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# American National Standard



## ANSI/AAMI ST58:2013/ (R)2018

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Chemical sterilization and  
high-level disinfection in  
health care facilities

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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.

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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.

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American National Standard

**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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Approved 21 August 2013 and reaffirmed 9 September 2018 by **American National Standards Institute Inc.** to be prepared for a purchasing decision.

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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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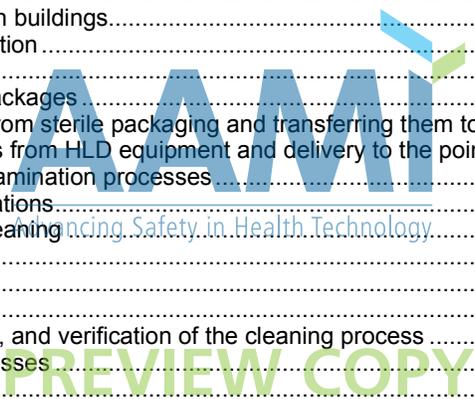


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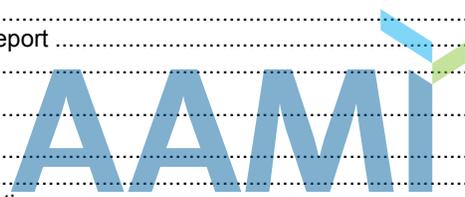
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#### AAMI Chemical Sterilants Hospital Practices Working Group

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:

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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.

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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.<sup>1</sup> 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;

<sup>1</sup>This 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.