commission for Health Care (ACHC). Licensing agencies include the Centers for Medicare and Medicaid Services, as well as state departments of health and other licensing bodies.

1.2 Inclusions

This standard specifies characteristics of a management program designed to support the safe and effective use of medical equipment used in a healthcare delivery organization (HDO). The document addresses the structure of such a program, the documentation that must be produced by the program, program staffing, and resources that should be allocated to those responsible for maintaining medical equipment. Definitions of terms and normative references are also included, as are notes that expand on the provisions of the document.

2 Normative references

There are no normative references for this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
acceptance date
date on which a piece of medical equipment is placed into service for its intended use by the HDOs

3.2
acceptance testing
interaction with medical equipment designed to verify that it performs its intended function, meets manufacturer’s safety and performance specifications, and conforms to specified requirements prior to being placed into service or returned to patient care

3.3
benchmarking
measurement of any aspect of performance against a known metric, such as a budget, technical specification, regulatory standard, or the performance level of peers