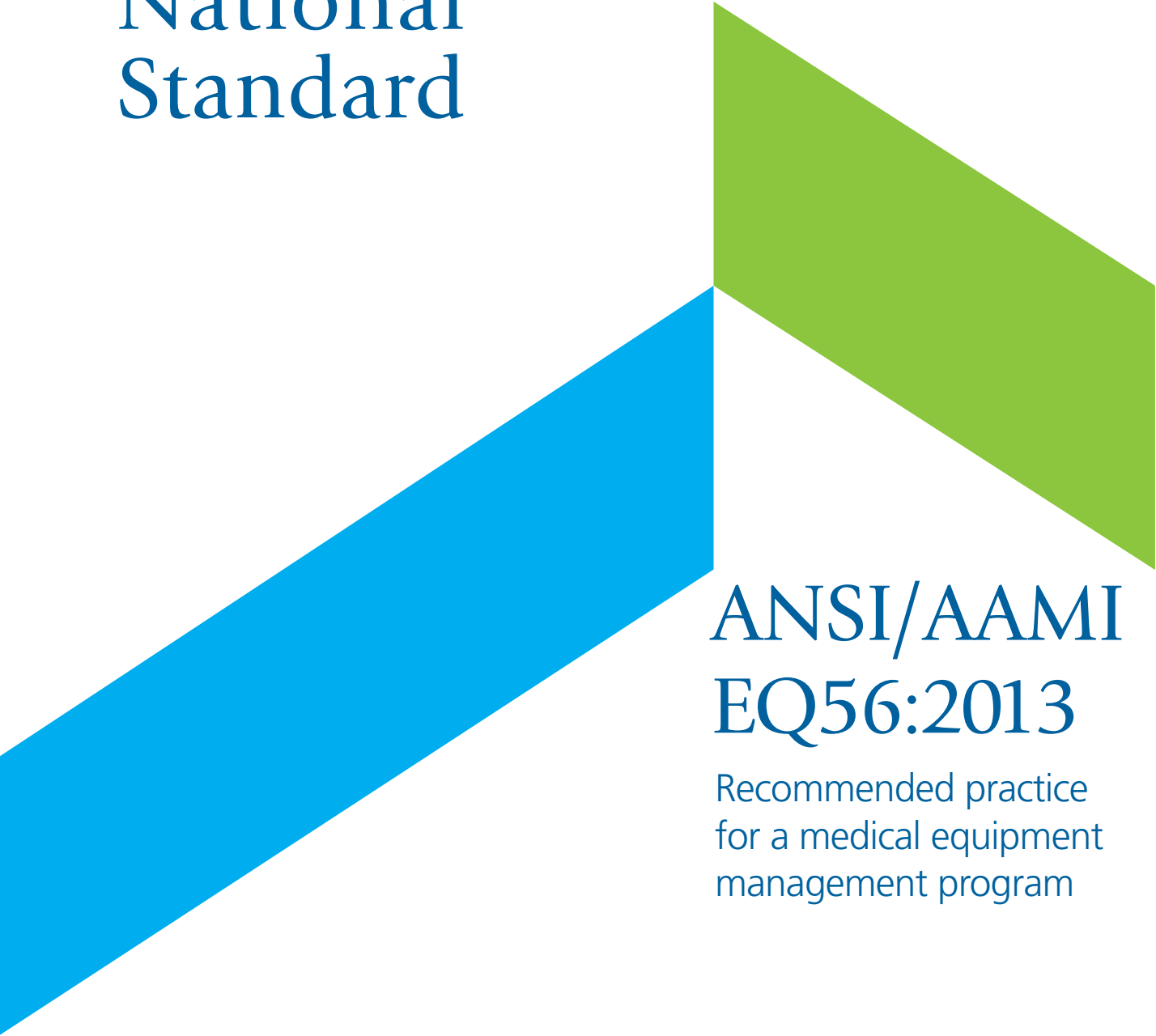


American  
National  
Standard



ANSI/AAMI  
EQ56:2013

Recommended practice  
for a medical equipment  
management program

# 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*.

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

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## **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](http://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:* Stuart Albert, MBA CBET-E CHSP  
Chester Arnold, Harris County Hospital District  
Kendall Ashe, CS Medical LLC  
Bruce H. Barkalow, CCE PhD PE, BH Barkalow P.C.  
Britton E. Berek, CCE MBA, Sodexo Healthcare  
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Daidi Zhong, PhD, Chongqing University

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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.

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## 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.

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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.

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## **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.

# Recommended practice for a medical equipment management program

## 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.