American National Standard

ANSI/AAMI EQ56:2013

Recommended practice for a medical equipment management program

HISTORICAL

AAMI
Advancing Safety in Health Technology

American National Standard **ANSI/AAMI EQ56:2013 [HISTORICAL]**
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Recommended practice for a medical equipment management program

Developed by
Association for the Advancement of Medical Instrumentation

Approved 13 March 2013 by
American National Standards Institute, Inc.

Abstract: This recommended practice specifies minimum criteria for a management program designed to minimize certain risks associated with equipment that is used during the routine care of patients in a health care organization. The recommended practice addresses the structure of the program, documentation requirements, staffing, and resources allocated to those responsible for maintaining medical equipment.

Keywords: accreditation, maintenance, medical equipment

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www.aami.org/standards/glossary.pdf

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:

Chairs:
Jeffrey L. Eggleston, MS PE, Covidien
Paul W. Kelley, CBET, Washington Hospital

Members:
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Daidi Zhong, PhD, Chongqing University

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

This recommended practice was developed by the AAMI Medical Equipment Management Committee. This recommended practice specifies the minimum required characteristics for a management program designed to minimize certain risks associated with equipment that is used during routine care of patients in a health care organization. The document addresses the structure of the program, the documentation that should be produced by the program, and the staffing and resources allocated to those responsible for maintaining the medical equipment.

This recommended practice should be considered flexible and dynamic. As technology advances and new data are brought forward, the recommended practice will be reviewed and, if necessary, revised. AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

Within the context of this recommended practice, "shall" indicates requirements strictly to be followed in order to conform to the recommended practice; "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" is used to indicate that a course of action is permissible within the limits of the recommended practice; 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.

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

NOTE—This foreword does not contain provisions of ANSI/AAMI EQ56:2013, *Recommended practice for a medical equipment management program*, but it does provide important information about the development and intended use of the document.

Introduction

This recommended practice has been developed by experts in the field of health care technology management: clinical engineers, biomedical engineers, biomedical equipment technicians, and medical equipment manufacturing engineers. This recommended practice defines the minimum components of an equipment management program. Many existing programs exceed these standards by very wide margins. It is hoped that this recommended practice will help provide a clear understanding of the minimum expectations for an equipment management program and the resources necessary to achieve those expectations. This second edition of AAMI EQ56 includes new guidance on leadership and staffing, equipment acquisition, and benchmarking, as well as a crosswalk showing key points of different regulatory and accreditation agencies' requirements.

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1 Scope

1.1 General

This AAMI Recommended Practice applies to any entity responsible for the management of medical equipment used as part of the routine care of patients, including health care organizations as a whole; divisions and departments within health care organizations; and outside vendors such as medical equipment manufacturers, shared service providers, and independent service organizations.

Medical equipment is an essential part of health care. 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 agencies. Accrediting agencies include the Joint Commission, DNV Healthcare, and the American Osteopathic Association. 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 AAMI Recommended Practice specifies required characteristics for a management program designed to minimize certain risks associated with equipment that is used in a health care organization during routine care of patients. 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 and rationale that expand the provisions of the document.