American National Standard

ANSI/AAMI ST58:2013/(R)2018

Chemical sterilization and high-level disinfection in health care facilities

HISTORICAL

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Advancing Safety in Health Technology

American National Standard

ANSI/AAMI ST58:2013 [HISTORICAL]
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Chemical sterilization and high-level disinfection in health care facilities

Developed by
AAMI

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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.

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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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:

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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.

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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.

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;

[1]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.