

American
National
Standard

ANSI/AAMI
ST58:2013/
(R)2018

Chemical sterilization and
high-level disinfection in
health care facilities

HISTORICAL

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

Currently in preview, click buy full version

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

American National Standard

ANSI/AAMI ST58:2013 [HISTORICAL]
(Revision of ANSI/AAMI ST58:2005(R)2010)

Chemical sterilization and high-level disinfection in health care facilities

Developed by
AAMI

Approved 21 August 2013 and reaffirmed 9 September 2018 by
American National Standards Institute Inc.

Abstract: This recommended practice provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration for use in hospitals and other health care facilities. Included within the scope of this recommended practice are functional and physical design criteria for chemical sterilization and high-level disinfection processing areas; staff qualifications, education, and other personnel considerations; criteria for selecting LCSs/HLDs and gaseous chemical sterilizers; safety and efficacy considerations in the use of LCSs/HLDs and gaseous chemical sterilizers; preparation of devices for processing by chemical sterilization or high-level disinfection; quality control methods; and quality process improvement. Definitions of terms and informative annexes are also provided.

Key words: chemical sterilization, chemical sterilizers, chemical vapor, formaldehyde, gaseous chemical sterilants, glutaraldehyde, high-level disinfectants, high-level disinfection, hydrogen peroxide, hydrogen peroxide gas plasma, liquid chemical sterilants, materials compatibility, ortho-phthalaldehyde, ozone, peracetic acid, sodium hypochlorite

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

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 standard. 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 may 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
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2013 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, complete the reprint request form at www.aami.org, or contact AAMI at 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: +1-703-525-4890; Fax: +1-703-525-1067.

Printed in the United States of America

ISBN 978-1-57020-505-7

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

Contents

	Page
Glossary of equivalent standards.....	vii
Committee representation.....	viii
Acknowledgments.....	x
Foreword.....	xi
1 Scope.....	1
1.1 General.....	1
1.2 Inclusions.....	1
1.3 Exclusions.....	2
2 Definitions and abbreviations.....	3
3 Work area design considerations.....	9
3.1 General rationale.....	9
3.2 Processing area.....	9
3.3 Traffic control.....	9
3.4 Ventilation of processing areas and equipment.....	10
3.4.1 General considerations.....	10
3.4.2 General room ventilation.....	10
3.4.3 Local exhaust ventilation.....	10
3.5 Automated processing equipment for chemical sterilants.....	12
3.5.1 Selection of equipment.....	12
3.5.2 Installation.....	12
3.5.3 Equipment location.....	12
3.6 Storage of chemical sterilants.....	12
3.7 Disposal of chemical sterilant waste.....	13
3.7.1 Chemical sterilant solutions.....	13
3.7.2 Chemical solution containers.....	13
3.8 Regulatory requirements.....	13
4 Personnel considerations.....	14
4.1 General rationale.....	14
4.2 Qualifications.....	14
4.2.1 Supervisory personnel.....	14
4.2.2 Processing personnel.....	14
4.3 Training and continuing education.....	15
4.3.1 Processing personnel.....	15
4.3.2 Service personnel.....	16
4.3.3 Other personnel.....	16
4.4 Personal protective equipment.....	16
4.4.1 General considerations.....	16
4.4.2 Eye protection (liquid).....	17
4.4.3 Skin protection (liquid).....	17
4.4.4 Respiratory protection.....	17
4.5 Health and personal hygiene.....	18
5 Selection of liquid and gaseous chemical sterilants.....	19
5.1 General rationale.....	19
5.2 Categories.....	19
5.3 LCS/HLD types.....	19
5.4 Gaseous chemical sterilization types.....	20
5.5 Selection criteria.....	20
5.5.1 General considerations.....	20
5.5.2 Health and safety considerations.....	21
5.5.3 Effectiveness.....	22

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

5.5.4	Materials compatibility	23
5.5.5	Cost-effectiveness	24
5.5.6	Matrix of selection criteria	24
6	Decontamination and preparation of instruments	25
6.1	General rationale	25
6.2	Receiving	25
6.2.1	Receiving of purchased items	25
6.2.2	Disposition of sterile items (issued but not used)	25
6.3	Handling, collection, and transport of contaminated items	26
6.3.1	General considerations	26
6.3.2	Separation of waste and reusable items at point of use	26
6.3.3	Care and handling of contaminated reusable items at point of use	27
6.3.4	Containment	27
6.4	Transport	28
6.4.1	Segregation of clean/sterile items	28
6.4.2	Transportation scheduling and routes	28
6.4.3	Transportation equipment	28
6.4.4	Hand transport	28
6.4.5	Dedicated lifts	29
6.4.6	Transport between buildings	29
6.4.7	Off-site transportation	29
6.5	Aseptic presentation	29
6.5.1	Opening sterile packages	29
6.5.2	Removing items from sterile packaging and transferring them to the sterile field	30
6.5.3	Removing devices from HLD equipment and delivery to the point of use	30
6.6	Cleaning and other decontamination processes	31
6.6.1	General considerations	31
6.6.2	Preparation for cleaning	31
6.6.3	Disassembly	31
6.6.4	Cleaning	32
6.6.5	Rinsing	37
6.6.6	Drying, inspection, and verification of the cleaning process	37
6.6.7	Microbicidal processes	37
6.7	Packaging	38
7	Using chemical sterilants safely and effectively	39
7.1	Introduction	39
7.2	General considerations	39
7.2.1	Establishing policies and procedures	39
7.2.2	Manufacturers' written IFU	39
7.2.3	Ensuring cleaning effectiveness	40
7.3	General safety considerations	41
7.3.1	Introduction	41
7.3.2	Emergency procedures	41
7.4	Liquid chemical sterilants/high-level disinfectants	42
7.4.1	General considerations	42
7.4.2	Relationship between LCSs and HLDs	42
7.4.3	Single vs. multi-use	43
7.4.4	Consideration for selection	43
8	Device storage and transport	45
8.1	General rationale	45
8.2	Devices processed with LCSs/HLDs	45
8.3	Devices processed with gaseous chemical sterilants	45
9	Quality control	46
9.1	General rationale	46
9.2	Product identification and traceability	46
9.2.1	Lot control numbers	46
9.2.2	Cycle documentation and record-keeping	46
9.2.3	Expiration dating	47
9.3	Monitoring manual processes that use LCSs/HLDs	47
9.3.1	General considerations	47

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

9.3.2	Use of physical monitors	47
9.3.3	Solution test strips and chemical monitoring devices	48
9.4	Monitoring automated processes that use LCSs/HLDs	49
9.4.1	General considerations.....	49
9.4.2	Use of physical monitors and chemical process monitoring devices	49
9.4.3	Automated processing equipment malfunction.....	50
9.4.4	Inadequate processing	50
9.5	Monitoring gaseous chemical sterilization processes	51
9.5.1	Use of physical monitors	51
9.5.2	Gaseous chemical sterilizer malfunction	51
9.5.3	Chemical indicators	52
9.5.4	Biological indicators.....	52
9.6	Product release.....	56
9.7	Product testing.....	56
9.7.1	General considerations.....	56
9.7.2	Gaseous chemical sterilization processes.....	56
9.7.3	LCS/HLD automated processing equipment	58
9.8	Product recalls.....	58
9.8.1	General considerations.....	58
9.8.2	Recall procedure	59
9.8.3	Recall order	59
9.8.4	Recall summary report	59
9.8.5	Outbreak report	59
10	Quality process improvement.....	60
10.1	General rationale	60
10.2	Quality process	60
10.2.1	General considerations.....	60
10.2.2	Risk analysis.....	60
10.2.3	Decontamination.....	61
10.2.4	Liquid chemical sterilization, high-level disinfection, and gaseous chemical sterilization.....	61
10.3	Functional areas for product and process improvement.....	62
10.3.1	Workplace design	62
10.3.2	Processing policies and procedures	62
10.3.3	Product use	63
10.4	Implementation of product and process improvements.....	63
Annexes		
A	Microbial lethality, materials compatibility, and toxicity	65
B	Glutaraldehyde solutions	71
C	Hydrogen peroxide solutions.....	79
D	Ortho-phthalaldehyde solutions	83
E	Peracetic acid–hydrogen peroxide solutions.....	88
F	Sodium hypochlorite solutions	94
G	Chemical vapor sterilization using alcohol and formaldehyde	98
H	Hydrogen peroxide gas sterilization	101
I	Ozone sterilization	104
J	Government regulation	107
K	Occupational exposure to bloodborne pathogens (29 CFR Part 1910.1030).....	114
L	Use, verification of cleaning processes.....	128
M	Example of documentation of premature release of implants	133
N	Gas and vapor monitoring.....	135
O	Bibliography	146

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

Tables

1	LCS/HLD and gaseous chemical sterilant annexes	20
2	Selection criteria for chemical sterilants/high-level disinfectants.....	24
A.1	Microorganisms listed in descending order of resistance to chemical sterilants and disinfectants.....	66
B.1	Examples of labeled contact conditions for high-level disinfection for FDA-cleared glutaraldehyde products.....	72
J.1	Summary of MDR requirements.....	110
J.2	Occupational exposure limits for some chemical sterilants.....	111
L.1	In-use tests available to assess efficacy of cleaning of medical devices	131
L.2	In-use tests available to assess efficacy of washer-disinfectors used for medical device reprocessing	132
N.1	Technologies for the detection of gases and vapors of high-level disinfection and sterilization chemicals	136

Figures

1	Recommended ventilation for areas in which chemical sterilants are used	11
2	A ductless fume hood showing the airflow pattern	11
3	Microbicidal processes and use of PPE.....	38
M.1	Implantable devices load record	133
M.2	Exception form for premature release of implantable device/tray.....	134

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

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

Currently in preview, click buy full version

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Chemical Sterilants Hospital Practices Working Group

This recommended practice was developed by the AAMI Chemical Sterilants 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 Chemical Sterilants Hospital Practices Working Group** had the following members:

Cochairs: Geetha C. Jayan, PhD, FDA/CDRH

Janet M. Prust, 3M Healthcare

Members: Nola Bayes, MBA, Sanford Health

Jennifer Burrell, Integrated Medical Systems

Marc Chaunet, TSO3 Inc.

Nancy Chobin, RN CSPDM, St Barnabas Healthcare System

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

Jacqueline Daley, Sinai Hospital of Baltimore

Betty D. Edge, North Shore University Hospital

Gloria H. Frost, PhD DABT, Cardinal Health (MP&S)

Zory R. Glaser, PhD MPH CSPDM, Johns Hopkins University School of Public Health

Steve N. Goldstine, PhD, Steve Goldstine Consultants

Shelley Green, WuXi AppTec Inc.

Charles Oren Hancock, RAC, H&W Technology LLC

Jason Harrington, VA Medical Center of Cincinnati

Rachel Hill, CareFusion

Jim Kaiser, Bausch & Lomb Inc.

Susan G. Klacik, CCSMC FCS ACE, IHCSMM

Colleen Patricia Landers, RN, Landers Consulting

Jo Ann Barbara Maltais, PhD, Maltais Consulting

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

Theresa A. Matthews, PhD CR CSPDM, Community Medical Center at Toms River

Gerald E. McDonnell, PhD, Steris Corporation

Candace McManus, DrPH

Emily Mitzel, MS, Neogen Laboratories Inc.

Thomas K. Moore

Frank Myers, JIS, Indian Health Service

Richard M. Omsbee, Medivators Inc.

Charles C. Roberts, MS, Johnson & Johnson

Cherone Hojo, Childrens Hospital Central California

Rose E. Seavey, RN MBA CNOR CRCST, Seavey Healthcare Consulting, LLC

Frank Sizemore, Wake Forest University Baptist Medical Center

Wanda Stone, RN BSPA CNOR

Betty Strickland, Pryce Consultants

Karen Swanson, Connecticut Childrens Medical Center

Radhakrishna S. Tirumalai, US Pharmacopeia Convention Inc.

Donald Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc.

Donna Ungvarsky, MSN MEd RN CNOR, Olympus America Inc.

P. Richard Warburton, ChemDAQ Inc.

Nora E. Wikander, RN, CSPDM, St Josephs Wayne Hospital

Martha L. Young, Martha L Young, LLC

Alternates: Marcia Benedict, BS MI RAC MT ASCP, Steris Corporation

Mary Ann Drosnock, MS, Olympus America Inc.

Sylvie Dufresne, PhD, TSO3 Inc.

Gordon M. Ely, WuXi AppTec Inc.

Chris Evans, Integrated Medical Systems

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

Susan Flynn, 3M Healthcare
Brent Geiger, MS RAC, Medivators Inc.
David M. Hilliker, ChemDAQ Inc.
Charles A. Hughes, Medivators Inc.
Danny Hutson, CareFusion
Natalie Lind, IAHCSSM
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Michael Neilson, Nelson Laboratories Inc.
Samantha Spindel, FDA/CDRH
Sharon Van Wicklin, MSN RN CNOR/CRNFA, Association of Perioperative Registered Nurses

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

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

Cochairs: Victoria M. Hitchins, PhD, FDA/CDRH
Michael H. Scholla, PhD, Dupont Protection Technologies

Members: Christopher Anderson, Boston Scientific Corporation
Trabue D. Bryans, BryKor LLC
Nancy Chobin, RN CSPDM, St Barnabas Healthcare System
Charles Cogdill, Covidien
Ramona Conner, RN MSN CNOR, Association of Perioperative Registered Nurses
Jacqueline Daley, Sinai Hospital of Baltimore
Kimbrell Darnell, CR Bard
Lisa Foster, Medpoint LLC
Joel R. Gorski, PhD, NAMSA
Joyce M. Hansen, Johnson & Johnson
Douglas F. Harbrecht, Sterility Assurance LLC
Deborah A. Havlik, Hospira Worldwide Inc.
Susan G. Klacik, CCSMC FCS ACE, IAHCSSM
Byron J. Lambert, PhD, Abbott Laboratories
Colleen Patricia Landers, RN, Timmins & District Hospital
Reynaldo Lopez, Cardinal Health (MP&S)
Lisa N. Macdonald, Becton Dickinson & Company
Jeff Martin, Alcon Laboratories Inc.
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Gerald E. McDonnell, PhD, Steris Corporation
Janet M. Prust, 3M Healthcare
Nancy Rakiewicz, Moog Medical Devices
Mark Seybold, Baxter Healthcare Corporation
Andrew Sharavara, PhD, Propper Manufacturing Co Inc.
Mark N. Smith, Getinge USA
Martell Kress Winters, BS SM, Nelson Laboratories Inc.
William E. Young
William T. Young, Sterigenics International

Alternates: Lloyd Brown, Covidien
Peter A. Burke, PhD, Steris Corporation
Glenn W. Calvert, Becton Dickinson & Company
Dave Dion, Cardinal Health (MP&S)
Gordon M. Ely, WuXi AppTec Inc.
Thomas J. Frazar, Johnson & Johnson
Martha M. Kadas, Sterigenics International
Jim Kaiser, Bausch & Lomb Inc.
Natalie Lind, IAHCSSM
Ralph Makinen, Boston Scientific Corporation
Mary S. Mayo, CR Bard
David Ford McGoldrick, BS, Abbott Laboratories
Jerry R. Nelson, PhD, Nelson Laboratories Inc.
Patrick Polito, Moog Medical Devices
Karen Polkinghorne, Dupont Protection Technologies

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

Shaundrea L. Rechsteiner, NAMSA
Mike Sadowski, Baxter Healthcare Corporation
Craig A. Wallace, 3M Healthcare

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

Acknowledgments

The working group thanks Dr. Candace McManus, who served as co-chair through much of this revision to ANSI/AAMI ST58. We appreciated her expertise and straightforward approach to help create a useful document for health care users. Her years of experience in the regulatory environment combined with AAMI standards development participation greatly contributed to the task of the working group and her skill as co-chair will be missed.

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

Foreword

This recommended practice was developed by the AAMI Chemical Sterilants Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee.

The first edition of ANSI/AAMI ST58, *Safe use and handling of glutaraldehyde-based products in health care facilities*, was published in 1996. The second edition incorporated AAMI TIR7, *Chemical sterilants and high-level disinfectants: A guide to selection and use*, and was published in 2005. Key updates to this third edition include additional and current workplace safety information; new and updated annexes specific to vapor monitoring; expansion of the types of sterilization processes described to address new systems available to the health care user; improved guidance for workplace design; alignment of recommendations to companion health care facility documents, including ANSI/AAMI ST79 and ANSI/AAMI ST41; a revised product testing selection to simplify recommendations; expanded recommendations for personnel training; and updated quality process recommendations.

As used within the context of this document, “shall” indicates requirements strictly to be followed in order 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” indicates that a course of action is permissible within the limits of the recommended practice; and “can” is used as a statement of possibility and capability. “Must” is used only to describe unavoidable situations, including those mandated by government regulation.

The provisions of this recommended practice should be reviewed by department managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with the appropriate hospital committees (e.g., safety and hazardous materials).

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

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Chemical sterilization and high-level disinfection in health care facilities* (ANSI/AAMI ST58:2013), but it does provide important information about the development and intended use of the document.

This document is no longer being maintained by AAMI and should not be used for new designs. Every AAMI standard is subjected to review at least every five (5) years. When a standard is more than five years old, has not undergone revision or review, and/or no longer carries the ANSI designation, it is reasonable to conclude that the contents, while still of some historic value, do not reflect the present state of the art. All copyrights remain in full effect.

Chemical sterilization and high-level disinfection in health care facilities

1 Scope

1.1 General

This recommended practice provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for use in hospitals and other health care facilities.¹ These guidelines are intended to assist health care personnel in the safe and effective use of gaseous chemical sterilizing systems, LCSs/HLDs, and associated equipment.

Chemical sterilants can be classified into two basic categories:

- a) LCSs/HLDs in which the items to be processed are immersed manually or processed in an automated system under defined conditions
- b) Gaseous chemical sterilants that are used in a sterilizer under defined cycle conditions

Processes that use liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization processes are validated by different methods. Therefore, they may or may not provide the same level of sterility assurance. Medical devices undergoing gaseous chemical sterilization can be packaged to maintain product sterility. However, devices processed with liquid chemical sterilization/high-level disinfection are not packaged. LCSs/HLDs are most often used for high-level disinfection of semicritical medical devices or for sterilization of critical or semicritical medical devices that are not amenable to physical sterilization processes (e.g., steam, dry heat, radiation) or gaseous chemical sterilization processes (e.g., ethylene oxide [EO], hydrogen peroxide, ozone).

NOTE 1—The information provided in this recommended practice was accurate at the time the document was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and written instructions for use (IFU) change accordingly. Therefore, it is essential that health care personnel obtain up-to-date information for the products that they use—or are considering using—and refer to manufacturers' current label directions and written IFU.

NOTE 2—The information provided in this recommended practice and its annexes is for general reference and is not intended to imply endorsement of individual products.

1.2 Inclusions

This recommended practice specifically addresses

- a) work area design considerations for processing areas in which liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization systems are used;
- b) staff qualifications, education, and other personnel considerations;
- c) criteria for selecting liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization systems;

¹This recommended practice covers LCSs/HLDs and gaseous chemical sterilization systems known to be commercially available at the time of this writing. For up-to-date information on gaseous chemical sterilization systems and LCSs/HLDs cleared by FDA, check the Center for Devices and Radiological Health (CDRH), FDA's web site at <http://www.fda.gov/cdrh>; or contact the Chief of the Infection Control Devices Branch, Office of Device Evaluation (ODE), CDRH, FDA, White Oak, Building 66, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002; 301-796-5580. A list of LCSs/HLDs provided at the FDA web site: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/UCM133514> identifies the products cleared by FDA in a 510(k) with general claims for processing reusable medical and dental devices. This list does not include preamendment products (products that were on the market before 1976 and that have not been modified since that time); FDA-cleared germicides dedicated to specific devices, such as hemodialyzers or hemodialysis machines; or gaseous chemical sterilization systems.