American National Standard

ANSI/AAMI ST58:2024

Chemical sterilization and high-level disinfection in health care facilities

AAMI
Advancing Safety in Health Technology

American National Standard

ANSI/AAMI ST58:2024
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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, ethylene oxide, ethylene oxide emission control, ethylene oxide monitoring, 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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Association for the Advancement of Medical Instrumentation

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Foreword

This standard 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 the third edition included 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. This fourth edition includes chemical sterilants both liquid chemical and gaseous. ANSI/AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness* has been withdrawn and is now updated and included in this standard.

In a 2017 multi-disciplinary stakeholders meeting hosted by AAMI, high-level disinfection practices were reviewed. Based on recent research that show some pathogens are resistant to high-level disinfectants (HLD), medical devices and instructions for use (IFU) are becoming more complex, and the introduction of new low temperature sterilization modalities that in many instances are the same amount of time as HLD or less. The output of the 2017 meeting included a recommendation that endoscopes used as semi-critical devices be sterilized.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;.

The provisions of this standard 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 standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Rd., Suite 300, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities* (ANSI/AAMI ST58:2024), 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 standard 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 three basic categories:

a) LCSs/HLDs in which the items to be processed are immersed manually or processed in an automated system under defined conditions; and

b) gaseous chemical sterilants that are used in a sterilizer under defined cycle conditions;

c) foam or gel in which the items to be processed are manually or in an automated system coated with foam under defined conditions.

Processes that use liquid chemical sterilization/high-level disinfection and gaseous chemical sterilization are validated by different methods. Although each method achieves acceptable microbial lethality, some methods have limitations. 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, hydrogen peroxide-ozone).

NOTE 1 The information provided in this standard 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 standard and its annexes is for general reference and is not intended to imply endorsement of individual products.

[1] This standard 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 Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection, DHT4B: Division of Infection Control and Plastic Surgery Devices, OHT4: Office of Surgical and Infection Control Devices, Office of Product Evaluation and Quality (OPEQ). FDA-Cleared Sterilants and High-level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices are provided at the FDA website. The list 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.

