



# ANSI/AAMI ST79:2017

& 2020 Amendments A1, A2, A3, A4 (Consolidated Text)

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

**American  
National  
Standard**

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

**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, immediate-use steam sterilization (IUSS), moist heat sterilization, packaging, quality control, quality system, saturated steam, sterile storage, sterilization containers, surgical instruments, table-top sterilizers

## AAMI Recommended practice

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.

**CAUTION NOTICE:** This AAMI recommended practice may be revised or withdrawn at any time.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

AAMI  
901 N. Glebe Road, Suite 300  
Arlington, VA 22203  
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, visit the Copyright Clearance Center.

With the permission of Canadian Standards Association, (operating as CSA Group), material is reproduced from CSA Group standard **Z314.8-00, Decontamination of reusable medical devices** which is copyrighted by Canadian Standards Association, 178 Rexdale Blvd., Toronto, ON, M9W 1R3. This material is not the complete and official position of CSA Group on the referenced subject, which is represented solely by the standard in its entirety. While use of the material has been authorized, CSA Group is not responsible for the manner in which the data is presented, nor for any interpretations thereof. No further reproduction is permitted. For more information or to purchase standards from CSA Group, please visit <http://shop.csa.ca/> or call 1-800-463-6727.

Printed in the United States of America

**ISBN 978-1-57020-675-7**

# Contents

Page

Glossary of equivalent standards.....	ix
Committee representation.....	xii
Foreword.....	xv
Introduction: Need for the recommended practice .....	1
1 Scope.....	3
1.1 General.....	3
1.2 Inclusions.....	3
1.3 Exclusions .....	3
2 Definitions and abbreviations.....	4
3 Design considerations.....	12
3.1 General considerations.....	12
3.2 Work area design and functional workflow .....	12
3.2.1 Design criteria.....	12
3.2.2 Functional workflow patterns .....	14
3.2.3 Traffic control.....	15
3.3 Utilities.....	17
3.3.1 Mechanical systems .....	17
3.3.2 Electrical systems.....	17
3.3.3 Steam for sterile processing .....	17
3.3.4 Utility monitoring and alarm systems .....	18
3.3.5 General facility design requirements .....	18
3.3.6 Special area requirements and restrictions .....	21
3.3.7 Emergency eyewash/shower equipment.....	24
4 Personnel considerations.....	25
4.1 General considerations.....	25
4.2 Qualifications .....	25
4.2.1 Supervisory personnel.....	25
4.2.2 Sterile processing personnel .....	25
4.3 Education and training.....	26
4.3.1 Sterile processing personnel .....	26
4.3.2 Service personnel.....	26
4.3.3 Other personnel.....	27
4.4 Health and personal hygiene .....	27
4.5 Attire .....	27
4.5.1 General considerations.....	27
4.5.2 Decontamination area/room .....	28
4.6 Standard and transmission-based precautions.....	29
5 Receiving.....	30
5.1 General considerations.....	30
5.2 Receiving of purchased or loaned items.....	30
5.2.1 General considerations.....	30
5.2.2 New, repaired, and refurbished reusable items .....	30
5.2.3 Loaned or borrowed instrumentation .....	30
5.2.4 Rigid sterilization container systems.....	31
5.2.5 Disposable items .....	32
5.3 Disposition of sterile items (issued but not used).....	32
6 Handling, collection, and transport of contaminated items.....	33
6.1 General considerations.....	33
6.2 Separation of waste and reusable items at point of use .....	33
6.3 Point-of-use care and handling of contaminated reusable items .....	34
6.4 Containment .....	35
6.5 Transport .....	36

6.5.1	Segregation of clean/sterile items.....	36
6.5.2	Transportation scheduling and routes .....	36
6.5.3	Transportation equipment.....	36
6.5.4	Hand transport.....	36
6.5.5	Dedicated lifts.....	37
6.5.6	Transport between buildings.....	37
6.5.7	Off-site transportation.....	37
7	Cleaning, disinfection (microbicidal processes), and other decontamination steps .....	39
7.1	General considerations.....	39
7.2	Policies and procedures .....	39
7.3	Manufacturer's written IFU.....	40
7.4	Decontamination.....	40
7.4.1	General considerations for all devices and utensils.....	40
7.4.2	Special considerations.....	41
7.5	Preparation for cleaning.....	41
7.5.1	Presoaking.....	41
7.5.2	Sorting and disassembly .....	41
7.6	Cleaning .....	43
7.6.1	General considerations.....	43
7.6.2	Devices with lumens.....	44
7.6.3	Cleaning agents.....	44
7.6.4	Methods of cleaning .....	44
8	Preparation and assembly of instruments.....	50
8.1	General considerations.....	50
8.2	Instruments.....	50
8.3	Devices with lumens .....	51
8.4	Basins and basin sets.....	51
8.5	Textile packs.....	51
9	Packaging.....	52
9.1	General considerations.....	52
9.2	Selection of sterile barrier systems.....	52
9.3	Package labeling .....	52
9.4	Package closures .....	53
9.5	Sterilization wrap .....	53
9.5.1	General considerations.....	53
9.5.2	Woven wraps.....	53
9.5.3	Nonwoven wraps .....	53
9.5.4	Paper-plastic pouches .....	54
9.6	Wrapping techniques.....	55
9.6.1	Simultaneous double-wrapping: envelope fold.....	55
9.6.2	Simultaneous double wrapping: square fold.....	56
9.6.3	Sequential wrapping: envelope fold.....	57
9.6.4	Sequential wrapping: square fold .....	58
9.7	Sterility maintenance covers.....	59
9.8	Rigid sterilization container systems.....	59
10	Sterilization.....	61
10.1	Loading the sterilizer.....	61
10.1.1	General considerations.....	61
10.1.2	Paper-plastic pouches .....	61
10.1.3	Instrument sets.....	61
10.1.4	Textile packs.....	61
10.1.5	Utensils and glassware.....	61
10.1.6	Rigid sterilization container systems.....	62
10.1.7	Liquids.....	62
10.1.8	Powders and oils .....	63
10.2	Sterilization parameters.....	63
10.2.1	General considerations.....	63
10.2.2	Sterilization cycles.....	63
10.2.3	Immediate-use steam sterilization .....	63

10.3	Unloading the sterilizer .....	64
10.3.1	Unloading sterilizers having a chamber volume larger than 2 cubic feet .....	64
10.3.2	Unloading table-top sterilizers (sterilizers having a chamber volume of less than or equal to 2 cubic feet) .....	64
10.4	Handling and inspection after unloading the sterilizer .....	65
11	Storage and transportation .....	66
11.1	Sterile storage .....	66
11.1.1	Storage facilities .....	66
11.1.2	Sterility maintenance covers .....	66
11.1.3	Shelf life .....	66
11.2	Distribution .....	67
11.2.1	Handling and inspection .....	67
11.2.2	Distribution containers .....	67
11.3	Transport of sterile packaged items .....	67
11.3.1	General considerations .....	67
11.3.2	Tables and carts (open or closed) .....	67
11.3.3	Hand transport .....	67
11.3.4	Dedicated lifts .....	68
11.3.5	Off-site transportation .....	68
12	Installation, care, and maintenance of sterilizers .....	69
12.1	General rationale .....	69
12.2	Instruction manuals .....	69
12.3	Installation .....	69
12.4	Routine care .....	69
12.5	Preventive maintenance .....	70
12.5.1	General considerations .....	70
12.5.2	Scheduled maintenance .....	70
12.6	Calibration .....	70
12.7	Record-keeping .....	70
13	Process monitoring, testing, and quality control .....	72
13.1	General considerations .....	72
13.2	Monitoring of mechanical cleaning equipment .....	72
13.3	Product identification and traceability .....	72
13.3.1	General considerations .....	72
13.3.2	Package labeling and expiration dating, if applicable .....	72
13.3.3	Sterilizer records .....	73
13.3.4	Record retention .....	73
13.4	Sterilization process monitoring .....	73
13.5	Sterilization process monitoring devices .....	77
13.5.1	Physical monitors .....	77
13.5.2	Chemical indicators .....	77
13.5.3	Biological indicators .....	80
13.5.4	Process challenge devices .....	81
13.6	Routine load release .....	82
13.6.1	Process monitoring devices .....	82
13.6.2	Release criteria for nonimplants .....	82
13.6.3	Release criteria for implants .....	82
13.6.4	Sterilization process failure .....	83
13.7	Routine sterilizer efficacy monitoring .....	84
13.7.1	General considerations .....	84
13.7.2	Routine biological monitoring of sterilizers larger than 2 cubic feet .....	84
13.7.3	Routine biological monitoring of table-top sterilizers (less than or equal to 2 cubic feet) .....	87
13.7.4	Routine biological sterilizer efficacy monitoring of gravity-displacement cycles .....	88
13.7.5	Actions to take when BIs, CIs, or physical monitors indicate a sterilization process failure .....	89
13.7.6	Routine Bowie-Dick testing of dynamic-air-removal sterilizers .....	94
13.8	Qualification testing .....	97
13.8.1	General considerations .....	97
13.8.2	Qualification testing of sterilizers have a chamber volume larger than 2 cubic feet .....	97
13.8.3	Qualification testing of table-top sterilizers (sterilizers having a chamber volume less than or equal to 2 cubic feet) .....	99
13.9	Periodic product quality assurance testing of routinely processed items .....	101

13.9.1	General considerations.....	101
13.9.2	Process verification .....	102
13.9.3	Product families .....	102
13.9.4	Verification testing procedure .....	103
13.10	Periodic product quality assurance testing of rigid sterilization container systems .....	104
13.10.1	General considerations.....	104
13.10.2	User responsibilities .....	104
14	Quality process improvement .....	106
14.1	General considerations.....	106
14.2	Quality process.....	106
14.2.1	General considerations.....	106
14.2.2	Quality system model .....	106
14.2.3	Risk analysis.....	107
14.3	Supplier communication .....	110
14.4	Repair records .....	110
14.5	Processing policies and procedures .....	110
15	New product evaluation .....	111
15.1	General rationale .....	111
15.2	Considerations.....	111

**Tables**

1	IES-recommended illuminance levels for work environments.....	20
2	Sterilization process monitoring recommendations.....	75
3	Types and applications for use of sterilization monitoring device .....	76
4	Potential causes to be investigated for steam sterilization process failures.....	92
5	Summary of test configurations for prepurchase evaluation of rigid sterilization container systems.....	105
E.1	Levels of disinfection according to type of microorganism .....	131
E.2	Occupational exposure limits for some chemical sterilants and disinfectants .....	134
J.1	16 towel pack survey .....	150
J.2	Biological-indicator results from 121°C (250°F) gravity-displacement cycle .....	152
J.3	Biological-indicator results from 132°C (270°F) deep-vacuum cycle .....	153
J.4	Biological-indicator results from 132°C (270°F) pulsing vacuum cycle .....	153
J.5	Comparison of the 16 towel pack with the 12 × 12 × 20 inch pack by Most Probable Number and sterility assessment of spore strips (121°C [250°F] gravity-displacement cycle) .....	154
J.6	Fraction-negative results in a 121°C (250°F) gravity-displacement cycle .....	154
J.7	Biological-indicator results from 121°C (250°F) steam-flush pressure-pulse cycle.....	155
J.8	Biological-indicator results from 132°C (270°F) steam-flush pressure-pulse cycle.....	155
N.1	Comparison of terminology and differences between performance requirements of ANSI/AAMI/ISO 11140-1 and FDA (2003) guidance recommendations .....	165
O.1	Moisture assessment check list .....	167

**Figures**

1	Workflow .....	16
2	Example of single- and double-packaging with paper-plastic pouches .....	54
3	Simultaneous double-wrapping: envelope fold .....	55
4	Simultaneous double-wrapping: square fold .....	56
5	Sequential wrapping: envelope fold .....	57

6	Sequential wrapping: square fold.....	58
7	Examples of sterilizer cart loads .....	62
8	Preparation of the 16 towel PCD (BI challenge test pack) .....	85
9	Placement of the 16 towel PCD (BI challenge test pack) for routine biological monitoring of sterilizers larger than 2 cubic feet .....	86
10	Decision tree for conducting investigations of steam sterilization process failures .....	91
11	Composition of the Bowie-Dick test pack.....	95
12	Placement of the Bowie-Dick test pack.....	95
13	Placement of the 16 towel PCD (BI challenge test pack) for qualification testing .....	99
A.1	Example of a work area design and workflow pattern for a sterile processing area in a typical small hospital .....	112
A.2	Example of a work area design and workflow pattern for a sterile processing area in a typical medium-sized hospital .....	113
A.3	Example of a work area design and workflow pattern for a sterile processing area in a typical regional processing center.....	114
A.4	Example of an ambulatory surgery facility .....	115
A.5	Example of a dental facility .....	116
B.1	The chain of infection, components of the infectious disease process .....	117
B.2	Blood-borne pathogen strike-through conversion chart .....	119
I.1	Typical rigid sterilization container system processed in a gravity-displacement cycle at 121°C (250°F).....	147
I.2	Muslin-wrapped, 16 pound instrument set processed in a gravity-displacement cycle at 121°C (250°F).....	148
I.3	Typical rigid sterilization container system processed in a prevacuum cycle at 132°C (270°F).....	148
J.1	Temperature profiles for two different configurations of 12 × 12 × 20 inch packs .....	151
J.2	Temperature profiles for huck and absorbent 16 towel packs in a 121°C (250°F) gravity-displacement cycle .....	151
J.3	Average temperature profile for the 16 towel pack in a 121°C (250°F) gravity-displacement cycle .....	152
K.1	Exception form for emergency release of sterilizer load .....	156
O.1	Moisture assessment flow chart.....	170

## Annexes

A	Examples of work area design .....	112
B	Infection transmission and standard precautions.....	117
C	Processing CJD-contaminated patient care equipment and environmental surfaces .....	121
D	User verification of cleaning processes.....	126
E	Selection and use of chemical disinfectants .....	129
F	Thermal disinfection.....	135
G	Devices returned to the manufacturer.....	136
H	Development of a prepurchase evaluation protocol for rigid sterilization container systems .....	142
I	Effect of container systems on load come-up time .....	147
J	Development and qualification of the 16 towel PCD (biological-indicator challenge test pack).....	149
K	Example of documentation of emergency release of implants.....	156

<b>L</b>	Steam quality .....	157
<b>M</b>	Toxic anterior segment syndrome (TASS) and the processing of intraocular surgical instruments .....	159
<b>N</b>	Comparison of the differences between AAMI and FDA classifications of chemical indicators .....	162
<b>O</b>	Moisture assessment.....	166
<b>P</b>	General considerations for cleaning and disinfection.....	171
<b>Q</b>	Alternatives for keeping cool in the sterile processing environment.....	175
	Bibliography .....	177

Currently in preview, click buy full version

## 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.

[www.aami.org/standards/glossary.pdf](http://www.aami.org/standards/glossary.pdf)

Currently in preview, click buy full version

## 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, FAAN  
Cynthia Spry, MA, MS, RN, CNOR(E), CSPDT

*Members:* Steven Adams  
Anas Aljabo, SteriPro Canada Inc  
Rajee Arunan, Mercy Medical Center  
Richard Bancroft, STERIS Corporation  
Ralph J. Basile, MBA, Healthmark Industries Company Inc  
Nola Bayes, MBA, Sanford Health  
Gary Benning, Midmark Corporation  
Damien Berg, CRCST, St. Anthony Hospital  
Holger Biering, PhD  
Hassan Bilal, Medline Industries Inc  
Dave Billman, Innovative Sterilization Technologies LLC  
Jennifer Burrell, St Lukes Hospital and Health Network  
Bradley J. Bushman, Standard Textile Co Inc  
Mike Cain, Getinge USA  
Dennis Champagne, Avista Pharma Solutions  
Karen Cherry, SIPS Consults Corp  
Nancy Chobin, RN, CSPDM, Sterile Processing University LLC  
Fiona Collins, American Dental Association  
Linda Condon, Johns Hopkins Hospital  
Ramona Conner, RN, MSN, CNOR, FAAN, Association of periOperative Registered Nurses  
Lena Cordie, Qualitas Professional Services LLC  
Gaye Currier  
Jacqueline Daley, Sharp Metropolitan Medical Campus  
Courtney Mace Davis, University of Iowa Hospitals and Clinics  
Michael D'Onofrio, Presage Health  
Jennifer Durbin, Mary Rutan Hospital  
Mark Duro, CRCST, FCS, Crosstex/A Cantel Medical Company  
Lee Ford, Floyd Medical Center  
Brian Fortier, Quality Processing Resource Group LLC  
Sarah Friedberg, Stryker Instruments Division  
Marcia Ann Frieze, Case Medical Inc.  
Joel R. Gorski, PhD, NAMSA  
Sharon Hadley, Integrated Medical Systems  
Barbara Ann Harmer, RN, BSN, MHA  
Seth Hende, The University of Vermont Medical Center Inc  
Rachel Hill, Becton Dickinson & Company  
David M. Jagrosse, Middlesex Hospital  
Nupur Jain, Intuitive Surgical Inc  
Jackie Johnson, Flexible Packaging Association  
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service  
Materiel Management  
Marcy Konja, CRCST, CSPDT, CHL, CSPDM, SpecialtyCare  
Mary Kneec Lane, BS, MHA, CSPDS, CSPDM  
Jack LeClair  
Angela M. Lewellyn, LPN, CSPDT, CRCST, Advantage Support Services Inc  
Steve Loes, Sterilucent Inc  
JoAnn Maltais, Maltais Consulting  
Patrick J. McCormick, PhD, Bausch & Lomb Inc.  
Gerry McDonnell, PhD, Johnson & Johnson

Kathleen McMullen, Association for Professionals in Infection Control and Epidemiology  
 Megan Middaugh, Cardinal Health  
 Emily Mitzel, MS, Nelson Laboratories Inc.  
 Thomas K. "Chip" Moore, Consultant  
 Clarence Murray, FDA/CDRH  
 Frank Myers, UC San Diego Healthcare System  
 Karen Nauss, CRCST, Mount Auburn Hospital  
 John Nies, Belimed Inc  
 Lawayne Perkins, Advantage Support Services Inc  
 Adrian Ponce, Verrix LLC  
 Janet M. Prust, 3M Healthcare  
 Melinda Rogers, Northside Hospital Forsyth  
 Cheron Rojo, Valley Childrens Hospital  
 Don Rotter, Ecolab  
 Rose E. Seavey, RN, MBA, CNOR, CRCST, Seavey Healthcare Consulting LLC  
 Andrew Sharavara, PhD, Propper Manufacturing Co. Inc  
 Chuck Sidebottom, PPO Standards LLC  
 Frank Sizemore, Wake Forest University Baptist Medical Center  
 Gary Socola, HIGHPOWER Validation Testing & Lab Services Inc  
 Alison Sonsteli, Sanford Health  
 Joan M. Spear, B Braun of America Inc.  
 Steve Spencer, Halyard Health  
 Cynthia Spry, MA, MS, RN, CNOR(E), CSPDT, Independent Clinical Consultant  
 James Stanicki, Cleveland Clinic Foundation  
 Suzanne Stefanik  
 Andy Sun, SciCan Ltd  
 Karen Swanson, Connecticut Childrens Medical Center  
 Donna Swenson (Independent Expert)  
 Jania Torreblanca, University of Michigan Health System  
 Mary Velasco, Henry Ford Macomb Hospital  
 P. Richard Warburton, ChemDAQ Inc  
 Jill Warren, WuXi AppTec Inc  
 Sid Wiggs (Independent Expert)  
 Don Williams, Swedish Medical Center/Cherry Hill Campus  
 Roberto Zumbado, Philips  
 Cheri Ackert-Burr, Cantel Inc  
 Stacey Burgardt, Cardinal Health  
 John Erickson, Univeristy of Iowa Hopsitals and Clinics  
 Nancy Fellows, Johnson & Johnson  
 Susan Flynn, 3M Healthcare David Hilliker, ChemDAQ Inc  
 Stephen M. Kovach, Healthmark Industries Company Inc  
 Kristie Kunzer, Bausch & Lomb Inc  
 Natalie Lind, International Association of Healthcare Central Service Materiel Management  
 Tania Lupu, Case Medical Inc.  
 Viktoriya Lusignan, Getinge USA  
 Kelly Makimoto, SciCan Ltd  
 Roger Martin, Sterilucent Inc  
 Christena Nash, Halyard Health  
 Ed Nuber, B Braun of America Inc  
 Walt Oko, Innovative Sterilization Technologies LLC  
 Ramesh Panguluri, FDA/CDRH  
 Rod Parker, Stryker Instruments Division  
 Alpa Patel, Nelson Laboratories LLC  
 Kim Patton, Becton Dickinson & Company  
 Mandy Ryan, Stryker Instruments Division  
 Richard Schule, STERIS Corporation  
 Krista Schulte, Boston Scientific Corporation  
 Jana Silor, Zimmer Inc  
 Frank Smith, Department of Veterans Affairs  
 Joe Smith, Belimed Inc  
 Leslie Tavares, WuXi AppTec Inc  
 Dawn Tomac, Association for Professionals in Infection Control  
 Janelle Trbojevich, Boston Scientific Corporation  
 Don Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc

*Alternates:*

Sharon Van Wicklin, Association of periOperative Registered Nurses  
Kristy Vogt, American Dental Association  
Brian Wallace, Intuitive Surgical Inc  
Ann Young, The University of Vermont Medical Center Inc

---

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**

*Cochair:* Michael H. Scholla, MS, PhD  
*Members:* 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  
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 Prust, 3M Healthcare  
Nancy Rakiewicz, IUVO BioScience  
Michael H. Scholla, MS, PhD, Dupont Protection Technologies  
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

---

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.

---

## 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.

From 2010 to 2013, numerous amendments of the document were adopted. This third edition of ANSI/AAMI ST79 incorporates these amendments, as well as additional changes such as guidance pertaining to heating, ventilation, and air conditioning (HVAC) and a new Annex on keeping cool in the sterile processing environment. In addition, the document reflects general editorial revisions (e.g., updating of references) and reorganization of content.

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 new ST79 publication formats are available. To register, visit <http://www.aami.org/ST79Notify>. 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 American National Standard, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2017), but it does provide important information about the development and intended use of the document.

---

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

## Introduction: Need for the recommended practice

Saturated steam under pressure is one of the oldest and safest methods used in health care facilities to sterilize medical devices. Because this method has been available for so many years, it is thought to be a simple process, one that is well understood and controlled. However, the efficacy of any sterilization process, including saturated steam, depends on a consistent system for lowering and limiting bioburden before sterilization, preparing items for sterilization, selecting the sterilization parameters, and establishing and implementing controls to maintain the sterility of sterilized items until they are used. These four phases are critically interdependent, and each should be accomplished to produce and maintain a sterile product.

The delivery of sterile health care products for use in patient care depends not only on the efficacy of the sterilization process itself but also on

- a) efficient facility design,
- b) equipment, personnel and other resources,
- c) education and training of personnel,
- d) infection prevention and control practices designed to prevent health-care-associated infections,
- e) effective quality control and process improvement systems that encompass all aspects of device reprocessing from point of use through sterilization to reuse, and
- f) documentation and reporting practices that enable traceability of each facility-sterilized medical device to the patient on whom it was used.

Health care facilities differ in their physical design and equipment and in the level of personnel expertise, competence, and training. This recommended practice has been developed to set forth guidelines for facility design, work practices, and process controls that will help ensure that sterile items are consistently produced using saturated steam under pressure.

This recommended practice addresses elements of a quality management system, but it is not intended to provide comprehensive guidance on this subject.

Many of the activities that affect sterilization processing occur in areas separate from the location where sterilization is actually carried out. Therefore, the policies and procedures governing sterilization processing should be developed in consultation with the managers of areas that use sterile medical devices and with appropriate committees or functional groups within the facility (e.g., infection prevention and control, safety, hazardous materials, risk management). In addition, the support of the facility's administration is vital, especially in those facilities where the establishment of a quality system to implement steam sterilization process validation and parametric release is being considered (ANSI/AAMI/ISO TIR17665-2).

It might not be possible for a health care facility to implement all the provisions of this recommended practice because of environmental restrictions and/or limitations in capital funding. However, it is recommended that the health care facility's administration be made aware of any current deficiencies so that the allocation of needed resources can be planned.

This comprehensive guide encompasses cleaning, transport, quality monitoring, storage, product evaluation, equipment maintenance, personnel considerations, and steam sterilization in all health care facilities, including, but not limited to, hospitals, ambulatory surgery facilities, physicians' offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, dental offices, and other areas where sterile products are reprocessed, stored, and used.

## **Steam sterilization in office-based, ambulatory-care medical, surgical, and dental facilities**

Advances in medical, surgical, and dental practice have led to the increased use of alternative health care sites, such as offices, ambulatory-care clinics, and similar clinical settings; many such facilities use table-top steam sterilizers (less than or equal to 2 cubic feet). Office-based practices can differ greatly from hospitals in their physical design and in the education and training of personnel. The general concepts in this comprehensive guide apply to these settings. In some sections, processes or equipment used most frequently within the office-based and ambulatory setting are specifically addressed.

# 1 Scope

## 1.1 General

This document includes guidance for sterile processing facility design, personnel, receiving, transporting, handling, cleaning, decontamination, preparation, packaging, steam sterilization of reusable medical devices, quality process improvement and new product evaluation.

## 1.2 Inclusions

This recommended practice specifically addresses

- a) functional and physical design criteria for sterilization processing areas;
- b) staff qualifications, education, and other personnel considerations;
- c) processing recommendations;
- d) installation, care, and maintenance of steam sterilizers;
- e) quality control;
- f) product evaluation; and
- g) quality process improvement.

Definitions of terms, a bibliography, and informative annexes also are provided.

## 1.3 Exclusions

This recommended practice does not cover

- a) specific construction and performance criteria for steam sterilizers (see ANSI/AAMI ST8 and ANSI/AAMI ST55), rigid sterilization container systems (see ANSI/AAMI ST77), or rigid, protective organizing cases that require wrapping before sterilization (see ANSI/AAMI ST77);
- b) the use of containment devices for packaging items other than instrument sets or procedural trays;
- c) procedures and techniques for handling and laundering contaminated reusable surgical textiles (see ANSI/AAMI ST65), reusable laboratory items, food service items, and items assigned to a patient for the length of stay (e.g., bedpans, thermometers);
- d) decontamination of hemodialysis machines, hemodialyzers, and hemodialyzer blood tubing (see ANSI/AAMI/IEC 60601-2-16, ANSI/AAMI RD47, and ANSI/AAMI/ISO 8638, respectively);
- e) the use of dry heat for decontamination purposes or for terminal sterilization of reusable medical devices (see ANSI/AAMI ST40);
- f) the use of ethylene oxide sterilization in health care facilities for other than decontamination purposes (see ANSI/AAMI ST41);
- g) the use of chemical sterilization and high-level disinfection in health care facilities for other than decontamination purposes (see ANSI/AAMI ST58);
- h) the reprocessing of devices labeled for single use only (see Food and Drug Administration [FDA], 2000c); and
- i) aseptic presentation.

NOTE—For more information on the subjects excluded from the scope of this recommended practice, and for additional background information on the inclusions, refer to the references listed in the bibliography.