

**August 2006**

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**Learning Objectives**

1. Determine the correct processing methods to use according to Spaulding's classification system.
2. Review the Association for the Advancement of Medical Instrumentation's (AAMI's) 2005 recommended practice on Chemical Sterilization and High-level Disinfection in Health Care Facilities (ANSI/AAMI ST58).
3. Develop a policy and procedure for routine efficacy monitoring of chemical sterilization and high-level disinfection processes.
4. Develop a recall procedure for materials undergoing gaseous chemical sterilization processes.

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**SELF-STUDY Series**

**Monitoring chemical sterilization and high-level disinfection**

by Rose Seavey, RN, MBA, CNOR, ACSP

New technologies are being introduced in healthcare almost every day. Along with these advancements comes a variety of invasive and non-invasive surgical instrumentation and devices. Many devices today cannot withstand the high temperature and/or humidity associated with steam sterilization. As a result, other methods have been developed over the years to help tackle the needs. These methods include:

**Liquid chemical sterilants (LCSs):**

- Glutaraldehyde solutions
- Peracetic acid-hydrogen peroxide solutions
- Chemical vapor sterilants using alcohol and formaldehyde

**High-level disinfectants (HLDs):**

- Glutaraldehyde solutions
- Ortho-phthalaldehyde solutions
- Hydrogen peroxide
- Sodium hypochlorite solutions

**Gaseous chemical sterilants (GS):**

- Hydrogen peroxide gas plasma sterilization
- Ozone sterilization
- Ethylene oxide

This article will focus on the new Association for the Advancement of Medical Instrumentation standard, *Chemical sterilization and high-level disinfection in health care facilities* ST58:2005. This recommended practice provides guidelines for the use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilants (GS) that have been cleared for marketing by the Food and Drug Administration (FDA) for use in hospitals and other health care facilities.<sup>1,2</sup> Ethylene oxide is not covered in this document since it has its own document (ANSI/AAMI ST41:1999 *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*).

**Spaulding's classifications**

Health care workers must make certain that all surgical instruments and medical devices used in procedures on patients have been appropriately cleaned, disinfected or sterilized according to the nature of the item and the manner in which it is to be used.

In 1968 Earl Spaulding developed the Spaulding classification system. This system helped to determine the correct processing methods for items to be used on patients. With the Spaulding system, the level of processing needed is based on the nature of the item and the how it will be used. Devices that are used on sterile tissue are categorized as critical and must be sterilized. Devices that come in contact with mucous membranes or nonintact skin are considered semi-critical and must be high-level disinfected immediately before use. Devices that come in contact with intact skin are categorized as noncritical items and should receive intermediate or low-level disinfection.<sup>3</sup>

The chart below was created from the 2006 edition of The Association of periOperative Registered Nurses (AORN) Recommended Practices for High-Level Disinfection.<sup>3</sup>

**Work area designs**

Chemical sterilization and high-level disinfection should be performed in designated areas. To limit the possibility of cross-contamination, cleaning and decontamination must be performed in a separated space from patient procedure areas and personnel support areas. This area should be a controlled area. Only personnel knowledgeable about the potential hazards should have access to the area where

Items that come in contact with:	Nature of item	Processing required	Examples
Sterile tissue or the vascular system	Critical	Sterile	Surgical instruments, cutting endoscopic accessories, catheters, needles
Nonintact skin or mucus membranes	Semi-critical	Minimum of high level disinfection immediately before use	Respiratory therapy equipment, bronchoscopes and GI scopes
Intact skin	Noncritical items	Intermediate-level disinfection, low-level disinfection, or cleaning	Tourniquets, blood pressure cuffs, linens, and OR furnishings

chemical sterilization and high-level disinfection is performed.

“Chemical sterilization should be used in an area that is properly ventilated. Rooms in which chemical disinfection and sterilization are performed should be large enough to ensure adequate dilution of vapor and should have a minimum air exchange rate of 10 air exchanges per hour (local regulations may require a higher minimum exchange rate).”<sup>1,2</sup> Overhead fume hoods may also be recommended.

**Personnel considerations**

Accountability for performing chemical high level disinfection, and sterilization processes should be assigned to competent individuals who have knowledge of all aspects of disinfection and sterilization procedures and safety precautions.

Supervisory personnel responsible for chemical sterilization and high level disinfection should have formal training and be knowledgeable about each method used. “They should understand the need to obtain and follow the device manufacturer’s written instructions for high-level disinfection or sterilization of the device, as well as the chemical sterilant manufacturer’s written instructions for use.”<sup>1,2</sup>

Follow the chemical sterilant and equipment manufacturer’s written instructions for use of personal protective equipment (PPE) necessary to prevent operator exposure to the chemical. Different types of PPE will be required for different chemical products and disinfection equipment. PPE is intended to be the primary barrier for protecting employees from exposure and may include some or all of the following:

- Splash proof eye protection
- Face shields
- Gloves
- Protective clothing

As with all processing activities, employees performing these duties should be given special training, and their competencies should be verified.

**Using chemical sterilants and high level disinfectants safely and effectively**

According to AAMI, “The safety and performance characteristics of a gaseous chemical sterilant or LCS/HLD can be categorized in terms of (a) its effectiveness in killing microorganisms under the prescribed conditions of use, (b) its effects on the materials and devices it is intended to sterilize or dis-

infect, and (c) its toxicity and potential to harm health care personnel and patients.”<sup>1,2</sup>

If you are using manual LCS/HLD or automated LCS/HLD equipment, the manufacturer’s written instructions for use should be followed. These instructions should include instructions for safe and effective use, identification of compatible materials, devices or soaking trays. For automated equipment, they should state if there is a cleaning cycle, utility needs, water quality and temperature. For gaseous chemical sterilization equipment the manufacturer should include instructions for installation, safe and effective operations of the sterilizer and instructions for cleaning and maintaining the sterilizer.<sup>1,2</sup>

To assure effective sterilization or high-level disinfection all items must be thoroughly cleaned. Bioburden can interfere with the sterilization or disinfectant process. Excess moisture should also be removed for most LCS/HLD and all gaseous sterilization processes. Moisture can dilute or inactivate the chemical solution, or interfere with the sterilization process.<sup>1,2</sup>

All processes using LCSs, HLDs and GCs require efficacy monitoring to ensure the correct level of processing has been obtained. LCS and HLDs also require vapor monitoring to ensure employee safety. Individual manufacturer’s written recommendations for air sampling and vapor monitoring should be followed.

**Efficacy monitoring for LCSs/ HLDs manual processes**

*Physical monitors*

Manual LCS/HLD processes should be physically monitored with a thermometer and time. The accuracy and precision of the thermometer and timer should be documented. In addition, a visual inspection of the solution should be done just prior to use. If any precipitates are seen, the solution should be discarded; even if it is within the use-life or the test strip or chemical monitoring devices showed it has an adequate concentration of the active ingredient(s).<sup>1,2</sup>

*Chemical monitors*

There are no biological indicators (BIs) or chemical indicators (CIs) for monitoring processes that use LCSs/HLDs with the exception of one peracetic acid processing system. However, there are test strips and chemical monitoring devices available which determine if there is adequate concentration of the active ingredient(s) [i.e., minimum effective concentration (MEC)]

in a LCS/HLD solution. The solution should be tested just prior to each use.<sup>2</sup>

“Health care personnel should use the FDA-cleared test strip or chemical monitoring device recommended by the LCS/HLD manufacturer or a test strip or chemical monitoring device cleared by the FDA as substantially equivalent. Solution test strips or chemical monitoring devices are needed to detect inadequate concentration of the active ingredient(s) of the LCS/HLD.” If the test strip indicates that the concentration is inadequate, the solution should be discarded.<sup>1,2</sup>

**Efficacy monitoring for LCSs/ HLDs automated processes**

*Physical Monitors*

The physical monitoring parameters of automated processing equipment for LCSs/HLDs include displays, digital printouts, and gauges. “Processing equipment that does not have physical monitor recording devices should not be used.”<sup>1,2</sup>

The majority of these automated processing devices are equipped with a computer program designed to detect insufficient cycle conditions. If a malfunction is noted by the physical monitoring devices, the load should be considered inadequately processed and not used. All items in the incomplete cycle should be reprocessed, before being used. “To restore processing equipment to proper performance, it is necessary to identify the exact cause of the malfunction.”<sup>1,2</sup>

*Chemical Monitors*

The chemical used in the automated processes should be tested just prior to each cycle to ensure there is adequate concentration of the active ingredient(s) [i.e., minimum effective concentration (MEC)] in a LCS/HLD solution. An “FDA-cleared test strip or chemical monitoring device recommended by the LCS/HLD manufacturer or a test strip or chemical monitoring device cleared by the FDA as substantially equivalent” should be used.<sup>2</sup>

If the test strip or chemical monitoring device indicates that the concentration of the active ingredient is insufficient the equipment should be removed from service. An investigation as to the cause of the failure should be conducted. A docu-

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

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mented report of the incident should be maintained and should include a description of the processing equipment, the results of the investigation and who was notified. After the corrections are made the LCS/HLD should be retested with a test strip or chemical monitoring device before being put back into service.<sup>1,2</sup>

**Efficacy monitoring for gaseous chemical sterilization processes**

*Physical monitors*

Gaseous chemical sterilization processes have time, temperature, and pressure recorders; displays; digital printouts; and gauges that physically monitor the machines. These physical monitors provide real time measurement of the sterilization cycle conditions, and provide permanent records. If there is any indication of malfunction or suspicious operation, the load should not be used and all products reprocessed. The facility maintenance personnel should be notified and the malfunction corrected.<sup>1,2</sup>

*Chemical Indicators*

Chemical indicators help sense any potential sterilization failures resulting from incorrect packaging, incorrect loading or malfunction of the sterilizer. Only FDA-cleared CIs recommended by the manufacturer of the selected gaseous sterilization system or a CI cleared by FDA as substantially equivalent should be used. The CI manufacturer's written instructions for use should be followed with regards to placement, result readings, reliability and shelf life.<sup>1,2</sup>

If the CI results show insufficient processing, the contents of the package should not be used. "The department head or designee in the sterilizing department should then decide whether to recall that sterilized load. This decision should be based on the results of physical monitoring, the results of CIs elsewhere in the load; and, if applicable, the results of biological monitoring. If biological monitoring was performed but the results are not yet available, the remaining packages from the same load should be quarantined and not used until the BI results are obtained."<sup>1,2</sup>

*Biological Indicators*

Biological indicators are designed to demonstrate whether or not the process conditions were sufficient to achieve sterilization. Challenge test packs containing a BI and/or a CI are designed to simulate a device

to be sterilized are called Process challenge test packs (PCDs). Only FDA-cleared BIs/BI PCDs recommended by the manufacturer of the chosen gaseous chemical sterilization system or BIs/BI PCDs cleared by FDA as substantially equivalent should be used.<sup>1,2</sup>

"Process challenge devices containing appropriate BIs should be used for sterilizer qualification testing during initial installation of the sterilizer; after relocation, major repairs or malfunctions of the sterilizer, and after sterilization process failures." PCDs with a suitable BI should also be used at least once each day, but preferably in every load.<sup>1,2</sup>

All monitoring results, including results from BI controls, should be interpreted by a qualified individual and should be included in the sterilizer record." If a BI tests positive a recall of all products sterilized in that load as well as any products in previous loads since the last negative BI should be conducted. The sterilizer in question should be taken out of service until the investigation is complete, the problem identified and resolved and three consecutive negative BIs have been performed.

**Summary**

Technology in healthcare is changing rapidly. With improved technologies come increased challenges in reprocessing surgical instrumentation and other devices. The level of reprocessing needed is addressed by the Spalding classification method and should be followed to ensure safe patient care. LCSs/HLDs and chemical gaseous sterilization processes are frequently used in healthcare facilities to reprocess items that cannot withstand the high temperature associated with steam sterilization. Whatever processes a facility uses, it is important that these processes are monitored to ensure efficacy to the level of reprocessing required (high level disinfection or sterilization). Other requirements such as work area design, PPE, air sampling and vapor monitoring are also essential to ensure personnel safety. No matter what disinfection or sterilization process you use, it is imperative that all manufacturer's written recommendations are followed. Healthcare facilities should follow AAMI's 2005 recommended practice on *Chemical sterilization and high-level disinfection in health care facilities* (ANSI/AAMI ST58) which provides guidelines for the selection and use of liquid

chemical sterilants/high level disinfectants and gaseous chemical sterilants. **HPN**

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1. Recommended Practices for Sterilization in Perioperative Practice Settings. Association of periOperative Registered Nurses. AORN Standards, Recommended Practices, and Guidelines. 2006.
2. The Association for the Advancement of Medical Instrumentation. Chemical sterilization and high-level disinfection in health care facilities. ANSI/AAMI ST58:2005.
3. AORN Standards, Recommended Practices, and Guidelines. Recommended Practices for High-Level Disinfection. 2006.

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**CONTINUING EDUCATION TEST — August 2006**

**Monitoring chemical sterilization and high-level disinfection in health care facilities**

**Circle the one correct answer**

- |   |   |   |
|---|---|---|
| <p>1. Devices that come in contact with intact skin are considered critical and must be sterile.<br/>a. True<br/>b. False</p> <p>2. Chemical sterilants should be used in an area that is properly ventilated.<br/>a. True<br/>b. False</p> <p>3. Supervisory personnel responsible for chemical sterilization and high level disinfection should have formal training and be knowledgeable about each method used<br/>a. True<br/>b. False</p> <p>4. All automated and manual processes using LCS/HLD solutions should be tested for adequate concentration of the active ingredient with a test strip or chemical monitoring devices just prior to each use.<br/>a. True<br/>b. False</p> | <p>5. All LCSs/HLDs have biological indicators and chemical indicators available to monitor these processes.<br/>a. True<br/>b. False</p> <p>6. Solution test strips or chemical monitoring devices are needed to detect inadequate concentration of the active ingredient(s) of LCS/HLDs.<br/>a. True<br/>b. False</p> <p>7. If a malfunction is noted by the physical monitoring device of a HLDs solution the processed items can still be used since sterilization is not a requirement.<br/>a. True<br/>b. False</p> | <p>8. The physical monitors for gaseous chemical sterilization provide real time measurement of the sterilization cycle conditions and provide permanent records.<br/>a. True<br/>b. False</p> <p>9. Process challenge devices with suitable BIs should be used at least once per day, but preferably in every load in gaseous chemical sterilization processes.<br/>a. True<br/>b. False</p> <p>10. If a facility follows the AAMI guidelines they do not have to consult the original manufacturer's recommendation for use.<br/>a. True<br/>b. False</p> |
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