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 safe use 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 procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

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 Online monthly newsletter. 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 Standards Monitor Online.
Medical equipment management—Vocabulary used in medical equipment programs

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Approved 5 December 2018 by AAMI

Approved 18 April 2019 by American National Standards Institute, Inc.

Abstract: Specifies consensus terms relating to medical device servicing and repair.

Keywords: refurbish, service, repair, remarket, remanufacture
AAMI Standard

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Committee representation

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:

**Chair:** Britt Berek

**Members:**
- Britt Berek, Vizient Inc
- Chester Arnold, Harris County Hospital
- Bruce Barkalow, B.H. Barkalow & Associates Inc
- Katelyn Bittleman US FDA/CDRH
- Dennis Carr, STERIS Corporation
- Scott Colburn, US FDA/CDRH
- Randall Cowens, Sodexo USA
- Gary Fansler, Association of Medical Device Service Organizations (AMDSO)
- Jonathan Gaev, ECRI Institute
- Elisabeth George, Philips
- Steve Grimes, ACCE
- Ethan Hertz, Duke University Health System
- Julio Huerta, Aramark
- Katrina Jacobs, Department of Veterans Affairs National Center for Patient Safety
- Paul Kelley, Washington Hospital Health System
- John Knapp, LifeBridge Health
- Ilir Kullolli, Kaiser Foundation Health Plan/Hospitals
- Jeff May, Adventist Health Clinical Engineering
- Mike Schiller, American Hospital Association
- James Faze, DNV
- Priya Upendra, Intermountain Healthcare
- Steve Vanderzee, Advocate Health Care
- Karen Waninger, Franciscan Health Corporate Office
- Peter Weems, Medical Imaging & Technology Alliance, a Division of NEMA
- Daidi Zhong, Chongqing University

**Alternates:**
- Shawn Kimmel, Medical Imaging & Technology Alliance, a Division of NEMA
- Pat Baird, Philips
- Andrew Durfor, FDA/CDRH
- Brandyn Zoeller, STERIS Corporation

**NOTE**—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.
Foreword

This American National Standard was developed by the AAMI Medical Equipment Management Committee. This standard provides clear and distinct definitions for key terms related to medical device servicing and repair.

This standard should be considered flexible and dynamic. 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.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Introduction

There is a pressing need in medical equipment management, servicing and repair for clear and distinct definitions for key terms. Without clarity about what constitutes refurbishing, repair, servicing or remarketing, assigning roles and responsibilities around performing these tasks becomes difficult. Creating agreements, contracts or even regulations governing these activities is even more problematic.

The terms in this standard are based on a list of terms originally prepared by the FDA in its review of servicing issues. The EQ Committee revised these definitions to ensure that they clearly defined and delineated the terms in a way that will be useful to the community. They are provided here in an American National Standard.

One term—REMANUFACTURE—was originally considered for inclusion in this American National Standard. This term was taken directly from current federal regulations (21 CFR 820 (w)) and defined there as follows:

**Remanufacture**

Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

The committee determined that this was defined by regulation and could not subject to change for that reason. The definition as provided, however, would not be suitable for more general use. The committee was concerned that developing an alternate consensus definition could be confusing.

NOTE—The Foreword and the Introduction do not contain provisions of the AAMI EQ93 Medical equipment management—Vocabulary used in medical equipment programs (AAMI EQ93:2019), but they do provide important information about the development and intended use of the document.