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Chemical sterilization and
high-level disinfection in
health care facilities

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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

Chemical sterilization and high-level disinfection in health care facilities



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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.

Keywords:

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

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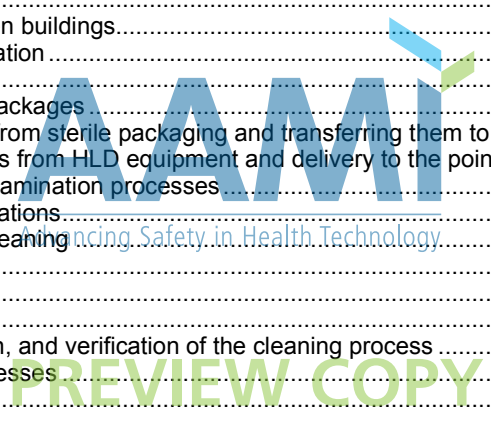


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Committee representation

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, IAHCSSM

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, RN CNOR CSPDM, Community Medical Center at Toms River

Gerald E. McDonnell, PhD, Steris Corporation

Candace McManus, DrPH

Emily Mitzel, MS, Nelson Laboratories Inc.

Thomas K. Moore

Frank Myers, USPHS Indian Health Service

Richard M. Ormsbee, Medivators Inc.

Charles G. Roberts, MS, Johnson & Johnson

Cheron Rojo, Childrens Hospital Central California

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

Frank Sizemore, Wake Forest University Baptist Medical Center

Linda Slone, 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

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

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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, CSMC 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

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

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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.



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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.

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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.