Using chemical sterilants and high-level disinfectants in health care facilities

The update of the Association for the Advancement of Medical Instrumentation American National Standard Chemical sterilization and high-level disinfection in health care facilities, ANSI/AAMI ST58:2013, is available for purchase and should become part of health care facilities’ evidence-based library. Below is a brief description of the contents of the recommended practice, and ordering information is provided at the end of this article.

Sections 1 and 2
Chemical sterilization and high-level disinfection in health care facilities (Section 1) and Definitions and abbreviations (Section 2).

This document provides information on the safe use of liquid chemical sterilants (LCS), high-level disinfectants (HLD), and gaseous chemical sterilants (GCS) cleared for marketing by the Food and Drug Administration (FDA). Not included is ethylene oxide, which has its own AAMI recommended practice (Ethylene oxide sterilization in health care facilities, ANSI/AAMI ST418:2008).

In this document, “chemical sterilants/high-level disinfectants” includes both liquid and gaseous chemical sterilants unless otherwise noted.

Section 3
Work area design considerations. This section discusses the information needed for workplace design, traffic control, ventilation, and containment to minimize potential employee exposure. Proper environmental monitoring to ensure the levels of chemicals in the air do not exceed recommended limits is also discussed. Annexes A-I and N provide more information on the monitoring requirements for all LCS/HLD and GCS.

Section 4
Personnel considerations. This section discusses staff qualifications for supervisors and processing personnel. Competencies needed for working with LCS/HLD and GCS, which should be part of a department’s education program, are also covered.

Personnel protective equipment (PPE) is discussed for eye, skin, and respiratory protection. More specific PPE is discussed in Annexes A-I and in the chemicals safety data sheet (SDS) and instructions for use (IFU).

New information is included about eyewash/facewashes and showers:
• Water temperature should be between 15°C and 43°C (60°F and 100°F) and routinely tested and documented.
• Plumbed eyewashes/facewashes and showers “should be activated weekly for a period long enough to verify operation and ensure that the flushing solution is available.” This section also states that routine testing should be documented.

Section 5
Selection of liquid and gaseous chemical sterilants/high-level disinfectants. This section provides questions for the user to answer “when choosing disinfecting and
sterilizing agents and equipment.” Also provided is a list of questions users “should ask” the manufacturers of LCS/HLD products and automated processing equipment, the manufacturers of GCS sterilization systems, and the manufacturers of medical devices to be processed.

Section 6
Decontamination and preparation of instruments. This section discusses the “sterility assurance measures [that] should be used from the time items are received into the health care facility until they are used.” The areas of discussion include:

• Receiving of purchased items at loading dock (Section 6.2).
• Handling, collection, and transport of contaminated items (Section 6.3).
• Transport of clean/sterile items and contaminated items, trash, and food from each area to decontamination within a facility, between buildings, or to an off-site location (Section 6.4).
• Aseptic presentation of sterile packages and removal of devices from HLD equipment and delivery to point of use (Section 6.5).
• Cleaning and other decontamination processes (Section 6.6).
• Packaging (Section 6.7).

The cleaning and other decontamination processes (Section 6.6) are further broken down into these sections:

• Preparation for cleaning (Section 6.6.2).
• Disassembly (Section 6.6.3).
• Cleaning (Section 6.6.4).
• Rinsing (Section 6.6.5).
• Drying, inspection, and verification of the cleaning process (Section 6.6.6).
• Microbial processes (Section 6.6.7).

This update addresses:

• Receiving and documentation of delivery of loaned items.
• The “usage of rigid sterilization container systems with closed valves or intact, dry filters” to transport contaminated items.
• Information on brushes that should be supplied by the medical device manufacturer to ensure effective cleaning of lumens.
• Monitoring of mechanical equipment “when evaluating or changing to a new type of cleaning chemistry, upon installation, weekly (preferably daily) during routine use, and after major repairs. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment.”
• The use of water-soluble lubricants—not lubricants containing mineral oil or other oil bases unless specified by the medical device manufacturer’s IFU.

Section 7
Using chemical sterilant/high-level disinfectants safely and effectively. This section covers general safety and efficacy considerations when using LCS/HLD or GCS and includes:

• Establishing policies and procedures (Section 7.2).
• Following device manufacturer’s written IFU (Section 7.2.2).
• Following LCS/HLD manufacturer’s written IFU (Section 7.2.2.1).
• Following mechanical LCS/HLD equipment manufacturer’s written IFU (Section 7.2.2.2).
• Following gaseous chemical sterilization equipment manufacturer’s written IFU (Section 7.2.2.3).
• A new section on ensuring cleaning effectiveness (Section 7.2.3) notes that “The use of methods that are able to measure cleaning effectiveness that is not detectable by visual inspection may be considered in facility cleaning policy and procedures.”

• A new section on excess moisture (Section 7.2.3.1) notes that it is necessary to remove excess moisture from items being processed with LCS/HLD and GCS.

• General safety considerations as stated in the products’ SDS and the OSHA Hazard Communication Standard (29 CFR 1910.1200) (Section 7.3).

• The need for a LCS/HLD spill containment “response team” (Section 7.3.2.1) and a written plan for containment of LCS/HLD spills (Section 7.3.2.2).

• Liquid chemical sterilants/high-level disinfectants (Section 7.4) was divided into more sections to discuss the relationship between LCSs and HLDs, single vs multi-use, process parameters, water quality for dilution and rinsing, containers for solution storage, and monitoring, which is also discussed in Section 9.

Section 8
Device storage and transport. This section covers postprocess handling and storage of items processed by LCSs/HLDs and GCS.

Section 9
Quality control. This is the only recommended practice that addresses quality control in the use of LCS/HLD and GCS. This section covers:

• Lot control numbers (Section 9.2.1).

• Cycle documentation (Section 9.2.2). Documentation now includes the shelf-life date, lot number, and date the original container of LCS/HLD was opened.

• Expiration dating (Section 9.2.3).

• Monitoring manual processes that use LCSs/HLDs (Section 9.3). Physical monitoring, which includes a thermometer and timer as well as visual inspection of the solution, should be used for each process. Solution test strips or chemical monitoring devices should be used before each use to determine if the minimum recommended concentration (MRC)/minimum effective concentration (MEC) is correct. This section also covers what to do if the monitors indicate a problem.

• Monitoring automated processes that use LCSs/HLDs (Section 9.4). Physical monitoring involves checking the automated processing equipment printout before and after each cycle. Solution test strips or chemical monitoring devices should be used before each cycle to determine if the MRC/MEC is correct. For LCS, use a chemical indicator according to the manufacturer’s IFU (e.g., each cycle is appropriate). Follow the manufacturer’s IFU for the spore test strips that have been FDA-cleared for 1 LCS process. This section also covers what to do if the monitors indicate a problem.

• Monitoring gaseous chemical sterilization processes (Section 9.5). Physical monitoring involves checking the automated processing equipment printout before and after each cycle. A chemical indicator should be used on the outside and inside of each package. A biological indicator process challenge device should be used at least daily, but preferably in every sterilization cycle, for sterilizer qualification testing and product testing. This section also covers what to do if the monitors indicate a problem.

• Product release (Section 9.6). Active decision based on evaluation of all data.

• Product testing (Section 9.7). This new section discusses how to perform product testing for both LCS/HLD and GCS processes by testing a master product identified from a family of products.
• Product recalls (Section 9.8). This section discusses recall procedures, recall order, recall summary report, and outbreak reports.

Section 10
Quality process improvement. This section lists specific performance measures to use when performing a risk analysis as part of the health care facility’s quality process improvement.

Annexes
Annexes A to I provide valuable information on properties and applications, effective and safe use, procedures for cleaning up spills, and disposal for FDA-cleared LCS/HLD and GCS.

Other annexes include:
• Annex A: Microbial lethality, materials compatibility, and toxicity.
• Annex J: Government regulation.
• Annex L: User verification of cleaning processes.
• Annex M: Example of documentation of premature release of implants.
• Annex N: Gas and vapor monitoring.

This recommended practice can be used to update policies and procedures to protect employees from potentially hazardous materials and to ensure safe and effective processing of medical devices for patient care when using liquid chemical sterilants, high-level disinfectants, and gaseous chemical sterilants. ❖

Martha Young, MS, CSPDT President, Martha L. Young, LLC, providing SAVVY Sterilization Solutions for Healthcare
Woodbury, Minnesota

Martha Young is an independent consultant with long experience in medical device sterilization and disinfection.

Reference

Ordering information
ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities can be purchased through AAMI by credit card using the following options:
1. Internet: http://www.aami.org and click on publications
2. Call: 1-877-249-8226
3. Fax: 1-240-396-5781
4. Mail: AAMI publications, PO Box 211, Annapolis Junction, MD 20701-0211