Objectives

After completion of this self-study activity, the learner will be able to:
1. Identify department policies and procedures for processing medical devices using chemical sterilants and high-level disinfectants that need updating.
2. Identify the appropriate personal protective equipment (PPE) for routine protection for all FDA-cleared liquid chemical sterilants (LCS), high-level disinfectants (HLD), and gaseous chemical sterilants (GCS).
3. Develop a policy and procedure for routine monitoring of high-level disinfectants (HLD), liquid chemical sterilants (LCS) and gaseous chemical sterilants (GCS).
4. Describe why 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 document should become part of a health care facility’s evidence based library.¹

Test Questions

1. The area used for chemical sterilants/high-level disinfectants should be separate from the cleaning/decontamination, patient procedure, and personnel support areas.
   A. True  B. False

2. 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.
   A. True  B. False

3. The only personnel protective equipment (PPE) needed when working with chemicals is gloves for skin protection.
   A. True  B. False

4. Mechanical cleaning equipment should be tested to verify cleaning efficacy when evaluating or changing to a new type of cleaning chemistry, upon installation, weekly (preferably daily) during routine use, and after major repairs.
   A. True  B. False

5. Follow the manufacturer of the medical device, liquid chemical sterilant (LCS)/high-level disinfectant (HLD), mechanical LCS/HLD equipment, and gaseous chemical sterilant (GCS) sterilizer’s written IFU to ensure medical devices are safe for patient use.
   A. True  B. False

6. A test strip or chemical monitoring device should be used before each use when monitoring a manual or automated process employing a LCS/HLD solution.
   A. True  B. False

7. When monitoring a GCS processes (except for ethylene oxide processes) a chemical indicator (CI) should be used on the outside and inside of each package and a biological indicator process challenge device (BI PCD) should be used daily, but preferably in every sterilization cycle.
   A. True  B. False

8. To perform sterilizer qualification testing after a GCS sterilizer process failure (except for ethylene oxide processes) follow the BI PCD manufacturer’s written IFU on which BI and PCD to use, placement of the BI PCD in the load or chamber, whether the chamber should be full or empty, and the number of cycles to run.
   A. True  B. False

9. Retrieve and reprocess all items processed since the sterilization cycle with the last negative BI when a positive BI occurs.
   A. True  B. False

10. Product testing is done to validate that the manufacturer’s written IFU can be successfully performed in the user facility.
    A. True  B. False
Introduction

The objective of this article is to introduce the updated Association for the Advancement of Medical Administration Chemical sterilization and high-level disinfection in health care facilities recommended practice, ANSI/AAMI ST58:2013 by briefly discussing the contents of each section. The recommended practices covered by this document are in place to protect the health care professional from exposure to these important but potentially hazardous materials and to ensure safe and effective processing of the medical devices for patient care when using liquid chemical sterilants (LCS), high-level disinfectants (HLD) and gaseous chemical sterilants (GCS) cleared for marketing by the U.S. Food and Drug Administration (FDA). The gaseous chemical sterilant ethylene oxide is not discussed in AAMI ST58 because it has its own recommended practices called Ethylene oxide sterilization in health care facilities, ANSI/AAMI ST418:2008.

AAMI ST58 is the most comprehensive recommended practice on this subject and should be part of your evidence-based reference library. Purchase information is available at the end of this inservice.

Chemical sterilization and high-level disinfection in health care facilities (Section 1)

This recommended practice is intended to assist health care personnel in the safe and effective use of liquid chemical sterilants (LCS), high-level disinfectants (HLD) and gaseous chemical sterilants (GCS).

This document addresses:
- Work area design;
- Staff qualifications, education and other personnel considerations;
- Criteria for selecting LCS/HLD and GCS systems;
- Decontamination and preparation of instruments;
- Safety and efficacy considerations in the use of LCS/HLD and GCS systems;
- Storage and transport of disinfected and sterilized devices;
- Quality control methods; and
- Quality improvement process.

This recommended practice also has updated annexes (see Table 1 on p. 13) with information not covered in other recommended practices or guidelines.
Definitions and abbreviations (Section 2)

The definitions and the abbreviations listed in AAMI ST58 and used in this inservice are documented below.

2.12 biological indicator (BI): “Test system containing viable microorganisms providing a defined resistance to a specified sterilization process.”

2.13 ceiling limit: “According to the Code of Federal Regulations, “the employee’s exposure to an air contaminant which shall not be exceeded during any part of the work day. If instantaneously monitoring is not feasible, then the ceiling shall be assessed as a 15-minutes time weighted average (TWA) exposure which shall not be exceeded at any time over a working day” (29 CFR 1910.1000). “See also threshold limit value (TLV®).”

2.14 chemical indicator CI): “Device used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment.” The six classes of CIs are defined.

2.15 chemical sterilant/high-level disinfectant: "Chemical agent capable of rendering a product free of viable microorganisms.

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

2.23 EPA: U.S. Environmental Protection Agency

2.27 gaseous chemical sterilization (GCS): “Validated process employing gaseous chemical sterilants (e.g., ethylene oxide [EO], hydrogen peroxide, ozone).”

2.30 high-level disinfectant (HLD): “Agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions.

NOTE-According to the FDA, HLD is a liquid chemical sterilant (LCS) used for shorter exposure time than that required to pass the AOAC Sporicidal activity test as a sterilant.”

2.35 liquid chemical sterilant (LCS): “Solution of a chemical that has been validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim.”

2.42 minimum effective concentration (MEC): “Minimum concentration of a liquid chemical sterilant/high-level disinfectant that achieves the claimed microbicidal activity; the MEC is determined by dose response testing (FDA 2000a).”

NOTE-The term “minimum recommended concentration” (MRC) is sometimes used interchangeably with “minimum effective concentration.” The MRC is not necessarily an MEC as determined by dose response testing.”

2.43 minimum recommended concentration (MRC): “Minimum concentration at which the manufacturer tested the product and validated its performance.

NOTE-the term “minimum effective concentration” (MEC) is sometimes used interchangeably with “minimum recommended concentration.” The MRC is not necessarily an MEC as determined by dose response testing.”

2.47 OSHA: Occupational Safety and Health Administration.

2.50 permissible exposure limits (PELs): “According to the Code of Federal Regulations, “limits developed by OSHA to indicate the maximum airborne concentration of a contaminant to which an employee may be exposed over the duration specified by the type of PEL assigned to that contaminant” (29 CFR 1910.1000). See also threshold limit value (TLV®).”

2.51 personal protective equipment (PPE): “According to the Code of Federal Regulations, “specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment” (29 CFR 1910.1030).”

2.52 ppmv: “Parts per million volume.

NOTE 1-Concentration of gas vapor in air are commonly measured in parts of gas vapor per million parts of air by volume: 1 ppmv equals 1 volume of gas vapor per 1,000,000 volumes of air.

NOTE 2-Concentrations in gases are typically expressed as parts per million by volume (ppmv) or percent by volume (ppmv) or percent by volume, whereas in liquids concentrations are expressed as parts per million by weight or percent by weight, in both cases, common usage often is to refer to the concentration as ppm or percent.

2.55 process challenge device (PCD): “Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

NOTE-For purposes of this recommended practice, a PCD is a challenge test pack containing a BI or a BI and a Cl. See AAMI TIR31.”

2.62 SDS: Safety Data Sheet

NOTE-As of March 2012, Material Safety Data Sheets (MSDSs) are known as Safety Data Sheets (SDSs). See also MSDS.”

2.65 short-term exposure limit (STEL): “According to the Code of Federal Regulations, “the employee’s 15-minute time weighted average exposure which shall not be exceeded at any time during a work day unless another time period is specified [by OSHA]. If another time period is specified, the time weighted average exposure over that time period shall not be exceeded at any time during the working day” (29 CFR 1910.1000). See also threshold limit value (TLV®).”

2.67 spore test strip: “Test system containing a known number of bacterial spores (at least 10® per strip) of known resistance to a sterilization process.”

2.74 threshold limit value (TLV®): “According to ACGIH®, “Threshold Limit Values (TLVs®) refer to airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects” (ACGIH, 2013). Three categories of TLVs® are specified by ACGIH®: TLV®-TWA, TLV®-STEL, and TLV®-ceiling (TLV-C).”

2.75 time-weighted average (TWA): “According to the Code of Federal Regulations, “the employee’s average airborne exposure in any 8-hour work shift of a 40-hour work week which shall not be exceeded” (29 CFR 1910.1000). See also threshold limit value (TLV®).”
Work area design considerations (Section 3)

This section provides guidelines for the work area in which chemical sterilants/high-level disinfectants are used. It includes:

(a) Workplace design, traffic control, ventilation, and containment
(b) Storage of chemical solutions
(c) Disposal of chemical solutions and solution containers

The area for chemical sterilants/high-level disinfectants “should be separate” from the cleaning/decontamination, patient procedure, and personnel support areas. This area should be in a restricted-access not high traffic area. There needs to be enough sinks of adequate size to dispose of liquid chemical disinfectants/sterilants. All of these factors minimize potential employee exposure by ensuring proper engineering controls are in place.

The Facility Guidelines Institute recommends a general ventilation of minimum of 10 air exchanges/hour. Local regulations should be checked to see if they require a higher minimum exchange rate. "Ideally local exhaust ventilation should be located at the level of the point of discharge of the vapors and pull vapors away from the work area, not toward personnel in the room." Ventilation information is available in the safety data sheet (SDS) formerly called the material safety data sheet (MSDS) for each chemical. If general room ventilation is not adequate, "a self-contained, freestanding system or a local exhaust hood should be installed to capture chemical vapor during processing." Environmental monitoring should be done to ensure the levels in the air do not exceed the recommended limits. See AAMI ST58 Annex N for more information on monitoring.

Automated processing equipment should be installed according to the manufacturer’s written instructions for use (IFU) to ensure the equipment functions properly and vapor monitoring should be performed to ensure the vapor level is at or below the levels required by law or recommended by appropriate government agencies such as National Institute for Occupational Safety and Health (NIOSH), Environmental Protection Agency (EPA), American Conference of Governmental Industrial Hygienist (ACGIH), or other organizations. See AAMI ST58 Annexes A-I and N for more information on monitoring.

The chemical sterilant/high-level disinfectant product should be stored according to the manufacturer’s written IFU and per the SDS to prevent accidental damage to the containers. The area should be cool, secure, properly marked, well-ventilated, and not under a sink. Outdated chemicals should be disposed of according to the manufacturer’s written IFU and the requirements of the local publicly owned treatment works to reduce the environmental impact of the chemicals. Empty containers should also be disposed of in “accordance with the disposal restrictions given on the product label” to prevent accidental chemical exposure or improper reuse of containers. "Compliance with federal, state, and local regulatory requirements is mandatory."

Update questions:
- Is the area used for chemical sterilants/high-level disinfectants separate from the cleaning/decontamination, patient procedure, and personnel support areas?
- Do you have 10 air exchanges/hour in the work area?
- Are you properly storing and disposing of the chemical sterilants/high-level disinfectants?

Personnel considerations (Section 4)

This section discusses the qualifications needed for supervisory and processing personnel including demonstrated knowledge and documented competence in:

- The operation of the specific high-level disinfection or chemical sterilization system;
- The operation of the manual and automated equipment used for LCSs/HLDs by the processing department;
- Worker safety; and
- Personal protective equipment (PPE).

New to this document are the recommendations that:
- There “should be a training manual that documents all aspects of training related to the on-site approved protocols.”
- It “should include checklists to document that training was performed and when competency was achieved.”
- It “should be based on the facility’s policies and procedures, accepted standards of practice, and manufacturers’ recommendations.”

PPE is used to protect workers skin, eyes, mucous membranes, and clothing from chemical splashes and comply with OSHA standards. OSHA requires employers “conduct a hazard assessment to determine the hazards that necessitate use of PPE (29 CFR 1910.132 [d]).” There are documentation and training requirements for this activity.

Manufacturer’s SDS and AAMI ST58 Annex’s B-I can provide information on eye, skin, and respiratory protection, first aid, and vapor monitoring requirements but they also reference the sections discussed next.
**Eye Protection (Section 4.4.2)**

“Eyes must be protected against contact with chemical solutions.” See AAMI ST58 Annexes B-I for information on eye protection and first-aid. “To prevent eye irritation, vapor levels musts be kept below any applicable OSHA permissible exposure limit (PEL).” “In the absence of an Occupational Safety and Health Administration (OSHA) limit, refer to the ACGIH threshold limit values (TLVs).” AAMI ST58 Annex N discusses gas and vapor monitoring.

Eyewash stations (drench hoses or eyewash bottles are not acceptable):

- “should be located within 10 seconds of travel time or 100 feet travel distance of all chemical use locations”
- “must supply a minimum of 0.4 gallons per minute continuously for at least 15 minutes for both eyes simultaneously and be hands-free”
- “should be identified with a highly visible sign and maintained in accordance with the manufacturer’s written IFU”

New to this document are the recommendations:

- That water temperature should be between 15°C and 43°C (60°F and 100°F), routinely tested and documented
- That 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.”
  - “Routine testing should be documented.”

**Skin Protection (liquid) (Section 4.4.3)**

Protect skin against contact with chemical solutions by wearing the following PPE:

- To protect hands wear impervious gloves.
- To protect forearms wear elbow-length gloves or protective sleeves made of material impervious to the chemical.
- To protect skin and clothing wear isolation gowns or aprons plus sleeve protectors made of appropriate protective materials.

**Respiratory Protection (Section 4.4.4)**

OSHA requires that “all employees who could be overexposed to chemical vapor during routine or emergency work procedures” use an appropriate respirator. This requires training in the care and application and use of the respirators which are only a temporary measure until chemical vapor exposure is reduced by engineering, administrative, and work-practice controls. Respirators must be approved by NIOSH. In cases of spills only a self-contained breathing apparatus (SCBA) is acceptable.

**Update questions:**

- Are personnel wearing the appropriate PPE for all the LCS, HLD, and GCS being used?
- Are the types of eye wash stations acceptable and activated weekly for a period long enough to verify operation and ensure that the flushing solution is available?

**Selection of liquid and gaseous chemical sterilant/high-level disinfectants (Section 5)**

This section provides users with “questions they should ask themselves when choosing disinfecting and sterilizing agents and equipment.” A list of question is also included that 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.

Included are:

- General considerations (Section 5.5.1)
- Health and safety considerations (Section 5.5.2)
- Effectiveness (Section 5.5.3)
- Materials compatibility (Section 5.5.4)
- Cost-effectiveness (Section 5.5.5)

When using LCS/HLD processes items “are immersed manually or processed in a mechanical system under defined conditions.” Items undergoing GCS are packaged and processed in a “sterilizer under defined cycle conditions. LCS/HLD are most often used for high-level disinfection of semi-critical medical devices or for sterilization of critical or semi-critical medical devices that cannot be processed by steam, dry heat, radiation or GCS (e.g., ethylene oxide, hydrogen peroxide, ozone).

In this update is the current website to use that lists the FDA-cleared LCS/HLD and GCS products: http://www.fda.gov/MedicalDevice/DeviceRegulationsandGuidance/ ReprocessingofSingle-useDevices/ucm133514.htm. Annexes B-F provide more specific information on the effective use of currently available LCSs/HLDs and annexes G, H, and I provide more specific information on the effective use of currently available GCS.

**Update question:**

- Are you using the lists of questions included in this section when selecting LCS/HLD and equipment, GCS equipment, and medical devices?
Decontamination and preparation of instruments (Section 6)

This section discusses “sterility assurance measures” that “should be used from the time items are received into the health care facility until they are used.” These include:

Receiving of purchased items at loading dock (Section 6.2)
“Clean or sterile items should be handled separately from foodstuffs, waste material, contaminated instrumentation, soiled laundry, and other potential sources of contamination.” Store bulk items in shipping cartons in the central receiving area but remove from external shipping containers “before they enter the sterile storage area of the department.”

In this update, loaned items are addressed to stress that “personnel should document”
• Loaned items were delivered to the receiving area; and
• The correct number of packages were delivered and received according to the packing slip.

The packaged items and written IFU “should be delivered to sterile processing, endoscopy, surgery, or other clean storage areas within the facility as soon as possible.”

Handling, collection, and transport of contaminated items (Section 6.3)
To protect personnel, patients, and the environment during these activities:
• Separate reusable items from waste.
• Discard contaminated disposable items into an appropriate container and remove from patient care areas.
• Place sharps in puncture-resistant containers.
• Handle contaminated items as little as possible.
• Immediately contain and transport;
  o If not possible, remove gross soil at point of use;
    • Wipe with a disposable sponge moistened with water (not saline);
    • Prevent biofilm formation using a non–aldehyde-based precleaning disinfectant.

This update addresses the use of “rigid sterilization container systems with closed valves or intact, dry filters” to “contain contaminated items for transport with no further coverings, provided that the external surfaces of the container have not been contaminated by blood or other body fluids” if the manufacturer’s written IFU permits this application.

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)
“As soon as possible” transport and clean items to prevent “formation of biofilm and the drying of blood, tissue, and mucus on items, which make cleaning even more difficult.” To facilitate transportation within a facility:
• Have a schedule for pick up and transportation
• Contain items in covered or closed transport carts
• Have a dedicated soiled lift in decontamination area

To facilitate transportation between building and off-site using a vehicle:
• Contain and package items
• Separate clean and sterile from contaminated using physical barriers
• Control temperature
• Secure carts in vehicles
• Comply with U.S. Department of Transportation (DOT) and state regulations

Aseptic presentation of sterile packages and removal of devices from HLD equipment and delivery to point of use (Section 6.5)
This is a new section that discusses sterile packages:
• How to open a sterile package, including inspection and reading of the external chemical indicator; and
• Checking the internal chemical indicator before removing the contents and placing on the sterile field.

For removal of devices from HLD equipment, items should be protected from contamination by following the HLD equipment manufacturer’s written IFU, transported to point of use without recontamination, and used immediately.

Cleaning and other decontamination processes (Section 6.6)
This section discusses cleaning and microbial processes. There is a list of six points to review when deciding whether a microbiocidal process is necessary. This primarily depends on the device manufacturer’s written IFU. The update is to be aware that some IFUs may specify the length of time the contamination can remain on the item before it is cleaned.

This section includes information on:
Preparation for cleaning (Section 6.6.2)
Personnel should “not reach into the container by hand to retrieve reusable sharps based on OSHA regulations (29 CFR 1910.1030).”

Disassembly (Section 6.6.3)
The device manufacturer’s IFU should be followed for disassembly and reassembly of medical devices to ensure “hidden surfaces and crevices are cleaned.”
Cleaning (Section 6.6.4)

Cleaning is the “first and most important step in decontamination.” Cleaning agents include “various types of detergents, enzymatic and non-enzymatic based cleaners, acidic, alkaline and neutral detergents.” The cleaning agent should be compatible with the device materials, the cleaning equipment and other chemicals used in the same process stage such as a washer disinfect or in previous (such as an ultrasonic) and subsequent stages (such as disinfection) to “minimize the adverse effects of any carryover.”

The medical device manufacturer’s written IFU will determine if a manual and/or a mechanical cleaning process is used. Information about brushes was added in the update and should be included in the IFU for manual cleaning. The brush information list for cleaning lumened devices should include:

• Type;
• Size (diameter and length);
• Bristle type; and
• Material to create friction with the walls of the lumen to loosen soils

If this information is not provided in the IFU contact the medical device manufacturer for written information to ensure lumens are clean.

Mechanical cleaning is addressed and this update includes the requirement that this equipment (e.g., ultrasonic cleaning equipment and medical washers):

“should be tested 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.”

Examples of a major repair include replacement of the:

• Water pump(s);
• Detergent deliver system;
• Heating system;
• Water delivery system;
• Water treatment system; or
• Computer control or an upgrade to software.

AAMI ST58 Annex L provides information on user verification of cleaning processes including tests used to assess the efficacy of the cleaning process.

Another update discusses lubricants. Water-soluble lubricants specifically identified by the manufacturer’s written IFU should be used. “Instrument lubricants containing mineral oil or other oil bases should not be used, except to lubricate the internal mechanisms of powered instruments as specified by the manufacturer.”

Rinsing (Section 6.6.5)

The medical device manufacturer’s written IFU should be followed to make sure the water quality (e.g., potable versus treated) and number of rinses will ensure patient safety. Using the appropriate water quality will eliminate staining issues.

Drying, inspection, and verification of the cleaning process (Section 6.6.6)

After rinsing, the instruments should be visually inspected for cleanliness and working condition and then dried. This section is updated to suggest that another test besides visual inspection may be done to verify the cleaning process of instruments. Available tests are included in AAMI ST58 Annex L.

Microbicidal processes (Section 6.6.7)

The update to this section includes Figure 3 which is a “flow chart illustrating the use of microbicidal processes to help ensure that items are safe for personnel to handle and indicating the processing stages at which PPE is required.” The device manufacturer’s written IFU should be accessed to determine if a “microbicidal process is required after cleaning and before high-level disinfection or sterilization.”

Packaging (Section 6.7)

Package medical devices for processing in GCS according to the written IFU of the manufacturer of the:

• Device;
• Sterilizer or high-level disinfectant system; and
• Packaging.

Update questions:

• Are you documenting in the receiving area the correct number of packages that were delivered according to the packing slip of the loaned instruments?
• Are you using the correct brushes for cleaning lumens?
• Are you testing mechanical cleaning equipment to verify cleaning efficacy when evaluating or changing to a new type of cleaning chemistry, upon installation, weekly (preferably daily) during routine use, and after major repairs?
• Are you testing instruments to verify cleaning efficacy?
Using chemical sterilant/high-level disinfectants safely and effectively (Section 7)

This section covers general safety and efficacy considerations in the use of any LCS/HLD product or GCS process. This 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)
  - As an update following instructions for spill containment and cleanup was added.
- 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)
  - As an update instructions for spill containment and cleanup and methods to monitor the efficacy of the process were added.
- A new section on ensuring cleaning effectiveness (Section 7.2.3)
  - “Visual inspection alone may not be sufficient for assessing the effectiveness of the cleaning process. 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)
  - It is necessary to remove excess moisture from items being processed with LCS/HLD and GCS. Follow the LCS/HLD and GCS manufacturer’s written IFU.
- General safety considerations as stated in the products SDS and the OSHA Hazard Communication Standard (29 CFR 1910.1200)(Section 7.3)
  - Emergency procedures (Section 7.3.2)
- The facility needs 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.
  - The LCS/HLD manufacturer’s written IFU should be followed

Update questions:
- Are you following the medical device, LCS/HLD, mechanical LCS/HLD equipment, and GCS sterilizer manufacturers’ written IFUs?
- Are you verifying the cleaning effectiveness of individual instruments?
- Do you have a spill containment “response team” and a written plan for containment of LCS/HLD spills?

Device storage and transport (Section 8)

This section covers the post-process handling and storage of items processed by LCSs/HLDs and GCSs. Items processed by LCSs/HLDs “should be either immediately used or stored in a manner that minimizes recontamination.” Sterile packaging should be handled carefully.

Update question:
- Are you properly storing and transporting items processed by LCS/HLD and GCS?
Quality control (Section 9)

The information covered in this section is summarized below and cannot be found for LCS/HLD and GCS in other recommended practices.

Lot control numbers (9.2.1), cycle documentation and record keeping (9.2.2) and expiration dating (9.2.3)

This section discusses the use of lot control numbers, cycle documentation and record keeping, and expiration dating. Documentation now includes the shelf-life date, lot number and date that the original container of LCS/HLD was opened.

Monitoring manual process that use LCSs/HLDs (Section 9.3)

This update has this new title which was previously titled “Solution test strips and chemical monitoring devices.”

BIs and CIs are not available for monitoring process that use LCSs/HLDs. Test strips and chemical monitoring devices are available to determine whether the concentration of the active ingredient is adequate.

Monitoring includes:
- Physical monitoring
  - “is done with a thermometer and timer” and documented
  - “visually inspect solution before each use and discard if precipitates are observed, even if within its use-life”
  - Ensure solution is covered to prevent evaporation and exposure to light which can affect efficacy of the chemical agent.
  - If physical monitors and visual inspection of solution “suggests inadequate process, items should not be dispensed or used.”
- Solution test strip or chemical monitoring devices
  - Use an FDA-cleared test strip or chemical monitoring device recommended by the LCS/HLD manufacturer’s IFU or cleared by the FDA as substantially equivalent.
  - Test the solution before each use to determine if the MRC/MEC is correct.
  - Do not use the solution if the monitoring product indicates the concentration of the active ingredient is inadequate.
    - Items processed since the last cycle with a monitoring device that indicated an adequate concentration should be consider unprocessed, retrieved and reprocessed, and the solution discarded.
    - The cause should be determined and corrected and another monitoring device used.
      - If the test result is inadequate this solution should also be discarded.

Monitoring automated processes that use LCSs/HLDs (Section 9.4)

- Physical monitoring
  - The automated processing equipment printout
    - Should be checked at the beginning of the cycle to verify
    - Cycle identification was recorded and the printer is functioning
    - Should be checked at the end of the cycle and before the items are removed to verify
      - Cycle parameters are met and operators initials recorded
    - “Automated equipment without electronic data transfer, recording, or printing capabilities should not be used.”
  - FDA-cleared biological indicators (BIs), spore test strips, chemical indicators (CIs), and solution test strips and chemical monitoring devices should be used.
    - Automated equipment should be tested at the same frequency as for manual processes.
      - Before each cycle if using solution test strips and chemical monitoring devices
      - CIs used according to manufacturer’s written IFU (e.g., each cycle is appropriate)
    - Spore test strips have only been cleared for one system and should be used according to manufacturer’s written IFU (this is an update based on a recent FDA-cleared monitoring product).
- If the interpretations of the physical monitors or processing monitoring devices (such as BIs, spore test strips, CIs, solution test strips, and chemical monitoring devices) or visual inspection of the chemical solution suggest inadequate processing, “the items should not be dispensed or used.”
  - Troubleshoot according to the equipment manufacturer’s written IFU
    - If malfunction cannot be corrected immediately, terminate the cycle, and remove the equipment from service.
    - “All items in the cycle should be reprocessed, if appropriate.”
    - If a major repair is needed, “follow the manufacturer’s written IFU for verification testing before the equipment is returned to service.”
      - “A major repair is a repair outside the scope of normal maintenance, such as rebuilding or updating controls.”
Monitoring gaseous chemical sterilization processes (Section 9.5)

- Physical monitoring
  - Should be checked at the beginning of the cycle to verify
    - Cycle identification was recorded and the printer is functioning
  - Should be checked at the end of the cycle and before the items are removed to verify
    - Cycle parameters are met and operators initials recorded
  - “Sterilizers without recording charts and printouts should not be used.”
  - If physical monitors suggest inadequate processing, items should not be dispensed or used and the supervisor informed.
  - Troubleshoot according to the equipment manufacturer’s written IFU.
    - If malfunction cannot be corrected immediately, terminate the cycle, and remove the equipment from service.
    - “All items in the cycle should be completely repackaged, all wrappers and disposable products should be replaced, and new process indicators used.”
  - If a major repair is needed, the sterilizer “should be requalified according to the manufacturer’s written IFU,” which should include (this is an update):
    - BI and PCD to use
    - Placement of the BI PCD in the load or chamber
    - Whether the chamber should be full or empty
    - Number of cycles to run
    - Obtain BI tests results to determine if satisfactory before sterilizer is returned to service.

- Chemical indicators
  - Use an FDA-cleared CI on the outside of each package unless the internal indicator is visible.
    - Examine the external CI after sterilization and before use to verify items were exposed to the sterilization process before opening the package.
  - Place an FDA-cleared CI on the inside of each package, tray, or containment device in the most challenging area.
    - Retrieve and read at time of use and before the item is placed on the sterile field.

- Biological indicators
  - Should be used for
    - Sterilizer qualification testing:
      - During initial installation of sterilizer
      - After relocation, major repairs, or malfunctions of sterilizer
      - After sterilization process failures

- Product testing (see Section 9.7)
- Routine testing in a PCD at least daily, but preferably in every sterilization cycle
- To monitor every load of implantables
  - It is not acceptable to release implants until BI results are known.
  - When documented emergency situations dictate early release
    - Use exception form (Annex M)
  - Documentation of implants should be fully traceable to the patient.
  - If a BI is positive
    - Retrieve and reprocess all items processed since the sterilization cycle with the last negative BI
    - Take the sterilizer out of service, investigate the cause of the sterilization process failure
    - Rechallenge the sterilizer with BI PCDs according to sterilizer manufacturer’s written IFU which should include (this is an update):
      - Appropriate BI and PCD to use
      - Placement of the BI PCD in the load or chamber
      - Whether the chamber should be full or empty
      - Number of cycles to run
    - Obtain BI tests results to determine if satisfactory before sterilizer is returned to service

Product release (Section 9.6)

“Product release should be an active decision based on evaluation of all available data from the sterilization high-level disinfection process for the particular load.”

Product testing (Section 9.7)

This is an entirely new section that discusses how to perform product testing for both LCS/HLD and GCS processes “to verify that manufacturer’s written IFU can be successfully performed in the user facility.” Product testing does not substitute for validation testing by the manufacturer so “the packaging, loading, type of process, or critical process parameters” cannot be changed based on the product testing results.
Product testing does not need to be done on all products but on the master product from a family of products. This section discusses:

- Identification of product families;
- When to do product testing;
- Placement of BIs and CIs for GCS processes;
- Testing using solution test strips or chemical monitoring devices, spore test strips and CIs for LCS/HLD automated processing equipment.

**Product recalls (Section 9.8)**

“Written policies and procedures for the recall of issued or stored packaged items that have been processed with a chemical sterilant/high-level disinfector should be developed in cooperation with the infection prevention and control committee and the risk management committee of the individual institution or integrated health care network, as appropriate.” A list of what a recall procedure, recall order, recall summary report, and outbreak report should have is listed.

**Quality process improvement (Section 10)**

This section lists specific performance measures for Decontamination (Section 10.2.3), Liquid chemical sterilization, high-level disinfection, and gaseous chemical sterilization (Section 10.2.4), Work place design (Section 10.3.1), Processing policies and procedures (Section 10.3.2), Product use (Section 10.3.3), and Implementation of product and process improvement (Section 10.4). This information can be utilized when performing a risk analysis as part of the health care facilities quality process improvement.

**Update questions:**

- When monitoring a manual processing which uses a LCS/HLD, is a solution test strip or chemical monitoring device used before each use?
- When monitoring an automated processing which uses a LCS/HLD, is a solution test strip or chemical monitoring device used before each use?
- When monitoring a GCS process, is a CI used on the outside and inside of each package and a BI PCD used daily, but preferably in every sterilization cycle?
- Is qualification testing of the GCS process being conducted according to the sterilizer manufacturer’s written IFU?
- For product testing who will identify the product families and master products and perform the testing?

**Annexes**

The annexes describing the FDA cleared LCS/HLD and GCS have been updated and provide valuable information which includes:

- Introduction
- Properties and applications
- Effective use
- Safe use
- Procedures for cleaning up spills
- Disposal

Table 1 provides some of the information about minimum PPE recommended and occupational exposure limits found in the annexes. Always check the chemical manufacturers IFU and SDS in addition to the annexes for a complete set of information about the safe use of these products.
<table>
<thead>
<tr>
<th>Annex</th>
<th>Description</th>
<th>Type of Chemical</th>
<th>Minimum PPE Recommended</th>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
</table>
| B     | Glutaraldehyde solutions | LCS/HLD | Eye protection  
2% solution  
• Safety glasses or goggles  
7.5%  
• Cup-type chemical goggles, a full-face shield, or both  
Gloves  
• Rubber, neoprene, vinyl, or nitrile gloves  
Protective clothing  
• Appropriate protective clothing including long sleeves | ACGIH® TLV® 0.05 ppm |
| C     | Hydrogen peroxide solutions | LCS/HLD | Eye protection  
2% solution  
• Safety glasses or goggles  
7.5%  
• Cup-type chemical goggles, a full-face shield, or both  
Gloves  
• Rubber, neoprene, vinyl, or nitrile gloves  
Protective clothing  
• Appropriate protective clothing including long sleeves | OSHA PEL 1 ppm as an 8-hour TWA |
| D     | Ortho-phthalaldehyde solutions | LCS/HLD | Eye protection  
2% solution  
• Safety glasses or goggles  
7.5%  
• Cup-type chemical goggles, a full-face shield, or both  
Gloves  
• Rubber, neoprene, vinyl, or nitrile gloves  
Protective clothing  
• Appropriate protective clothing including long sleeves | Currently, no OSHA PPL nor ACGIH®-recommended TLV® |
| E     | Peracetic acid-hydrogen peroxide solutions | LCS/HLD | Safety glasses or goggles  
Rubber or neoprene gloves | No OSHA permissible exposure limit for peracetic acid but there are recommendations:  
• 8-hour TWA limits for hydrogen peroxide vapor of (1 ppm)  
• 8-hour TWA limits for acetic acid (10 ppm)  
See annex for more details about NIOSH, ACGIH® and EPA occupational exposure limits |
| F     | Sodium hypochlorite solutions | LCS/HLD | Chemical safety goggles and a full-face mask if using highly concentrated solutions  
Protective gloves and clothing recommended by the manufacturer’s written IFU | Chlorine gas is principle vapor hazard:  
• OSHA PEL of a ceiling of 1 ppm  
• ACGIH® TLV® is 0.05 ppm calculated as an 8-hour TWA |
| G     | Chemical vapor sterilants using alcohol and formaldehyde | GCS | Safety glasses, safety goggles, or a face shield  
Protective gloves, see manufacturer’s IFU | Formaldehyde exposure limit  
OSHA:  
• 0.75 ppm as an 8-hour TWA  
• 0.75 ppm as a 15 min STEL  
• 0.5 ppm as an 8-hour TWA action level  
ACGIH®:  
• 0.3 ppm ceiling level  
Alcohol exposure limit:  
Consult label for type of alcohol and refer to OSHA for information |
| H     | Hydrogen peroxide gas sterilization | GCS | For eye protection see manufacturer’s IFU  
Polyvinylchloride or nitrile gloves when removing items from the sterilizer | OSHA:  
• 1 ppm as an 8-hour TWA  
ACGIH®:  
• TLV® of 1 ppm as an 8-hour TWA  
NIOSH:  
• 1 ppm as a TWA for up to a 10-hour workday or a 40 hour workweek |
| I     | Ozone sterilization | GCS | Eye protection  
• Not necessary during routine operation because an enclosed system  
Chemical safety goggles for nonroutine situations  
Skin protection  
• Not necessary during routine operation because an enclosed system  
Chemical protective gloves, coveralls, and other resistant protective clothing for nonroutine situations | OSHA:  
• PEL of 0.1 ppm as an 8-hour TWA  
• STEL of 0.3 ppm 15-minute TWA  
ACGIH®:  
• TLV® of 0.05 ppm TWA to 0.02 ppm TWA depending on the conditions and duration of exposure |
Other annexes

Other annexes include:
- Annex A: Microbial lethality, materials compatibility, and toxicity
  - General discussion as it relates to chemical sterilants/high-level disinfectants
- Annex J: Government regulation
  - Discussion of the role of EPA, FDA, and OSHA in regulating LCS, HLD, and GCS
- Annex L: User verification of cleaning processes
  - Information of why and how to verify the cleaning process
- Annex M: Example of documentation of premature release of implants
  - Includes an implantable device load record and an exception form for premature release of implantable device/trays that the Joint Commission will check during surveys, including the name of the physician who approved the early release of the implant
- Annex N: Gas and vapor monitoring
  - New annex with information on instrumentation, procedures, selecting vapor-monitoring equipment or services, and contracted services

Update question:
- Are you monitoring employee exposure limits to all the LCS/HLD and GCS in use?

Summary

The comprehensive and updated information in 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 document should become a part of a health care facilities evidence based library. Compliance with this document will reduce the risk of health care professional’s exposure to potentially hazardous materials and provide the highest level of assurance for safe and effective processing of the medical devices for patient use. This document provides information regarding liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilants (GCSs) cleared from marketing by the FDA. This is a resource you cannot afford to not buy.

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 four 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

Reference

Answers

1. A
2. A
3. B
4. A
5. A
6. A
7. A
8. A
9. A
10. B

Martha Young, BS, MS, CSPDT

Martha Young is president of Martha L. Young, LLC, providing SAVVY sterilization solutions to healthcare manufacturers and facilities. She retired from the 3M Infection Prevention Division, St. Paul, MN in 2009 after 31 years and has over 35 years of experience in the specialty area of cleaning/disinfection and sterilization. Ms. Young has lectured around the world, has over 80 publications on infection prevention with an emphasis on how to improve the performance of the sterilization process, and writes a quarterly column for OR Manager. She is a member of IAHCSMM, AORN (Past Professional/Practice Issues Chair for AORN Speciality Assembly for Sterilization Processing and Materials Management from 2006-2010), APIC and a certified Central Sterile Processing and Distribution Technician. Additionally, Ms. Young has been a voting member of several AAMI working groups developing recommended practices for over 20 years. She recently was the APIC representative to AAMI. In 2007 HPN acknowledged her as one of the “30 Pros Worth Knowing” who are the Most Influential in Healthcare Sterile Processing. In June 2012, Ms. Young received the 2012 Leadership Award from the Massachusetts Chapter of Central Service Professionals in recognition of outstanding education and leadership to the Sterile Processing Profession and in 2013 the Robert Hilbolt Award from the Michigan Society for Healthcare Central Service Professionals in recognition of her significant contributions for the advancement of healthcare Central Service. Ms. Young can be reached at marthalyoung1@aol.com.

Ms. Young is an education consultant for 3M HealthCare, Infection Prevention Division.
Sterile Process and Distribution CE Information

CE Applicant Name: __________________________ City: __________________________
Address: __________________________ State: __________________________
City: __________________________ Zip Code: __________________________

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1.5 contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, Inc. 148 Main St., Lebanon, NJ, 08833 or call 908-236-0530 or 1-800-555-9765 or visit the website at www.sterileprocessing.org. IAHCMM has awarded 1.5 approved contact points for completion of this continuing education lesson toward IAHCMM recertification.

Nursing CE Application Form

This inservice is approved by the California Board of Registered Nurses, CEP 5770 for 1 contact hour. This form is valid up to five (5) years from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. Keep a copy for your records.
6. Submit this form and the answer sheet to:
   3M Infection Prevention
   Attn: HC4160
   RR Donnelly Fulfillment Services
   585 Hale Avenue North
   Oakdale, MN 55128-9935
7. For questions please call the 3M Healthcare helpline: 1-800-228-3957.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of RR Donnelly’s receipt of the application.

Application  Please print clearly or type.

Name: __________________________
Mailing Address: __________________________
City: __________________________
State: __________________________ Zip Code: __________________________
Country: __________________________
Daytime phone: ( )

Position/Title: __________________________
Social Security or Nursing License Number: __________________________
Date application submitted: __________________________
Signature: __________________________

Offer expires November 2018

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