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Recommended practice for a medical equipment management program



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Recommended practice for a medical equipment management program

Developed by
Association for the Advancement of Medical Instrumentation

Approved 28 April 1999 and reaffirmed 17 December 2008 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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Committee representation

Association for the Advancement of Medical Instrumentation

Equipment Management Committee

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

The **AAMI Medical Equipment Management Committee** has the following members:

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Members: Stuart Albert, CBET, CHSP, Society of Biomedical Equipment Technicians
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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

This recommended practice was developed by the AAMI 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 must 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. 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 AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

This is a preview edition of an AAMI guideline document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

NOTE—This foreword does not contain provisions of the AAMI Recommended Practice, *Recommended practices for an equipment management program* (AAMI EQ56:1999), but it does provide important information about the development and intended use of the document.

Introduction

Medical equipment is an essential part of health care. Appropriate management of equipment maintenance is vital for ensuring that medical equipment remains safe 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 on Accreditation of Healthcare Organizations and the American Osteopathic Association. Licensing agencies include the Federal Health Care Financing Agency, as well as state departments of health and other licensing bodies.

This recommended practice has been developed by experts in the field of health care equipment management: clinical engineers, biomedical engineers, biomedical equipment technicians, and medical equipment manufacturing engineers. This recommended practice defines the minimal 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 minimal expectations for an equipment management program and the resources necessary to achieve those expectations.

It is our intention that this recommended practice be used as a baseline to inspire other programs to exceed these standards.


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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.

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.

1.3 Exclusions

This AAMI Recommended Practice does not cover training needs of equipment users, nor does it cover competency assessment of the users of equipment included in the equipment management program.

Rationale: This recommended practice focuses on medical equipment acquisition and maintenance, but consideration of other aspects of equipment management is also a requisite for a complete program. In most health care organizations, however, clinical engineers and biomedical equipment technicians are directly involved in equipment acquisition and maintenance, while the responsibility for other activities, such as training in the use of equipment, is delegated to others within the health care organization.

The expertise of the members of the AAMI Equipment Management Committee was primarily in the acquisition and maintenance of medical equipment. While some members had much broader experience, the Committee as a whole did not feel comfortable identifying requirements for other aspects of a complete equipment management program.

2 Normative reference

The following document contains provisions that, through reference in the text, constitute provisions of this recommended practice. At the time of publication, the edition indicated was valid.

Safe Medical Devices Act of 1990, implementing regulations

Medical Device User Facility and Manufacturer Reporting, Certification and Registration; Delegations of Authority; Medical Device Reporting Procedures: Final Rules; Department of Health and Human Services, Food and Drug Administration, 21 CFR Parts 803 and 807, as published in the Federal Register: December 11, 1995 (Volume 60, Number 237), pages 63577-63606.¹

¹ At the time of the publication of this American National Standard, the pamphlet, Medical Device Reporting for User Facilities, was available from the FDA's website at <http://www.fda.gov>.