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TUTORIALS

ST79:2006 Section 10: Quality Control Key Changes

Background:

The Association for the Advancement of Medical Instrumentation (AAMI) newest recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006) was recently published. ST79 is a comprehensive guideline for all steam sterilization activities in health care facilities and provides a resource for all health care personnel who use steam for sterilization. The **five** recommended practices incorporated into the new standard 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;*
- ANSI/AAMI ST33, *Guidelines for **the selection and use of reusable rigid sterilization container systems** for ethylene oxide sterilization and steam sterilization in health care facilities.*

The new ST79 covers the full range of activities for steam sterilization in health care facilities. The remainder of this tutorial will focus on a few key changes in ST79:2006 Section 10: Quality Control that details monitoring practices.

Key Change	Practical Application
1) ST79 provides two tables summarizing the essential elements of sterilization process monitoring.	Table 7 - Sterilization process monitoring recommendations and Table 8 - Types and applications for use of sterilization monitoring devices are useful quick reference tools. They are reprinted, with permission from AAMI, at the end of this tutorial.
2) 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.	When using 3M™ Attest™ Rapid Readout Biological Indicators you may record the 1 and 3 hour results and discard the vial according to manufacturer's instructions and your facility policy.
3) All loads containing implants should be monitored with "a PCD containing a BI and a Class 5 Integrating Indicator or a PCD containing a BI and an enzyme-only indicator."	If an emergency situation requires an implant be released before the BI result is known, a Class 5 Integrating Indicator or enzyme-only indicator provides you with more information regarding the sterility of that item than only the sterilizer physical monitors.
4) There are several references to using a Class 5 Integrating indicator or an "enzyme-only indicator."	An enzyme-only indicator is a chemical indicator comprised of multiple, interactive enzymes of bacterial origin (3M™ Rapid Enzymatic Indicator). *An enzyme-only indicator does not contain spores so not to be confused with biological indicators with enzyme-based early-readout capability (3M Attest Rapid Readout biological indicators).*
5) For documented medical emergencies, when implant loads are released before the BI results are known, ST79 10.6.3 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. 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 and an Exception Form for the premature release of implants in Annex L. (see attachment)
6) In ST79 10.5.3.2 Using Biological Indicators, the document 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 indictors 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 inside each pack for internal pack monitoring.

Quality Control Terminology Defined:

What is Routine Sterilizer Efficacy Testing? (defined in AAMI ST79 Section 10.7)
It 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 sterilization cycles 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 BI PCD should be run in each type of cycle for which the sterilizer is designed (i.e. pre-vacuum, gravity displacement, flash, etc…).

What is Sterilizer Qualification Testing? (defined in AAMI ST79 Section 10.8)
It is testing of the sterilizer "after sterilizer installation, relocation, malfunctions, major repairs, and sterilization process failures."

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 full cycles and the load quarantined until the BI results are available.

What is Periodic Product Quality Assurance Testing? (defined in AAMI ST79 Section 10.9)
It 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 BI PCDs 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 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 also 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? (defined in AAMI ST79 Section 10.7.5 and 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. Items processed in that sterilizer should be retrieved, if possible, and reprocessed (see 10.11). The sterilizer should be taken out of service.

Summary:

The guidelines presented in ST79 are considered "recommendations for optimum performance levels in 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.** This tutorial highlights key changes in Section 10: Quality Control only. 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.

The ANSI/AAMI ST79:2006
is available from AAMI
at www.aami.com
or by calling 1-877-249-8226

For more information,
call the 3M Help Line:
1-800-228-3957

Table 7-Sterilization process monitoring recommendations

Routine load release (see 10.6)		**Routine sterilizer efficacy monitoring (see 10.7)**	**Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 10.8)**	**Periodic product quality assurance testing (see 10.9)**
Nonimplants	**Implants**			
Physical monitoring of cycle External and internal chemical monitoring of packages Optional monitoring of the load with a PCD containing one of the following: • a BI • a BI and a Class 5 Integrating Indicator • a BI and an enzyme-only indicator • a Class 5 Integrating Indicator • an enzyme-only indicator	Physical monitoring of cycle External and internal chemical monitoring of packages Monitoring of every load with a PCD containing a BI and a Class 5 Integrating Indicator or a PCD containing a BI and an enzyme-only indicator	Physical monitoring of cycle External and internal chemical monitoring of packages Weekly, preferably daily (each day the sterilizer is used), monitoring of a full load with a PCD containing a BI. (The PCD may also contain a CI.) In flash sterilizers, monitoring is done in an empty chamber. For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber	Physical monitoring of cycle External and internal chemical monitoring of packages Monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in a empty chamber with a Bowie-Dick test pack	Physical monitoring of cycle Placement of BIs and, CIs within product test samples

Table 8-Types and applications for use of sterilization monitoring devices

Monitor	Frequency of use	Application (release of sterilizer, package, load)
Physical monitors		
Time, temperature, and pressure recorders, displays, digital printouts, and gauges	Should be used for every load of every sterilizer.	Part of load release criteria.
Chemical indicators (CIs)		
External CIs Class I (process indicators)	Should be used on outside of every package.	Part of load and package release criteria.
Bowie-Dick-type indicators Class 2 (Bowie-Dick)	For routine sterilizer testing (dynamic-air-removal sterilizers only), should be run, within a test pack, each day in an empty sterilizer before the first processed load. For sterilizer qualification testing (dynamic-air - removal sterilizers only), should be run, within a test pack, after sterilizer installation, relocation, malfunction, and major repairs and after sterilization process failures; test should be run three times consecutively in an empty chamber after BI tests.	Test of sterilizer for efficacy of air removal and steam penetration; part of release criteria for using sterilizer for the day. Part of release criteria for placing sterilizer into service after qualification testing.
Internal CIs	Should be used inside each package. Should be used in periodic product quality assurance testing.	Part of package release criteria at use site. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging. Release criteria should include BI results.
Class 3 (single-parameter indicator) Class 4 (multi-parameter indicator)	May be used to meet internal CI recommendation.	Part of package release criteria at use site; NOT to be used for release of loads.
Class 5 (Integrating Indicator) Enzyme-only indicator	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor nonimplant sterilizer loads. Within a PCD, should be used to monitor each sterilizer load containing implants. The PCD should also contain a BI.	Part of package release criteria at use site. Part of load release criteria for nonimplant loads. Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known.
Biological indicators (BIs)	Within a PCD, may be used to monitor nonimplant loads. Within a PCD, should be used in every load containing implants. The PCD should also contain a Class 5 Integrating Indicator or an enzyme-only indicator. Within a PCD, should be used for weekly, preferably daily (each day the sterilizer is used), routine sterilizer efficacy testing. (The PCD may also contain a CI.) Should be run in a full load for wrapped items; for table-top sterilization, should be run in a fully loaded chamber; for flash sterilization, should be run in an empty chamber. Within a PCD, should be used for sterilizer qualification testing (after sterilizer installation, relocation, malfunction, major repairs, sterilization process failures). (The PCD may also contain a CI.) Test should be run three times consecutively in an empty chamber, except for table-top sterilizers, where the test should be run three times consecutively in a full load. Should be used for periodic product quality assurance testing.	Part of load release criteria. Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known. Part of sterilizer/load release and recall criteria. Part of release criteria for placing sterilizer into service after qualification testing. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.

Annex L

(Informative)

Example of documentation of premature release of implants

This Annex 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.

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-Implantable devices load record

Exception Form for Premature Release of Implantable Device/Tray

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. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

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/tray