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Learning Objectives

1. Describe the contents and assembly of Process Challenge Devices (PCDs) used to monitor EO sterilization cycles (i.e. both routine and challenge BI test packs).

2. Evaluate whether your facility's Policy and Procedure on monitoring of EO sterilizers needs revision based on changes to ST41:2008.

3. Write a Policy and Procedure describing recommended routine load release criteria for EO sterilizers.

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ANSI/AAMI ST41 has been revised

It's time to review your facility's EO sterilization policy and procedures

by Susan Flynn, BESc, CSPDT

Ethylene oxide (EO) is used to sterilize heat- and/or moisture-sensitive medical devices that cannot be steam sterilized. Ethylene oxide is valued for its efficacy, its ability to penetrate complex medical devices, and for its long history of materials compatibility.

This self-study article discusses some of the updates found in the recently revised ANSI/AAMI ST41:2008, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness* (ST41). In addition to the revised recommendations in the Quality Control section, particularly to the content concerning qualification testing, the new edition of ST41 incorporates extensive information from ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ST79), regarding attire, the handling and transport of contaminated items, cleaning/decontamination processes, user verification of cleaning processes, the selection and use of chemical disinfectants, and thermal disinfection.

As indicated by the title of ST41, safety of personnel operating ethylene oxide sterilizers is one of the key themes of the recommended practice. To this end, guidance from the Occupational Safety and Health Administration's (OSHA's) regulation on occupational exposure to ethylene oxide, 29 CFR 1910.1047(3), is woven throughout the document.

Definitions

Two additions to the definitions section in ST41 are worth noting. First, the definition of **chemical indicator** has been updated to reflect the content of the current AAMI chemical indicator standard, ANSI/AAMI/ISO 11140-1:2005, *Sterilization of health care products – Chemical indicators – Part 1: General requirements.* While the definitions of all six classes of chemical indicators are provided, ST41 notes that "This edition of ANSI/AAMI ST41 does not cover the use and application of Class 6 emulating indicators".[1] The definitions for the various classes of chemical indicators are repeated in Section 10.5.2.1, General considerations for chemical indicators.

A second topical addition to this section is the definition of **health care-associated infections (HAIs):** "Infections that patients acquire during the course of receiving treatment for other conditions or that health care workers acquire while performing their duties within a health care setting."[1] This term is, of course, relevant with the recent changes to reimbursement provided by the Centers for Medicare and Medicaid Services (CMS) in which hospitals will no longer be reimbursed for certain conditions, such as surgical site infections following a coronary artery bypass graft (CABG), that could reasonably have been prevented through the use of evidence-based guidelines.[4] The introduction to ST41 points out that ethylene oxide sterilization of medical devices is one way to prevent HAIs.

Design considerations

ST41 discusses design considerations in Section 3. It is recommended that EO sterilizers and aerators be located in a containment area separate from other work areas. This area should have a minimum of 10 total air exchanges per hour. Yearly monitoring and documenting of ventilation rates is recommended. To comply with the OSHA EO regulation, signs with specified verbiage indicating the use of EO should be posted outside the containment or "regulated" area.

While the environmental recommendations haven't changed, it bears repeating that ST41 recommends general work areas maintain a temperature between 20°C and 23°C (68°F and 73°F) and an ideal relative

Self-Test Answers: 1. A, 2. A, 3. A, 4. A, 5. A, 6. A, 7. A, 8. A, 9. A, 10. B

humidity level of 50% and a minimum level of 35%. Because "Moisture hydrates microorganisms, making them more susceptible to destruction by EO"[1], this ideal RH level is provided in Section 3 and repeated in Section 8.3, Preconditioning.

Quality control

Concepts borrowed from the ST79 steam recommended practice document that appear at the beginning of the **Quality control** section of the updated ST41 include the recommendations that:

- Verification testing be done to ensure mechanical cleaning equipment is working properly, and
- All processed devices, especially implants, be fully traceable to the patient.

Additionally, in the sterilizer records section, ST41 now recommends documenting the time of day that a load was run and the specific load contents.

Table 2—Sterilization process monitoring recommendations

Routine load release (see 10.6)	Routine sterilizer efficacy monitoring (see 10.7)	Sterilizer testing after sterilization process failures[1] (see 10.6.4)	Sterilizer qualification testing after malfunctions, major repairs (see 10.6.4 and 10.8)	Sterilizer qualification testing after installation, relocation (see 10.8)	Sterilizer qualification testing after major redesign (see 10.8)	Periodic product quality assurance testing (see 10.9 and 10.10)
Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle
External and internal CI monitoring of packages	External and internal CI monitoring of packages					Placement of BIs and CIs within product test samples
Monitoring of every load with a PCD containing a BI and a CI (the routine test pack of 10.7.2)	Monitoring of every load with a PCD containing a BI and a CI (the routine test pack of 10.7.2)	Monitoring of one cycle with a PCD containing a BI and a CI (the routine test pack of 10.7.2) in a load similar in composition and density to the load exhibiting the sterilization process failure. The load should be quarantined until the BI results are known.	Monitoring of three consecutive cycles with one or more PCDs containing a BI and a CI (the routine test pack of 10.7.2) in a load similar in composition and density to the load exhibiting the sterilization process failure. If items in the test load are to be used in patient care, the load should be quarantined until the BI results are known.	Monitoring of three consecutive cycles with one or more PCDs containing a BI and a CI (the challenge test pack of 10.8.2) in a simulated load[2]	Monitoring of three consecutive half-cycles with one or more PCDs containing a BI and a CI (the challenge test pack of 10.8.2) in a simulated load[2] and three consecutive full-exposure cycles with one or more PCDs (the challenge test pack of 10.8.2) containing a BI and a CI in an otherwise empty chamber	
Quarantine of implants until BI results are known						

NOTE 1—A sterilization process failure has occurred if any monitoring device suggests that the process was inadequate.

NOTE 2—A "simulated load" is defined for each size of EO sterilizer in Table 3.

The Quality Control section includes a helpful new table, Table 2 above reprinted with permission from AAMI, which provides a high-level summary of monitoring recommendations.

Like the similar table in ST79, Table 2 summarizes recommendations for routine load release, routine sterilizer efficacy monitoring; and periodic product quality assurance testing. Unlike ST79, and in recognition of the complexity of EO sterilization and perhaps to increase user conformance with the standard, the committee separated the previous guidance for qualification testing into four categories that appear as separate columns in the table:

- sterilizer testing after sterilization process failures;
- sterilizer qualification testing after malfunctions and major repairs;
- sterilizer qualification testing after installation and relocation; and
- sterilizer qualification testing after major redesign.

Before discussing monitoring recommendations for these various situations, let's review the process challenge devices (or test packs) used to monitor EO sterilizers.

Composition of PCDs used in EO sterilization

It is sometimes overlooked that ST41 includes both a **routine** test pack and a **challenge** BI test pack or Process Challenge Device (PCD). While the basic contents of these packs didn't change with the revision to ST41, their use did change. Table A below summarizes the composition of these two PCDs.

In practice, rather than assembling routine BI test packs most health care facilities purchase commercially available process challenge devices that are equivalent in

*See **SELF-STUDY** on page 28*

Table A - Composition of BI PCDs for EO Sterilization Monitoring

	Routine BI Test Pack	Challenge BI Test Pack
Components	- 1 biological indicator placed in a syringe, syringe tip guard removed - 1 chemical indicator - surgical towel - peel pouch or wrapper	- 2 biological indicators, each placed in a separate syringe - a chemical indicator - one adult plastic airway - one 10" section of latex tubing (PVC tubing may be substituted) - four clean, 18-inch by 30-inch, reusable, freshly laundered, preconditioned surgical towels, each folded in thirds and then in half to create six layers per towel and then stacked one on top of another - two clean, 24-inch by 24-inch wrappers, either woven or nonwoven
Assembly	Place the BI in the syringe, orienting the cap per the BI manufacturer's instructions. Place the syringe and the CI inside the folded surgical towel and wrap using a peel pouch or wrapper. The PCD should be assembled at the same time as the load to be sterilized.	Place the syringes, latex tubing, plastic airway, and CI in the center of the stack of folded towels, double wrap the stack and secure with tape. (see Figure 6, reprinted with permission from AAMI) Note that PCD components should be preconditioned at room temperature and a relative humidity >35% for at least 2 hours prior to assembly.

SELF-STUDY from page 27

challenge to the routine test pack. Commercial equivalents to the challenge BI test pack are not available.

Routine load release

Back to Table 2, monitoring recommended for routine load release includes:

- user verification of the physical parameters reported on the cycle print-out;
- the use of external and internal chemical indicators with each package, tray or containment device (ST41 recommends the use of a Class 1 process indicator for the external CI while for internal chemical indicators, Class 4 multi-variable or Class 5 integrating indicator chemical indicators are recommended); and
- a BI PCD, either the routine test pack described in Table A or a commercially available equivalent. The BI PCD "should be placed in the area of the chamber and load that is considered to be least favorable to sterilization (usually the center of the load unless otherwise indicated by the sterilizer manufacturer)".[1]

In addition to verifying satisfactory results for all monitoring tools, load release should include verification that the prescribed aeration time is complete. Any "packages containing implants should be quarantined until the results of the BI testing (early readout or spore growth) are available".[1]

Routine sterilizer efficacy monitoring

ST41 continues to recommend the use of the routine BI test pack, or a commercially available equivalent, in each EO sterilization cycle. The standard also recommends the daily use of a positive control BI from the same lot as the test BI.

Sterilization process failure

A significant change to the standard that is sure to please end-users is the recommendation to use a routine BI test pack after a sterilization process failure, rather than the challenge BI test pack recommended in the previous edition of the standard. If any monitoring device (i.e. physical monitor, chemical indicator, biological indicator) suggests the sterilization process was inadequate, the operator should conclude a sterilization process failure has occurred. After investigation, if it is determined that the sterilizer itself has not malfunctioned, recommended testing is to run a routine BI test pack or a commercially equivalent BI PCD in a similar load and to quarantine that load until the BI result is negative.

If, however, it is determined the sterilizer has malfunctioned, the root cause of the malfunction must be determined and the sterilizer repaired. After a malfunction or major repair, the sterilizer must be requalified. This is done by running three consecutive cycles with a routine BI test pack (or commercially equivalent BI PCD) in loads "similar in composition and density to the load exhibiting the sterilization process failure".[1] If these test loads contain patient care items, the load contents should be quarantined until the BI results are negative.

Qualification testing

Qualification testing recommended after **sterilizer installation or relocation** includes running the challenge test pack, described in Table A, in three consecutive cycles. One or more BI challenge test packs are placed in the sterilizer. Rather than using patient care load items, additional PCDs, similar in composition to the challenge test pack but without the BI, are then used to create a simulated load. The simulated load creates a thermal challenge to the cycle and is similar to testing conducted by the sterilizer manufacturer. Many health care facilities now use small (chamber volume generally less than 10 cubic feet) EO sterilizers employing 100% ethylene oxide as the sterilant. For sterilizers having a chamber volume less than 16 cubic feet, which includes typical 100% EO sterilizers, one BI challenge test pack is placed in the lower front part of the chamber and then the additional non-BI PCDs are added to create a simulated load. Larger EO sterilizers require additional BI PCDs. ST41 provides information on the required quantity and placement of BI PCDs.

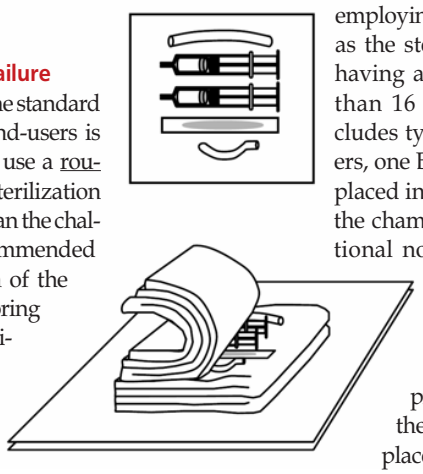

Figure 6—Placement of components in PCD (challenge BI test pack)

The newly installed or relocated sterilizer may be put into service after BIs from the three consecutive test cycles are negative, and a review of the cycle printouts and CI results all indicate acceptable results.

Should a sterilizer undergo **major redesign**, perhaps to run a different EO gas mixture, for example, the required qualification testing is slightly different and requires the assistance of the sterilizer manufacturer or other service provider. Three consecutive half-cycles are run, each with BI challenge test pack(s) in simulated loads. Following this, three consecutive full-cycles should be run, each with BI challenge test pack(s) in an otherwise empty chamber. The number of BI PCDs used in both the half-cycle and full-cycle testing is dictated by the chamber volume.

Product testing

A test program including both BIs and CIs should be implemented to periodically test products routinely sterilized in EO sterilizers. Changes in packaging, wrapping technique or load configuration should trigger product testing. This testing involves placing indicators in a sample tray/container, packaging and labeling the sample tray/container, and placing it in a routine sterilizer load in the most difficult location in the chamber for sterilant to penetrate. After the sterilization cycle, the sample tray/container should be aerated and then opened to examine the CIs and retrieve the BI for incubation. If all CIs have reached their endpoints and BI results are negative, the facility can continue to routinely sterilize that item. As with all quality control testing, the results of periodic product testing should be documented.

Annexes

ST41:2008 reorders the annexes found in the previous version of the document and provides additional annexes borrowed from ST79.

For example, OSHA's standard on occupational exposure to ethylene oxide (29CFR 1910.1047), while not new, remains an essential reference for Sterile Processing Managers and is reprinted in Annex A. This standard obligates employers to ensure employees' exposure to airborne ethylene oxide does not exceed the Permissible Exposure Limits (PEL) of 1 part per million (ppm) over an 8-hour time-weighted average.

SELF-STUDY SERIES

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Informational annexes originally published in ST79 and now included in this version of ST41 are:

- Processing CJD-contaminated patient care equipment and environmental surfaces;
- Selection and use of chemical disinfectants;
- User verification of cleaning processes;
- Thermal disinfection; and
- Development of a prepurchase evaluation protocol for rigid sterilization container systems.

Summary

Ethylene oxide sterilization of reusable medical devices requiring low temperature sterilization remains an important tool in the repertoire of technology and clinical practices hospitals employ to combat HAIs. The 2008 update to AAMI ST41 provides a comprehensive reference document on the safe and effective use of EO sterilizers. After reading this self-study article and ordering the new AAMI document, review your department's Policies and Procedures to determine whether they need revision to reflect the updated guidance provided in the revised standard. Pay particular attention to section 10.6.4 on testing sterilizers after sterilization process failures. HPN

Ordering Information:
To order a copy of ST41, visit http://marketplace.aami.org or call 877-249-8226. Order code: ST41.

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References

1. Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.* ANSI/AAMI ST41:2008. Arlington, VA: AAMI, 2008.

2. Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Amendment 1.* ANSI/AAMI ST79:2006/A1:2008. Arlington (VA): AAMI, 2008.

3. Occupational Safety and Health Administration. Occupational exposure to ethylene oxide. *Code of Federal Regulations,* Title 29, Part 1910.1047.

4. Centers for Medicare and Medicaid Services website: http://www.cms.hhs.gov/HospitalAcqCond

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ANSI/AAMI ST41 has been revised

It's time to review your facility's EO sterilization policy and procedures

Circle the one correct answer:

1. **Ethylene oxide (EO) is used to sterilize heat- and/or moisture-sensitive medical devices.**
   A. True
   B. False
2. **ST41:2008 provides a definition but does not discuss the use of Class 6 emulating indicators.**
   A. True
   B. False
3. **General work areas in the sterile processing department should ideally maintain a relative humidity level of 50%.**
   A. True
   B. False
4. **ST41:2008 includes a recommendation that mechanical cleaning equipment be monitored.**
   A. True
   B. False
5. **For internal chemical indicators, ST41:2008 recommends the use of Class 4 or Class 5 CIs.**
   A. True
   B. False
6. **A BI PCD is recommended for use with each EO cycle.**
   A. True
   B. False
7. **The challenge BI test pack or PCD is used to qualify a newly installed EO sterilizer.**
   A. True
   B. False
8. **A commercially available PCD of equivalent challenge may be substituted for the routine BI test pack when conducting routine sterilizer efficacy testing.**
   A. True
   B. False
9. **OSHA has established a permissible exposure limit to airborne ethylene oxide of 1 ppm over an 8-hour time-weighted-average.**
   A. True
   B. False
10. **Half-cycle testing is part of the qualification testing required after a sterilizer malfunctions.**
    A. True
    B. False

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