

October 2006

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Learning Objectives

1. Identify the key changes to Section 10 Quality Control of the Association for the Advancement of Medical Instrumentation's (AAMI's)

Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2006) ST79.

2. Identify what indicators should be placed in process challenge devices (PCD) for routine monitoring and for sterilizer qualification testing.

3. Describe the difference between Routine Efficacy Testing, Sterilizer Qualification Testing, and Periodic Product Quality Assurance Testing.

4. Determine when it is appropriate to initiate a recall.

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What's all the "steam" about? New recommended practice

by Dorothy Larson, CSPDT and Tammy Torbert, BA, MA

Have you heard the latest "steam" about sterilization? That's because there's a newly published recommended practice for steam sterilization and sterility assurance!

The Association for the Advancement of Medical Instrumentation's (AAMI's) newest recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006) is now available to order. ST79 is a comprehensive guide for all steam sterilization activities in health care facilities, regardless of the size of the sterilizer or the size of the facility, and provides a resource for all health care personnel who use steam for sterilization. The ST79 guidelines are considered "recommendations for optimum performance levels to the processing of reusable medical devices in a health care setting to ensure safe and effective patient care."

What's new about ANSI/AAMI ST79:2006 recommended practice?

Five existing recommended practices have been merged into one document, ST79. These recommended practices are:

- ANSI/AAMI ST46, *Steam sterilization and sterility assurance in health care facilities;*
- ANSI/AAMI ST42, *Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities;*
- ANSI/AAMI ST37, *Flash sterilization: Steam sterilization of patient care items for immediate use;*
- ANSI/AAMI ST35, *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings;* and
- ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid container systems for ethylene oxide sterilization and steam sterilization in health care facilities.*

This new ST79 recommended practice covers the full range of activities for steam sterilization in health care facilities. The main differences in ST79 are within Section 10: Quality Control, so we will cover some of the key changes in this area.

Key Changes

1. A "Process Challenge Device" (PCD) is a new term used in place of the term "test pack" or "challenge pack". A PCD is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed. (See *Process challenge devices*, Section 10.5.4).

- Depending upon the application in sterilization process monitoring, the PCD may contain a (an)
 - Biological indicator (BI)
 - BI and a Class 5 integrating chemical indicator (CI)
 - BI and an enzyme-only indicator
 - Class 5 integrating CI
 - Enzyme-only indicator
- 2. Internal chemical indicators are used to detect equipment malfunctions (e.g., air leaks, wet steam, inadequate temperature or time) and identify certain procedural errors (i.e., errors in loading or packaging). Internal CIs should be either Class 3, 4 or 5, or an enzyme-only indicator. (See *Internal chemical indicators*, Section 10.5.2.2).
- An enzyme-only indicator is a chemical indicator comprised of multiple, interactive enzymes of bacterial origin. Note that an enzyme-only indicator does not contain spores and should not be confused with a biological indicator.
- 3. Sterilization process monitoring uses physical monitors, BIs and CIs, all of which are indispensable. The ST79 format is different: It provides two tables summarizing the essential elements of sterilization process monitoring (See *Overview of sterilization process monitoring*, Section 10.4):
 - Table 7 – Sterilization process monitoring, and
 - Table 8 – Types and applications for use of sterilization monitoring devices.These tables are not designed to supply all the information on appropriate monitoring. Included in the tables are the following:
 - PCDs used for routine sterilizer efficacy (weekly, preferably every day the sterilizer is used), and qualification testing (after installation, relocation, malfunctions, major re-

Implantable Devices Load Record										
Date	Description of implants	Dept.	Time sterilized (specify AM/PM)	Sterilizer #	Load #	Date/time BI in incubator	Date/time and BI result	Early release?	Date/time released to OR	Released by (full name)

Figure L.1 Example of documentation of premature release of implants Devices Load^a
 Provides an Implantable Devices Load Record and an Exception Form for Premature Release of Implantable Device/Tray, as examples of the forms recommended in Section 10.5.3.3.

- pairs, sterilization process failures) should contain a BI and may also contain a CI.
- PCDs used for the release of loads containing implantable devices should contain a BI and either a Class 5 integrating indicator or an enzyme-only indicator.
 - PCDs used for the routine release of loads containing non-implantable items (testing of loads between routine sterilizer efficacy testing) may contain a:
 - BI
 - BI and a Class 5 integrating indicator
 - BI and an enzyme-only indicator
 - Class 5 integrating indicator
 - Enzyme-only indicator

It is very important to choose a PCD that is the appropriate challenge for the sterilization process being tested and that contains the correct monitoring products to determine that the sterilization process is effective and to meet the AAMI ST79 recommended practices. (See *Process challenge devices*, Section 10.5.4).

4. Section 10.5.3.2 *Using biological indicators*, clearly indicates that Class 5 Integrating Indicators are not the same as Biological Indicators: “While the performance of Class 5 Integrating CIs and enzyme-only indicators has been correlated to the performance of BIs, these sterilization monitoring devices do not contain spores and thus do not directly measure the lethality of a sterilization cycle; however, they provide additional information about the attainment of the critical parameters of the sterilization process.” There is an important role for both BIs and CIs in the monitoring process. ST79 clearly states when BIs should be used:

- To monitor all implant loads
- For Routine Sterilizer efficacy monitoring
- Sterilizer Qualification Testing
- Periodic Product Quality Assurance Testing

You may use a PCD containing only a Class 5 Integrating Indicator to monitor non-implant loads only. Use individual Chemical Indicators for internal pack monitoring.

5. ST79 has added a “Rationale” for the use of BIs and why Class 5 integrating indicators or enzyme-only indicators are not a replacement for BIs:

“Rationale: The use of BIs provides evidence of efficacy by challenging the sterilizer with

a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilizer cycle. Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs.” (See *Using biological indicators*, Section 10.5.3.2).

6. ST79 no longer requires periodic verification of enzyme-based early-readout biological indicators (BIs) and recommends that a facility follow manufacturer’s instructions and facility policies and procedures to establish their own protocol for periodic verification of the early readout with spore growth. (See *General considerations*, Section 10.5.3.1).

7. For documented medical emergencies, when implant loads are released before the BI results are known, ST79, Section 10.6.3 *Release criteria for implants* indicates:

- “It is critical this documentation be fully traceable to the patient.”
- “Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.”
- “Emergency situations should be defined in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management.”
- “Steps should be taken to reduce the frequency of emergency release of implantable items.”

Release of implants before the results of the BI are known should be a rare exception. The sterilizer operator should review the physical monitors and results of other indicators to determine if the results are appropriate. If not, the load should be reprocessed. Controls should be developed and implemented with input from all hospital functions that directly impact patient safety to minimize this occurrence. AAMI provides examples of an Implant Log (Fig L.1) and Exception Form (Fig. L.2) for the premature release of implants in ST79, Annex L.

Quality control terminology defined
What is routine sterilizer efficacy testing? (Section 10.7)

Routine sterilizer efficacy testing is establishing a regular pattern of testing the efficacy of the sterilizer if you do not monitor each load with a BI PCD. ST79 recommends you monitor a full load weekly, preferably daily, with a BI PCD for sterilizers larger than 2 cubic feet and table-top sterilizers. Flash sterilizers are monitored at the same frequency but the BI is placed inside each type of tray routinely processed and placed in an empty load. A BIPCD should be run in each type of cycle for which the sterilizer is designed (i.e. prevacuum, gravity displacement, flash, etc.). **What is sterilizer qualification testing?** (Section 10.8)

Sterilizer qualification testing is testing of the sterilizer “after sterilizer installation, relocation, malfunction, major repairs, and sterilization process failures.” For sterilizers larger than 2 cubic feet, three consecutive empty cycles should be run, one right after the other, with a BI PCD followed by three consecutive empty cycles with a Bowie-Dick PCD in dynamic-air-removal sterilizers. In table-top sterilizers the BI PCD is run in three consecutive cycles in a fully loaded chamber and the load quarantined until the BI results are available. A representative package or tray that is routinely processed and considered difficult to sterilize should be used as the PCD.

What is periodic product quality assurance testing? (Section 10.9)

Periodic product quality assurance testing is testing of routinely processed items to be done on an ongoing basis and whenever “major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper.” This testing is performed because the BIPCDs recommended in ST79 do not necessarily reflect the same challenge as items routinely processed. For example, loaner trays should be tested before they are put

See **SELF-STUDY SERIES** on page 38

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

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into routine use and whenever the contents change. Biological Indicators should be placed within the product test samples. Class 3, 4 or 5 chemical indicators may be used. There is no set number of BIs and CIs that should be used; determine the appropriate number based on the size and configuration of the pack to be tested. Test samples are processed and BI and CI results are analyzed before the product is put into routine use.

When do I initiate a recall? (Section 10.11)

A recall is initiated when a positive BI occurs. Retrieve, and reprocess all medical devices processed in that sterilizer since the last negative BI if it is determined that the sterilization failure was not a result of operator error such as selection of the incorrect cycle for the load. The sterilizer should be taken out of service.

Summary

The ST79 *Comprehensive guide to steam sterilization and quality assurance in health care facilities* (ANSI/AAMI ST79:2006) is the primary resource for steam sterilization and should be part of every health care facility's library. These guidelines are considered "recommendations for optimum performance levels to the processing of reusable medical devices in a health care setting to ensure safe and effective patient care". It is the responsibility of everyone involved with the sterilization process to ensure that recommended practices, policies and procedures are followed so that patient care is not affected.

All Health Care facilities that utilize steam sterilization should have a copy of this document and update their steam sterilization policies and procedures as necessary. Now that you know some of the key

changes to ST79:2006, Section 10: Quality Control you can "pass the word" so everyone knows what the "steam" is all about!

HPN

Ordering Information

AAMI

ANSI/AAMI ST79:2006, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Order code: ST79 or ST79-PDF

Available in an attractive binder featuring sturdy metal rings, ledger-weight pages, and a laminated tab for each section for easy navigation. AAMI will issue revised pages that can be substituted into the binder when changes are made.

Also available in PDF format and as part of AAMI's electronic CD and subscription products. Price/Member discount price: \$200/\$100

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1. Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST79, 2006.
2. Young, Martha. *Condensation of the AAMI Steam Sterilization Recommended Practices Quality Control* (Section 10), Part I. *Managing Infection Control*. September 2006.
3. Young, Martha. *Condensation of the AAMI Steam Sterilization Recommended Practices Quality Control* (section 10), Part 2. *Managing Infection Control*. October 2006.
4. Reprinted with permission from the Association for the Advancement of Medical Instrumentation, Inc. © 2006 AAMI. www.aami.org. All rights reserved.

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ SHIFT: _____ TIME: _____ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES: _____

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ AM PM DATE: _____

REASON PREMATURE RELEASE WAS NEEDED: _____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE/TRAY? _____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON: _____

Figure L.2

Exception form for premature release of implantable device/tray⁴

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. O.R. personnel should complete this form and return it to Central Service within 24 hours.

CONTINUING EDUCATION TEST — OCTOBER 2006

What's all the steam about?

New Recommended Practice

Circle the one correct answer

1. For documented medical emergencies, releasing implant loads before the BI results are known is unacceptable and should be the exception rather than the rule.
A. True
B. False
2. The ST79 guidelines are considered "recommendations for optimum performance levels to the processing of reusable medical devices in a health care setting to ensure safe and effective patient care."
A. True
B. False
3. The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores, and provides the only direct measure of the lethality of a sterilizer cycle.
A. True
B. False
4. A load containing implants should be quarantined until the results of the BI testing are available.
A. True
B. False
5. A PCD is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed.
A. True
B. False
6. Periodic product quality assurance testing is testing of routinely processed items to be done on an ongoing basis and whenever major changes are made in packaging, wraps, or load configuration (i.e., dimensional changes, weight changes, or changes in the type or material of packaging or wrapper).
A. True
B. False
7. Internal chemical indicators should be a Class 3, 4, or 5 chemical indicator or an enzyme-only indicator and used inside each package, tray, or rigid sterilization container system to be sterilized.
A. True
B. False
8. You may use a PCD containing only a Class 5 Integrating Indicator to monitor non-implant loads only.
A. True
B. False
9. Four existing recommended practices have been merged into one document, ST79.
A. True
B. False
10. When a positive biological indicator result occurs, recall all items processed in that sterilizer since the last cycle having the negative biological indicator.
A. True
B. False

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