American National Standard

ANSI/AAMI ST81:2004/(R)2010

Sterilization of medical devices— Information to be provided by the manufacturer for the processing of resterilizable medical devices

Association for the Advancement of Medical Instrumentation

AAMI
Single user license only. Copying, networking, and distribution prohibited.
Full document details: ANSI/AAMI ST81:2004, Sterilization of medical devices -- Information to be provided by the manufacturer for the processign of resteri...

The 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 fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care 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 decisionmaking.

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 Manager for Technical Development. 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
Single user license only. Copying, networking, and distribution prohibited.
Full document details: ANSI/AAMI ST81:2004, Sterilization of medical devices -- Information to be provided by the manufacturer for the processign of resteri...

Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices

Approved 2 December 2004 by
Association for the Advancement of Medical Instrumentation

Approved 13 December 2004 and reaffirmed 24 March 2010 by
American National Standards Institute, Inc.

Abstract: This standard specifies the information to be provided by the medical device manufacturer on the processing of medical devices claimed to be resterilizable and medical devices intended to be sterilized by the processor. Requirements are specified for the information to be provided by the medical device manufacturer so that the medical device can be processed safely and will continue to meet its performance specification. This standard also includes definitions, a bibliography, and informative annexes.

Keywords: cleaning, disinfection, labeling, packaging, sterilization

Documents
Document Sharing Hub

AAMI
Single user license only. Copying, networking, and distribution prohibited.
Full document details: ANSI/AAMI ST81:2004, Sterilization of medical devices -- Information to be provided by the manufacturer for the processign of resteri...

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 and recommended practices 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.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

© 2005 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of ISO, ANSI, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. 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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1–57020–229–X

AAMI
Single user license only. Copying, networking, and distribution prohibited.
Full document details: ANSI/AAMI ST81:2004, Sterilization of medical devices -- Information to be provided by the manufacturer for the processign of resteri...

Contents

Page

Glossary of equivalent standards iv

Committee representation vi

Foreword ix

Introduction x

1 Scope 1

2 Terms and definitions 1

3 Information to be provided by the medical device manufacturer 2

3.1 Reprocessing instructions 2
3.2 Limitations and restrictions on processing 2
3.3 Preparation at the point of use prior to processing 2
3.4 Preparation before cleaning 3
3.5 Cleaning 3
3.6 Disinfection 3
3.7 Drying 4
3.8 Inspection, maintenance, and testing 4
3.9 Packaging 4
3.10 Sterilization 4
3.11 Storage 5

4 Presentation of the information 5

5 Validation of the reprocessing information provided 5

6 Risk analysis 5

Annexes

A Commonly utilized reprocessing methods 6

B An example of reprocessing instructions for reusable medical devices 9

C Bibliography 12

D Background of the development of ANSI/AAMI ST81 and rationale for national deviations to EN ISO 17664 13

Tables

A.1 Examples of processes that may be applied 7

A.2 Blank table to define suitable reprocessing procedures 8

Figures

B.1 Template: Processing instructions (reusable medical devices) 9

B.2 Example of processing instructions (reusable medical devices) 11

Documents
Document Sharing Hub

AAMI
Single user license only. Copying, networking, and distribution prohibited.
Full document details: ANSI/AAMI ST81:2004, Sterilization of medical devices -- Information to be provided by the manufacturer for the processign of resteri...

Glossary of equivalent standards

International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by international designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:200x[1]	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical

[1] Currently at FDIS stage

Documents Document Sharing Hub
AAMI
Single user license only. Copying, networking, and distribution prohibited.
Full document details: ANSI/AAMI ST81:2004, Sterilization of medical devices -- Information to be provided by the manufacturer for the processign of resteri...

International designation	U.S. designation	Equivalency
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000 and A1:2004	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

Documents
Document Sharing Hub
AAMI
Single user license only. Copying, networking, and distribution prohibited.
Full document details: ANSI/AAMI ST81:2004, Sterilization of medical devices -- Information to be provided by the manufacturer for the processign of resteri...

Committee representation

Association for the Advancement of Medical Instrumentation

Instructions for Reusable Device Reprocessing Working Group

This standard was developed by the AAMI Instructions for Reusable Device Reprocessing 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 Instructions for Reusable Device Reprocessing Working Group** had the following members:

Cochairs:
Nancy Chobin, RN, CSPDM
Sandra A. Lee, RN

Members:
Michelle J. Alfa, PhD, FCCM, St. Boniface General Hospital, Winnipeg, Manitoba, Canada
Shelley Allen, AppTec Laboratory Services
Chris B. Anderson, St. Jude Medical Inc.
Lisa Baryschpolec, Ethicon Inc./Johnson & Johnson
Carl W. Bruch, PhD, Hudson, WI
Virginia C. Chamberlain, PhD, Hendersonville, NC
Nancy Chobin, RN, CSPDM, St. Barnabas Healthcare System, Lebanon, NJ
Anne M. Cofiell, CRCST, International Association of Healthcare Central Service Materiel Management
Jacqueline Daley, Sinai Hospital of Baltimore
Anthony J. DeMarinis, MS, CQA, CQM, Davol Inc./CR Bard
Michele Dawn DeMeo, Holy Name Hospital, Teaneck, NJ
Sue Ellen Erickson, MS, CNOR, Newark Beth Israel Medical Center, Cranford, NJ
LeRoy J. Fischbach, Minntech Corporation
France Frechette, MSc, TSO_3 Inc.
Gregory G. Ginsberg, MD, American Society for Gastrointestinal Endoscopy
Zory R. Glaser, PhD, MPH, CSPDM, Johns Hopkins University School of Public Health
Steve N. Goldstine, PhD, DDS, Albuquerque, NM
Wayne D. Grinthal, Olympus America Inc.
Douglas F. Harbrecht, Boston Scientific Corporation
Ronald J. Haselhorst, Cardinal Health
Stephen M. Kovach, Healthmark Industries
Colleen Patricia Landers, RN, Canadian Standards Association
Sandra A. Lee, RN, STERIS Corporation
Chiu Lin, PhD, U.S. Food and Drug Administration
Teckla A. Maresca, LPN, CSPDM, St. Clare's Health System, Denville, NJ
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Russell D. Mills, Zimmer Inc.
Emily Mitzel, MS, Nelson Laboratories Inc.
David Parente, NAMSA
Leslie Phillips, STS duoTEK
Janet Prust, 3M Health Care
Timothy Ramsey, Northview Biosciences
Marimargaret Reichert, RN, MA, Middleburg Heights, OH
Linda Slone, RN, CNOR, Sibley Memorial Hospital, Washington, DC
Eugenia Stern, MBA, MS, Alcon Laboratories Inc.
David B. Vogel, Smith & Nephew, Inc.
Nora Wikander, RN, CSPDM, St. Joseph's Wayne Hospital, Wayne, NJ
Christine H. Yunker, Abbott Laboratories

Alternates:
Solomon Alade, PhD, Alcon Laboratories Inc.
Ralph J. Basile, MBA, Healthmark Industries
Richard H. Bean, Zimmer Inc.
John Broad, NAMSA
Trabue D. Bryans, AppTec Laboratory Services
Anne Burke, TSO_3 Inc.
Carlos Chavez, PhD, Abbott Laboratories
Charles Cogdill, Boston Scientific Corporation
Kimbrell Darnell, CR Bard

Documents Document Sharing Hub
AAMI
Single user license only. Copying, networking, and distribution prohibited.
Full document details: ANSI/AAMI ST81:2004, Sterilization of medical devices -- Information to be provided by the manufacturer for the processign of resteri...

Thomas J. Frazar, DePuy/Johnson & Johnson
Jim Kaiser, Bausch & Lomb Inc.
Susan G. Klacik, International Association of Healthcare Central Service Materiel Management
Martha T. O'Lone, U.S. Food and Drug Administration
Sarah Toole, RM, Nelson Laboratories Inc.
David Tucholski, Cardinal Health
John W. Walker, STERIS Corporation
Martha Young, 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.

Documents
Document Sharing Hub
AAMI
Single user license only. Copying, networking, and distribution prohibited.
Full document details: ANSI/AAMI ST81:2004, Sterilization of medical devices -- Information to be provided by the manufacturer for the processign of resteri...