American National Standard

PREVIEW COPY

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

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

ANSI/AAMI ST90:2017

Processing of health care products—Quality management systems for processing in health care facilities

Advancing Safety in Healthcare Technology

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*.

AAMI
Advancing Safety in Health Technology
PREVIEW COPY
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.
For a complete copy of this AAMI document, contact AAMI at +1 877 249 8226 or visit www.aami.org

Processing of health care products—Quality management systems for processing in health care facilities

PREVIEW COPY

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

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Approved 11 June 2017 by
Association for the Advancement of Medical Instrumentation

Approved 18 July 2017 by
American National Standards Institute Inc.

Abstract: This document specifies minimum requirements for quality management systems (QMSs) to effectively, efficiently, and consistently process (transport, clean, decontaminate, disinfect, inspect, package, sterilize, and store) medical devices to prevent adverse patient events and non-manufacturer-related device failures.

Keywords: sterilization, medical device processing, quality systems, documentation, monitoring, measurement, communication, resources

AAMI Standard

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

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

PREVIEW COPY

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

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Dr., Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2017 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI at 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 978-1-57020-676-4

Contents

Page

AAMI
Advancing Safety in Health Technology

PREVIEW COPY

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

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Figures

AAMI
Advancing Safety in Health Technology

PREVIEW COPY

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

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

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

Advancing Safety in Health Technology

PREVIEW COPY

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

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Committee representation

Association for the Advancement of Medical Instrumentation

Quality Systems for Device Processing Working Group

This standard was developed by the AAMI Quality Systems for Device Processing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval.

At the time this standard was published, the **AAMI Quality Systems for Device Processing Working Group** had the following members:

Cochairs:
Damien Berg, CRCST
Richard William Schule, MBA, CST, FCS

Members:
Damien Berg, CRCST, St. Anthony Hospital
Angela H. Brightwell, Medtronic Inc
Nancy Chobin, RN, CSPM, CFER, Sterile Processing University LLC
Sean Colwell, WuXi AppTec Inc
Linda Condon, Johns Hopkins Hospital
Corinne M. Connor (Independent Expert)
Lena Cordie, Qualitas Professional Services LLC
Michael D'Onofrio, Presage Health
Mary Dadone, Noxilizer Inc
Jacqueline Daley, Sharp Metropolitan Medical Campus
Gordon Ely, MiMedx Group
Lisa Foster, Adiuvo QS & SA Consulting
Sarah Friedberg, Stryker Instruments Division
Brent Geiger, MS RAC, Medivators Inc
Becky Gilsdorf, Healthmark Industries Company Inc
William A. Grey-Mclaren (Independent Expert)
Seth Hendee, The University of Vermont Medical Center Inc
Brent Huberty, Boston Scientific Corporation
Nupur Jain, Intuitive Surgical Inc
Jackie Daly Johnson, Flexible Packing Association
Ed R. Kimmelman, BME, JD, Kimmelman Consultancy
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management (IAHCSMM)
Kasey Koenig, Key Surgical Inc
Marguerite D. Kolb, CSPDM, MA, Carle Foundation Hospital
Marcy Konja, CRCST, CSPDT, CHL, CSPDM, SpecialtyCare
Jack LeClair (Independent Expert)
Angela M. Lewellyn, LPN, CSPDT, CRCST, Advantage Support Services Inc
Tania Lupu, Case Medical Inc
Jason Marosi (Independent Expert)
Silas McAghon, 3M Healthcare
Emily Mitzel, MS, Nelson Laboratories LLC
Susan Pelton, Getinge USA
Cesar Perez, FDA/CDRH
Michael Quin, Johnson& Johnson
Gracia Schroeder, Accuratus Labs Services
Richard William Schule, MBA, CST, FCS, STERIS Corporation
Rose E. Seavey, RN, MBA, CNOR, CRCST, Seavey Healthcare Consulting LLC
Joan Spear, B Braun of America Inc
Cynthia Spry, MA, MS, RN, CNOR(E), CSPDT, Independent Clinical Consultant
Donna Swenson (Independent Expert)
Lynne A. Thomas, Integrated Medical Systems
Jania Torreblanca, University of Michigan Health System
Sharon Van Wicklin, MSN, RN, CNOR/CRNFA, Association of periOperative Registered Nurses
Eric Varty, Stryker Instruments Division
Lisa Wakeman, Indiana University Health
John Whelan, University of Michigan Health System

AAMI Advancing Safety in Health Technology
PREVIEW COPY
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.
For a complete copy of this AAMI document, contact AAMI at 1-877-249-8226 or visit www.aami.org.

James Sidney Wiggs, BSN, CRCST, Legacy Health System
Don T. Williams, CRCST, CIS, CHL, Swedish Medical Center/Cherry Hill Campus
Roberto Zumbado, Philips

Alternates:

Ralph Basile, Healthmark Industries Company Inc
Stacy Bohl, Boston Scientific Corporation
Thomas Chandler, STERIS Corporation
Peter J. Cheung, FDA/CDRH
Alexandra Cooper, Arthrex Inc
Courtney Mace Davis, University of Iowa Hospitals and Clinics
Regina Hammond, Johnson & Johnson
Lauren Knoll, Stryker Instruments Division
Viktoriya Lusignan, Getinge USA
Roger Martin, Sterilucent Inc
Seth Masek, Medtronic Inc
Nicole Pasquino, Case Medical Inc
Matt Sathe, Accuratus Labs Services
Larry Talapa, 3M Healthcare
Leslie Tavares, WuXi AppTec Inc
Jon Wilder, PhD, Quality Processing Resource Group LLC
Ann Young, The University of Vermont Medical Center Inc

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

AAMI
Advancing Safety in Healthcare Technology

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

Cochair:

Michael H. Scholla, MS, PhD

Members:

PREVIEW COPY
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.
For a complete copy of this AAMI document, contact AAMI at 877-249-8226 or visit www.aami.org.

Anas Aljabo, PhD, SteriPro Canada Inc
Brett Anderson, Cochlear Ltd
Hank Balch, University Health System
Richard Bancroft, STERIS Corporation
Trabue D. Bryans, BryKor LLC
Tim Carlson, Becton Dickinson & Company
Phil Cogdill, Medtronic Inc
Sean Colwell, WuXi AppTec Inc
Ramona Conner, RN, MSN, CNOR, FAAN, Association of periOperative Registered Nurses
Lena Cordie, Qualitas Professional Services LLC
Jacqueline Daley, Sharp Metropolitan Medical Campus
Gordon Ely, MiMedx Group
Lisa Foster, Adiuvo QS & SA Consulting
Joel R. Gorski, PhD, NAMSA
Joyce Hansen, Johnson & Johnson
Stephanie Homuth (Independent Expert)
Clark Houghtling, Cosmed Group Inc
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management
Byron J. Lambert, PhD, Abbott Laboratories
Michelle Luebke, Baxter Healthcare Corporation
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Gerry McDonnell, PhD, Johnson & Johnson
Gerry O'Dell, Gerry O'Dell Consulting
Adrian Ponce, Verrix LLC
Janet M. Prust, 3M Health Care
Nancy J. Rakiewicz, IUVO BioScience
Michael H. Scholla, MS, PhD, DuPont Protection Solutions
Joan Spear, B Braun of America Inc
Sid Wiggs (Independent Expert)
Martell Kress Winters, SM, Nelson Laboratories LLC
Stephen Yeadon, Boston Scientific Corporation

William E. Young, Sterigenics International
Roberto Zumbado, Philips

Alternates:
Stacy Bohl, Boston Scientific Corporation
Jonathan Bull, Johnson & Johnson
Greg Crego, IUVO BioScience
Niki Fidopiastis, Sterigenics International
Jeffrey Marx, STERIS Corporation
Kimberly Patton, Becton Dickinson & Company
Christine Render, Cosmed Group Inc
Michael Sadowski, Baxter Healthcare Corporation
Sharon Van Wicklin, Association of periOperative Registered Nurses
Craig A. Wallace, 3M Health Care

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

PREVIEW COPY

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

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Foreword

This standard was developed by the Quality Systems for Device Processing Working Group of the AAMI Sterilization Standards Committee. The purpose of this document is to provide guidelines for procedures and records designed and planned to support quality management systems (QMSs) for processing of medical devices in hospitals and other health care facilities. These guidelines are intended to promote quality processes and methods and to assist health care personnel in their proper application to achieve acceptable and reproducible results.

This standard reflects the conscientious efforts of health care professionals, in cooperation with medical device and equipment manufacturers, to develop recommendations for quality systems for the processing of medical devices. It is not intended that these recommendations be construed as universally applicable in all circumstances. Also, it is recognized that in many cases these recommendations might not be immediately achievable. Therefore, the document should be used to guide personnel towards desirable performance objectives, and all of its provisions should be considered and applied in the light of professional judgment and experience.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the standard. “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 standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The provisions of this standard should be reviewed routinely by departmental managers and quality management representatives and adapted to the needs of their particular institutions. Written policies, procedures, and work instructions should be developed and implemented in consultation with appropriate hospital committees (e.g., safety, infection prevention and control, and hazardous materials).

The concepts incorporated in this standard should be considered flexible and dynamic. The recommendations set forth in this document are reviewed and updated periodically to assimilate progressive technological developments. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every five years.

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

NOTE—This foreword does not contain provisions of the American National Standard, *Processing of health care products—Quality management systems for processing in health care facilities* (ANSI/AAMI ST90), but it does provide important information about the development and intended use of the document.

AAMI
Advancing Safety in Health Technology
PREVIEW COPY
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.
For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

PREVIEW COPY

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

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Processing of health care products—Quality management systems for processing in health care facilities

Introduction

General

This standard specifies requirements for a quality management system that can be used by an organization that processes medical devices.

It can also be used by internal and external parties to assess the organization's ability to meet customer and regulatory requirements.

It is emphasized that the quality management system requirements specified in this standard are complementary to technical requirements specified in other ANSI/AAMI standards and technical information reports.

The adoption of a quality management system should be a strategic decision of an organization/department. The design and implementation of an organization's quality management is influenced by varying needs, particular objectives, the products provided, the processes employed, and the size and structure of the organization. It is not the intention of this standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

AAMI
Advancing Safety in Health Technology
PREVIEW COPY
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to examine the content of the document before making a purchasing decision.
For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Process approach

This standard is based on a process approach to quality management.

Any activity that receives inputs and converts them to outputs can be considered a process.

For an organization/department to function effectively, it has to identify and manage numerous linked processes.

Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes and their management, can be referred to as the "process approach."

Relationship with other standards

Although this is a stand-alone standard, it is based on ANSI/AAMI/ISO 13485:2016.

Compatibility with other management systems

This standard follows the format of ANSI/AAMI/ISO 13485:2016.

This standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management.

However, this standard enables an organization/department to align or integrate its own quality management system with related management system requirements. It is possible for an organization/department to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this standard.