

***Comprehensive guide to steam sterilization and
sterility assurance in health care facilities,
Amendment 2***

Changes to this recommended practice are noted as follows:

Highlight for new info

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When using this to update your copy of ST79, please go through the Amendment page by page and remove the matching pages from your existing ST79 binder as you insert the replacement pages.

NOTE — All copies of ANSI/AAMI ST79:2010 incorporated Amendment 1 at the time of publication. Please use these pages to appropriately update each impacted page of your document. If you have the 2006 edition of ST79, you will need to obtain the 2010 edition. **This document will not bring the 2006 edition of ST79 up-to-date.**

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, method 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, as well as to 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* (i.e., 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.

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Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Developed by
Association for the Advancement of Medical Instrumentation

Approved 4 August 2010 by
Amendment 1 Approved 24 September 2010 by
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American National Standards Institute, Inc.

Abstract: This recommended practice covers steam sterilization in health care facilities. The recommendations are intended to promote sterility assurance and to guide health care personnel in the proper use of processing equipment. Included within the scope of the recommended practice are functional and physical design criteria for sterilization processing areas (decontamination, preparation, sterilization, and sterile storage areas); staff qualifications, education, and other personnel considerations; processing procedures; installation, care, and maintenance of steam sterilizers; quality control; and quality process improvement.

Keywords: ambulatory care facilities, cleaning, continuous quality improvement, decontamination, dental office, flash sterilization, moist heat sterilization, packaging, quality control, quality system, saturated steam, sterile storage, sterilization containers, surgical instruments, table-top sterilizers

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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. The code in the US column, “(R)20xx” indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

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 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 and ANSI/AAMI ES60601-1:2005/A2:2010 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2010	ANSI/AAMI/IEC 60601-2-4:2010	Identical
IEC 60601-2-16:2008	ANSI/AAMI/IEC 60601-2-16:2008	Identical
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-27:2011	ANSI/AAMI/IEC 60601-2-27:2011	Identical
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80001-1:2010	ANSI/AAMI/IEC 80001-1:2010	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC 62366:2007	ANSI/AAMI/IEC 62366:2007	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2010	ANSI/AAMI/ISO 8637:2010	Identical
ISO 8638:2010	ANSI/AAMI/ISO 8638:2010	Identical
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006/(R)2010	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007/(R)2010	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2010	ANSI/AAMI/ISO 10993-10:2010	Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006/(R)2010	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:2010	ANSI/AAMI/ISO 10993-13:2010	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical
ISO 11137-2:2006 (2006-08-01 corrected)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1:2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2:2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3:2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4:2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5:2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006/(R)2010	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006/(R)2010	Identical
ISO 11663:2009	ANSI/AAMI/ISO 11633:2009	Identical
ISO 11737-1:2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO/TS 12417:2011	ANSI/AAMI/ISO TIR12417:2011	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 13958:2009	ANSI/AAMI/ISO 13958:2009	Identical
ISO 13959:2009	ANSI/AAMI/ISO 13959:2009	Identical
ISO 14155:2011	ANSI/AAMI/ISO 14155:2011	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007/(R)2010	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006/(R)2010	Identical
ISO/TS 19218-1:2011	ANSI/AAMI/ISO TIR19218:2011	Identical
ISO 20857:2010	ANSI/AAMI/ISO 20857:2010	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO/TR 22442-4:2010	ANSI/AAMI/ISO TIR22442-4:2010	Identical
ISO 23500:2011	ANSI/AAMI/ISO 23500:2011	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 26722:2009	ANSI/AAMI/ISO 26722:2009	Identical
ISO 27186:2010	ANSI/AAMI/ISO 27186:2010	Identical
ISO 80369-1:2010	ANSI/AAMI/ISO 80369-1:2010	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Steam Sterilization Hospital Practices Working Group

This recommended practice was developed by the AAMI Steam Sterilization Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the recommended practice does not necessarily mean that all working group members voted for its approval.

At the time this recommended practice was published, the **AAMI Steam Sterilization Hospital Practices Working Group** had the following members:

Cochairs: Ramona Conner, RN, MSN, CNOR

Cynthia Spry, RN, MSN, CNOR

Members:

Richard Bancroft, Esq, Steris Corporation

Ralph J. Basile, MBA, Healthmark Ind Co Inc

Nola Bayes, MBA, Sanford Health

Damien Berg, Medical Center of the Rockies

Hassan Bilal, CRCST CST Member Independent Expert

Loran H. Bruso, BS MBA, Steritec Products Manufacturing Co. Inc.

Kathy M. Bury, INOVA Alexandria Hospital

Bradley J. Bushman, Standard Textile Co. Inc.

Mike Carragher, Getinge USA

Edward P. Casey, CSPDM, The Hospital of Central Connecticut

Bradley J. Catalone, PhD, Olympus America Inc.

Harriet Chan-Myers, Johnson & Johnson

David Chapman, Roche Molecular Systems

Marc Chaunet, TSO3 Inc.

Nancy Chobin, RN, CSPDM, St. Barnabas Health Care System

Ramona Conner, RN, MSN, CNOR, Association of Perioperative Registered Nurses

Jacqueline Daley, Association for Professionals in Infection Control and Epidemiology

Diana Davis, Brunswick Community Hospital

Michele Dawn Demeo, CRCST, CSPDT, Memorial Hospital

Shawn A. Doyle, Sterilator Company Inc.

Mark Duro, New England Baptist Hospital

Betty D. Edge, Northshore University Hospital

Rosie Fardo, RN, BSN, CIC, CHSP, Department of Veterans Affairs Medical Center

Jeff Felgar, Zimmer Inc.

Marcia Ann Frieze, Case Medical Inc.

Charles Oren Hancock, RAC, H&W Technology LLC

Barbara Ann Harmer, RN, BSN, MHA

Jennifer Harte, DDS, MS, American Dental Association

Rachel Hill, CareFusion

Charles A. Hughes, SPS Medical Supply Corp

David M. Jagrosse, Middlesex Hospital

Nupur Jain, Stryker Instruments Division

Nyla Skee Japp, PhD, RN, CSPDM, Integrated Medical Systems

David W. Johnson, Kimberly-Clark Corporation

Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service
Materiel Management

Colleen Patricia Landers, RN, Canadian Standards Association

Mary Kneece Lane, BS, MHA, CSPDS, CSPDM, The Medical University of South Carolina

Angela M. Lewellyn, LPN, CSPDT, CRCST, Advantage Support Services, Inc.

Chris Mannarino, Belimed Inc.

Teckla A. Maresca, LPN, CSPDM, St. Clare's Health System

Ruby Martinez, Cardinal Health (MP&S)

Patrick J. McCormick, PhD, Bausch & Lomb Inc.

Candace McManus, PhD, FDA/CDRH

Emily Mitzel, MS, Nelson Laboratories Inc.

Thomas K. Moore

Karen Nauss, CRCST, Mount Auburn Hospital

Scott Pignatella

Janet M. Prust, 3M Healthcare
Shaundrea L. Rechsteiner, NAMSA
Cheron Rojo, Childrens Hospital of Central California
Wendy Royalty, Raven Biological Laboratories
Rose E. Seavey, RN, MBA, CNOR, CRCST, Seavey Healthcare Consulting, Inc.
Andrew Sharavara, PhD, Propper Manufacturing Co. Inc.
Frank Sizemore, Wake Forest Univeristy - Baptist Medical Center
Linda Slone, RN, BSPA, CNOR
Joan M. Spear, Aesculap Inc.
Cynthia Spry, RN, Independent Clinical Consultant
Betty Strickland, Pryce Consultants
Donna Swenson, BS, CSPDM, West Suburban Medical Center
Mary Velasco, Henry Ford Macomb Hospital
P. Richard Warburton, ChemDAQ Inc.
Nora E. Wikander, RN, CSPDM, St. Joseph's Wayne Hospital, Wayne, NJ

Alternates:

Denise Adams, Aesculap Inc.
Richard P. Blasko, Steris Corporation
Annette Bojanski, Raven Biological Laboratories
Laureen C. Clark, M.T., Kimberly-Clark Corporation
Linda Clement, CRCST, Steris Corporation
Julie M. Conyer, Bausch & Lomb Inc.
Susan Flynn, 3M Healthcare
Joel R. Gorski, PhD, NAMSA
Thomas Grobaski, Belimed Inc.
Peter Hudnut, Getinge USA
Danny Hutson, CareFusion
Stephen M. Kovach, Healthmark Ind Co. Inc.
Natalie Lind, International Association of Healthcare Central Service Materiel Management
Tania Lupu, Case Medical Inc.
Sheila A. Murphey, FDA/CDRH
Charles D. Paige, Department of Veterans Affairs National Center for Patient Safety
Mahesh Patel, Propper Manufacturing Co. Inc.
Jason Pope, Nelson Laboratories Inc.
Elizabeth A. Riegel, FDA/CDRH
Kristen Singleton, PhD, Steritec Products Manufacturing Co. Inc.
Gary J. Socola, SPS Medical Supply Corp.
R. Brent Sweet, Zimmer Inc.
Raymond Taurasi, Healthmark Ind. Co. Inc.
Jeff Teeter, CareFusion
Martha Young, 3M Healthcare

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.

AAMI Sterilization Standards Committee

Cochairs: Victoria M. Hitchins, PhD
William E. Young

Members: Trabue D. Bryans, WuXi AppTec
Peter A. Burke, PhD, Steris Corporation
Nancy Chobin, RN, CSPDM, St. Barnabas Health Care System
Charles Cogdill, Boston Scientific Corporation
Ramona Conner, RN, MSN, CNOR, Association of Perioperative Registered Nurses
Jacqueline Daley, Association for Professionals in Infection Control and Epidemiology
Kimbrell Darnell, CR Bard
Dave Dion, Cardinal Health (MP&S)
Lisa Foster, Sterigenics International
Joel R. Gorski, PhD, NAMSA
Deborah A. Havlik, Hospira Worldwide Inc.
Victoria M. Hitchins, PhD, FDA/CDRH

Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service
 Materiel Management
 Byron J. Lambert, PhD, Abbott Laboratories
 Colleen Patricia Landers, RN, Canadian Standards Association
 Lisa N. Macdonald, Becton Dickinson & Company
 Jeff Martin, Alcon Laboratories Inc.
 Patrick J. McCormick, PhD, Bausch & Lomb Inc.
 Rainer Newman, Johnson & Johnson
 Janet M. Prust, 3M Healthcare
 Nancy Rakiewicz, Ethox International Inc.
 Michael H. Scholla, Dupont Nonwovens
 Mark Seybold, Baxter Healthcare Corporation
 Andrew Sharavara, PhD, Propper Manufacturing Co. Inc.
 Mark N. Smith, Getinge USA
 William N. Thompson, Covidien
 James L. Whitby, MA, MB, FRCPT
 Martell Kress Winters, BS, SM, Nelson Laboratories Inc.
 William E. Young

Alternates: Lloyd Brown, Covidien
 Glenn W. Calvert, Becton Dickinson & Company
 Steven J. Elliott, WuXi AppTec
 Thomas J. Frazar, Johnson & Johnson
 Kathy Hoffman, Sterigenics International
 Jim Kaiser, Bausch & Lomb Inc.
 Joseph J. Lasich, BS, Alcon Laboratories Inc.
 Natalie Lind, International Association of Healthcare Central Service Materiel Management
 Reynaldo Lopez, Cardinal Health (MP&S)
 Ralph Makinen, Boston Scientific Corporation
 Mary S. Mayo, CR Bard
 David Ford McGoldrick, BS, Abbott Laboratories
 Jerry R. Nelson, PhD, Nelson Laboratories Inc.
 Karen Polkinghorne, Dupont Nonwovens
 Mike Sadowski, Baxter Healthcare Corporation
 John R. Scoville, Jr., Steris Corporation
 Jason Voisinet, Ethox International Inc.
 Craig A. Wallace, 3M Healthcare
 Valerie Welter, Hospira Worldwide Inc.

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Acknowledgments

The AAMI Steam Sterilization Hospital Practices Working Group gratefully acknowledges the important contributions of both current and former Working Group members, who have been instrumental in preparing the first edition of this document, the 2008 and 2009 amendments, and this editorial revision, which offers users a comprehensive document on steam sterilization practices. The continuous maintenance process, which keeps this document current, demands a great deal of Working Group members' time, and all involved have willingly donated their time and expertise. The Working Group also gratefully acknowledges Judy Veale, the AAMI staff liaison who was invaluable in keeping this document, and the Working Group, on track through the amendment and revision process.

Foreword

This recommended practice was developed by the Steam Sterilization Hospital Practices Working Group of the AAMI Sterilization Standards Committee. The purpose of the guidelines in this document is to help ensure the steam sterilization of products in health care facilities and the maintenance of the sterility of processed items until the point of use.

To facilitate user access to all AAMI consensus recommendations for steam sterilization in health care facilities, the first edition of ANSI/AAMI ST79, published in 2006, consolidated into one comprehensive guide the following AAMI recommended practices:

- ANSI/AAMI ST46, *Steam sterilization and sterility assurance in health care facilities*
- ANSI/AAMI ST42, *Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities*
- ANSI/AAMI ST37, *Flash sterilization: Steam sterilization of patient care items for immediate use*
- ANSI/AAMI ST35, *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings*
- ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities*

In the course of the consolidation process, the five recommended practices listed above were updated and revised to reflect current good practice, and several annexes were added to provide additional information to users. The recommended practice serves as a comprehensive guideline for all steam sterilization activities in health care facilities, regardless of the size of the sterilizer or the size of the facility, and provides a resource for all health care personnel who use steam for sterilization.

In 2008 and 2009, numerous amendments of the document were adopted as part of the AAMI continuous maintenance process. These amendments addressed such topics as toxic anterior segment syndrome (TASS), paper-plastic pouches, steam quality, devices with lumens, chemical indicators, sterilization process failures, product families, evaluation of sterilization container systems, risk analysis, and verification of cleaning. This second edition of ANSI/AAMI ST79 incorporates these amendments, as well as additional changes in the provisions regarding steam quality. In addition, the document reflects general editorial revisions (e.g., updating of references).

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with medical device and equipment manufacturers, to develop recommendations for optimum performance levels in the processing of reusable medical devices to be steam sterilized. 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 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. “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 recommended practice should be reviewed routinely by departmental managers and adapted to the needs of their particular institutions. Written policies and procedures 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 recommended practice 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.

AAMI has created a notification registry that will send e-mail announcements when any amendments are issued to the recommended practice. To register, visit <http://www.aami.org/standards/st79.registry.html>. Suggestions for improving this recommended practice are invited. Comments or proposals for revisions to any part of the standard may be submitted to AAMI at any time. Written comments are to be sent to: Standards Dept., AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633. Comments may also be e-mailed to: standards@aami.org.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2010, A1:2010, & A2:2011), but it does provide important information about the development and intended use of the document.

Background on Amendments

This document consolidates the text of ST79:2010 and A1:2010 and A2:2011. The 2010 edition and amendment 1 were published together as a single document. Please see amendment 2 to identify exactly what has changed. Amendment 2 shows modifications to ST79 in redline/strikeout and is available in print or as a free PDF at <http://marketplace.aami.org>.

**From this point forward, only those pages of
ANSI/AAMI ST79:2010 and A1:2010
impacted by ANSI/AAMI ST79:2010/A2:2011 are provided.**

Changes to this recommended practice are noted as follows:

Highlight for new info
~~Strikethrough~~ for deleted text