Condensation of the AAMI Steam Sterilization Recommended Practices Quality Control (Section 10), Part I


by Martha Young, BS, MS, CSPDT

Objectives

After completion of this self-study activity, the learner will be able to:

1. Write a policy and procedure to use biological indicators (BIs) with enzyme-based early readout for routine monitoring and for sterilizer qualification testing, following the BI manufacturer’s incubation instructions.
2. Describe what indicators should be placed in a process challenge device (PCD) (test or challenge pack) for routine monitoring of sterilizers, for sterilizer qualification testing and to monitor every load containing implants.
3. Write a policy and procedure for release of implants.

Test Questions

True or False

1. Ideally, every reprocessed medical device, especially an implant, should be fully traceable to the patient on whom it is used or in whom it is implanted.
2. Chemical indicators verify that one or more conditions necessary for sterilization have been achieved within the package and/or at a specific location within the load.
3. Biological indicators verify that the conditions at a location within the load were adequate to kill a population of microorganisms resistant to the sterilization process and demonstrate the lethality of the sterilization process.
4. A sterilizer operator should review the physical monitors at the beginning (chart marked with correct date and sterilizer, monitor is functioning), and at the end of the cycle (verify cycle parameters were met, initial).
5. 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.
6. Biological indicators with enzyme-based early readout can be used for release of implants, routine sterilizer efficacy monitoring, sterilizer qualification testing and product testing without the need to further incubate, unless required by the manufacturer’s instructions for use or the facility policy and procedures.
7. For routine monitoring of sterilizers at least weekly, but preferably every day that the sterilizer is used, a biological indicator process challenge device (BI PCD) should be used in each type of cycle for which a sterilizer is designed to be used.
8. A load containing implants should be quarantined until the results of the BI testing are available.
9. Written documentation defining emergency situations in which an implant may be released before the biological indicator is available should be developed in consultation with infection prevention and control, the surgeon and risk management.
10. Sterilization process failures can occur in a normally functioning sterilizer as a result of poor steam quality, operator error or other factors.

Many thanks to the team at 3M Health Care for working with Managing Infection Control to provide the following accredited course. IAHCSMM has awarded one and one-half (1.5) contact points for completion of this continuing education lesson toward IAHCSMM recertification. The CBSPD has preapproved this inservice for one and one-half (1.5) contact hours for a period of five (5) years from the date of publication, and to be used only once in a recertification period. This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication. Instructions for submitting results are on page 97.

Managing Infection Control and 3M Health Care will be working collaboratively to provide continuing education courses in monthly editions of Managing Infection Control.
Introduction

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 available to order. ST79 is a comprehensive guideline for all steam sterilization activities in healthcare facilities, regardless of the size of the sterilizer or the size of the facility, and provides a resource for all healthcare personnel who use steam for sterilization. The five recommended practices incorporated into the new standard are:

铵 ANSI/AAMI ST46, Steam sterilization and sterility assurance in health care facilities
铵 ANSI/AAMI ST42, Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities
铵 ANSI/AAMI ST37, Flash sterilization: Steam sterilization of patient care items for immediate use
铵 ANSI/AAMI ST35, Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings
铵 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

Since ST79 is a condensation of the five steam documents, the contents are similar to the five previous documents. The main difference is Section 10 Quality Control. The format is different:

铵 Two tables were added to summarize the essential elements of sterilization process monitoring.
铵 Section 7.4.3.4 Biological indicators with enzyme-based early-readout capability contained in ANSI/AAMI ST46, 2002 recommended practice Steam sterilization and sterility assurance in health care facilities has been removed. This BI technology is discussed in ST79 in Section 10.5.3.1, page 82 General considerations under Section 10.5.3 Biological indicators.
铵 Routine sterilizer efficacy monitoring and qualification testing is divided into sections:
铵 sterilizers larger than 2 cubic feet;
铵 table-top sterilizers; and
铵 flash sterilization cycles.

Other significant points about the contents of ST79 are:

铵 The frequency of usage of BIs has not changed.
铵 A BI is the only monitoring tool that provides direct measure of the lethality of the process, and so Class 5 integrating chemical indicators or enzyme-only indicators are not a replacement for BIs.
铵 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.

This insert will highlight the monitoring recommended practices from Sections 10.1 to 10.6, listing the sections and page numbers where the information can be found to make it easier for you to read the document when you add it to your reference library. Sections 10.7 to 10.11 (Routine sterilizer efficacy monitoring, Routine Bowie-Dick testing of dynamic-air-removal sterilizers, Qualification testing and Periodic product quality assurance testing of routinely processed items and Recall) will be reviewed in Part 2, which will be next month’s insert. Every healthcare facility should have this AAMI document to meet the Joint Commission for Accreditation of Health Care Organizations (JCAHO) leadership requirements. Those requirements are for policies and procedures to be based on the most stringent recommended practices, standards and laws. It is important for the leadership of the healthcare facility to have this AAMI document to assist in making informed decisions to improve the quality of the steam sterilization process and improve patient outcomes. Ordering information is provided at the end of this insert, in addition to how to become a member of AAMI.

General rationale (Section 10.1, page 75)

AAMI’s general intent for this section 10 is to review:

铵 Mechanical cleaning equipment (new section);
铵 Product identification and traceability;
铵 Physical, chemical and biological monitoring of steam sterilization cycles;
铵 Residual air (Bowie-Dick type) testing of dynamic-air-removal sterilizers;
铵 Periodic product quality assurance;
铵 Product recalls; and
铵 Related quality control measures.

Section 10 is primarily concerned with these applications but also with “continuous supervision of personnel performance and work practices and ongoing verification of adherence to established policies and procedures.”

Monitoring of mechanical cleaning equipment (Section 10.2, page 75)

This new section briefly discusses that to “ensure that mechanical cleaning equipment is working properly, and
according to the manufacturer’s specifications, health care personnel may perform verification tests as part of the overall quality assurance program.”

The monitoring (verifying of the cleaning process [test devices, colored soil] and reviewing and initialing digital readouts or cycle printouts) for each cycle should be documented as part of quality control. “Ideally, cleaned medical devices should be traceable to the patients on whom they are to be used.”

**Product identification and traceability (Section 10.3, pages 75-77)**

**Lot control numbers (Section 10.3.1, pages 75-76)**

Each item or pack should be labeled with a lot control identifier (sterilizer identification number or code, date of sterilization and cycle number) to assist in recall, to trace problems such as wet packs to their source and for proper stock rotation. “Ideally, every reprocessed medical device, especially an implant, should be fully traceable to the patient on whom it is used or in whom it is implanted; such traceability can be accomplished by recording the sterilizer load identifier on the patient chart or the patient name on the load record.”

For flash sterilization, labels are not used, but the following information should be generated for each sterilization cycle using a load record:

- sterilizer identification and cycle number;
- contents of load;
- time and temperature of exposure phase of cycle;
- signature or identification of operator;
- date and time of cycle.

“Flash sterilization of implantable devices is not recommended; however, if it is unavoidable, full traceability to the patient should be maintained.”

**Sterilizer records (Section 10.3.2, page 76)**

Sterilization records for each cycle must be maintained either in a paper or electronic system, with electronic records recommended because it allows quicker access to information for a quicker response when sterilization process failures occur. Documentation ensures real-time monitoring of the process, that cycle parameters have been met, and assists with recalls and establishes accountability.

The information for each sterilization cycle includes:

- lot number;
- contents of load;
- exposure time and temperature if not on a recording chart;
- operator identification;

<table>
<thead>
<tr>
<th>Table 7—Sterilization process monitoring recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Routine load release (see 10.6)</strong></td>
</tr>
<tr>
<td>Nonimplants</td>
</tr>
<tr>
<td>Physical monitoring of cycle</td>
</tr>
<tr>
<td>External and internal chemical monitoring of packages</td>
</tr>
<tr>
<td>Optional monitoring of the load with a PCD containing one of the following:</td>
</tr>
<tr>
<td>• a BI</td>
</tr>
<tr>
<td>• a BI and an enzyme-only indicator</td>
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</table>

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

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Frequency of use</th>
<th>Application (release of sterilizer, package, load)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical monitors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time, temperature, and pressure recorders,</td>
<td>Should be used for every load of every sterilizer.</td>
<td>Part of load release criteria.</td>
</tr>
<tr>
<td>displays, digital printouts, and gauges</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Chemical indicators (CIs)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>External CIs</strong></td>
<td>Should be used on outside of every package.</td>
<td>Part of load and package release criteria.</td>
</tr>
<tr>
<td>Class 1 (process indicators)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bowie-Dick-type indicators</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 2 (Bowie-Dick)</td>
<td>For routine sterilizer testing (dynamic-air-removal sterilizers only), should</td>
<td>Test of sterilizer for efficacy of air removal and steam penetration; part of release criteria for using sterilizer for the day.</td>
</tr>
<tr>
<td></td>
<td>be run, within a test pack, each day in an empty sterilizer before the first</td>
<td>Part of release criteria for placing sterilizer into service after qualification testing.</td>
</tr>
<tr>
<td></td>
<td>processed load.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>For sterilizer qualification testing (dynamic-air-removal sterilizers only),</td>
<td></td>
</tr>
<tr>
<td></td>
<td>should be run, within a test pack, after sterilizer installation, relocation,</td>
<td></td>
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<tr>
<td></td>
<td>malfunction, and major repairs and after sterilization process failures; test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>should be run three times consecutively in an empty chamber after BI tests.</td>
<td></td>
</tr>
<tr>
<td><strong>Internal CIs</strong></td>
<td>Should be used inside each package.</td>
<td>Part of package release criteria at use site.</td>
</tr>
<tr>
<td></td>
<td>Should be used in periodic product quality assurance testing.</td>
<td>Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Release criteria should include BI results.</td>
</tr>
<tr>
<td><strong>Class 3</strong> (single-parameter indicator)</td>
<td>May be used to meet internal CI recommendation.</td>
<td>Part of package release criteria at use site; NOT to be used for release of loads.</td>
</tr>
<tr>
<td><strong>Class 4</strong> (multi-parameter indicator)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Class 5</strong> (integrating indicator)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enzyme-only indicator</td>
<td>May be used to meet internal CI recommendation.</td>
<td>Part of package release criteria at use site.</td>
</tr>
<tr>
<td></td>
<td>Within a PCD, may be used to monitor nonimplant sterilizer loads.</td>
<td>Part of load release criteria for nonimplant loads.</td>
</tr>
<tr>
<td></td>
<td>Within a PCD, should be used to monitor each sterilizer load containing implants.</td>
<td>Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known.</td>
</tr>
<tr>
<td></td>
<td>The PCD should also contain a BI.</td>
<td></td>
</tr>
<tr>
<td><strong>Biological indicators (BIs)</strong></td>
<td>Within a PCD, may be used to monitor nonimplant loads.</td>
<td>Part of load release criteria.</td>
</tr>
<tr>
<td></td>
<td>Within a PCD, should be used in every load containing implants.</td>
<td>Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known.</td>
</tr>
<tr>
<td></td>
<td>The PCD should also contain a Class 5 integrating indicator or an enzyme-only</td>
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<tr>
<td></td>
<td>indicator.</td>
<td>Part of sterilizer/load release and recall criteria.</td>
</tr>
<tr>
<td></td>
<td>Within a PCD, should be used for weekly, preferably daily (each day the</td>
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<td>sterilizer is used), routine sterilizer efficacy testing. (The PCD may also</td>
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<td></td>
<td>contain a CI.) Should be run in a full load for wrapped items; for table-top</td>
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<td></td>
<td>sterilization, should be run in a fully loaded chamber; for flash sterilization,</td>
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</tr>
<tr>
<td></td>
<td>should be run in an empty chamber.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Within a PCD, should be used for sterilizer qualification testing (after</td>
<td></td>
</tr>
<tr>
<td></td>
<td>sterilizer installation, relocation, malfunction, major repairs, sterilization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>process failures). (The PCD may also contain a CI.) Test should be run three</td>
<td></td>
</tr>
<tr>
<td></td>
<td>times consecutively in an empty chamber, except for table-top sterilizers,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>where the test should be run three times consecutively in a full load.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Should be used for periodic product quality assurance testing.</td>
<td></td>
</tr>
</tbody>
</table>

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Education & Training

- results of BI testing;
- results of the Bowie-Dick testing;
- results of chemical indicator (CI) in the PCD (BI challenge test pack, BI challenge test tray, CI challenge test pack);
- any reports of inconclusive or nonresponsive CIs in the load.

Expiration dating Section 10.3.3, (pages 76-77)

For proper stock rotation each item should be labeled with an expiration date. “Each item in a load should be labeled with a control date for stock rotation and the following statement (or its equivalent): ‘Contents sterile unless package is open or damaged. Please check before using.’”

Table 1: Chemical Indicator Classes, Enzyme-Only Indicator and How to Use

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Critical Parameters Measured</th>
<th>Placement</th>
<th>Frequency Of Use</th>
<th>Information Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1 Process indicators</td>
<td>Part or all</td>
<td>Outside of package</td>
<td>Each package unless internal chemical indicator is visible</td>
<td>To demonstrate that the unit has been exposed to the sterilization process and to distinguish processed from unprocessed items (Exposure control)</td>
</tr>
<tr>
<td>Class 2 Indicators for special tests (Bowie-Dick-type test)</td>
<td>All</td>
<td>In empty load, on rack over drain</td>
<td>Daily. Initial installation or relocation of sterilizer, after sterilizer malfunction, sterilization process failures and major repairs (3 consecutive empty loads tested)</td>
<td>Evaluates the efficacy of air removal systems in dynamic-air-removal steam sterilizers (Equipment control)</td>
</tr>
<tr>
<td>Class 3 Single-parameter indicators</td>
<td>One</td>
<td>Inside package</td>
<td>Inside each package in the areas considered the greatest challenge for sterilant penetration. Multi-parameter CIs and integrating CIs provide more information than do single parameter indicators</td>
<td>Indicates exposure inside the pack to one critical parameter of the sterilization process (Pack control)</td>
</tr>
<tr>
<td>Class 4 Multi-parameter indicators</td>
<td>Two or more</td>
<td>Inside package</td>
<td>Inside each package in the areas considered the greatest challenge for sterilant penetration</td>
<td>Indicates two or more critical parameters of the sterilization process were achieved inside the package (Pack control)</td>
</tr>
<tr>
<td>Class 5 Integrating Indicators</td>
<td>All</td>
<td>Inside package</td>
<td>Inside each package in the areas considered the greatest challenge for sterilant penetration</td>
<td>Indicates all critical parameters of the sterilization process were achieved inside the package or process challenge device in the load (Pack or additional monitoring tool to release loads not containing implants)</td>
</tr>
<tr>
<td>Enzyme-only indicator</td>
<td>All</td>
<td>Inside package</td>
<td>Inside each package in the areas considered the greatest challenge for sterilant penetration</td>
<td>Indicates all critical parameters of the sterilization process were achieved inside the package or process challenge device in the load (Pack or additional monitoring tool to release loads not containing implants)</td>
</tr>
</tbody>
</table>
of microorganisms resistant to the sterilization process and demonstrate the lethality of the sterilization process.”

Table 7 and Table 8 summarize sterilization process monitoring recommendations of ST79, the types of monitoring devices used and their application. These tables are not designed to supply all the information on appropriate monitoring. For more details on how to appropriately monitor implants, perform routine sterilizer efficacy testing, qualification testing, and periodic product quality assurance testing, see Sections 10.5-10.11. pages 80-107. These sections will be reviewed in Part 2, in next month’s inservice.

**Sterilization process monitoring devices (Section 10.5, pages 80-83)**

**Physical monitors (Section 10.5.1, page 80)**

Physical monitors include the time, temperature and pressure recorders; displays; digital printouts; and gauges on the steam sterilizers. “Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective action can be taken.” At the beginning of the cycle, the operator should ensure:

- Charts are marked with the correct date and sterilizer.
- Printouts have the cycle identification number recorded, and pen or printer is functioning.
- At end of cycle and before the load is removed, the operator should examine and interpret the chart or printout:
  - to verify all cycle parameters were met; and
  - initial to permit later identification of the operator.

“Sterilizers that do not have recording devices should not be used.”

**Chemical indicators (Section 10.5.2, pages 80-81) and General considerations (Section 10.5.2.1, pages 80-81)**

The five classes of chemical indicators and the enzyme-only indicator are defined (see Table 1). The enzyme-only indicator is composed of multiple, interactive enzymes of bacterial origin whose performance has been correlated to the performance of a BI. This indicator does not contain spores, so it should not be confused with the BI with enzyme-based early-readout.
“Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The ‘pass’ response of a CI does not prove that the item monitored by the indicator is sterile. The use of CIs is part of an effective quality assurance program: they should be used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process.”

Using chemical indicators (10.5.2.2, page 81) and External chemical indicators (10.5.2.1, page 81)

An external chemical indicator is used to distinguish processed from unprocessed items. A Class 1 process indicator (i.e., indicator tape, indicating label, indicating printed legend) “should be affixed or printed on each hospital package or rigid sterilization container system” except where the internal chemical indicator can be visually inspected. The external chemical indicator should have changed, or the items should not be used.

Internal chemical indicators (10.5.2.2, page 81)

Internal CIs 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.

“An internal CI should be used within each package, tray, or rigid sterilization container system to be sterilized. The CI should be placed in the area of the package, tray or container system considered to be the least accessible to steam penetration.”

“If the internal CI suggests inadequate steam processing the contents of the package should not be used.”

A single nonresponsive or inconclusive CI does not mean the entire load did not achieve sterilization, but other packages from that load should be quarantined until the BI results are known. If no BI result is available, the department head will need to decide based on established policies and procedures whether to recall the sterilized load based on the results of the physical monitoring and the results of CIs elsewhere in the load.
Biological indicators (Section 10.5.3, pages 82-83) and General considerations (10.5.3.1, page 82)

Biological indicators consist of spores on a carrier and in the case of self-contained BIs, incubation media are also provided. The BI should consist of spores of *Geobacillus stearothermophilus* that comply with ANSI/AAMI ST19:1999, which requires that the spore count not be less than $1 \times 10^5$ C.F.U. for steam sterilization processes.\(^2\)

Section 7.4.3.4, page 45 on Biological indicators with enzyme-based early-readout capability from ST46, 2002 was eliminated in this document. Biological indicators with enzyme-based early-readout capability are described in ST79 in the BI general considerations section and states: “Some types of BIs also contain spores with an enzyme-based early-readout capability. Periodic verification of the early readout with spore growth should be performed in accordance with the manufacturer’s instructions and facility policy and procedures. For this verification, the BI with enzyme-based early-readout capability can be further incubated to demonstrate spore growth by a visible color change.”

BIs with enzyme-based early-readout capability and those that do not have this capability can be used to monitor loads containing implants, and for routine sterilizer efficacy monitoring, qualification testing and product testing. The BI manufacturer’s incubation instructions should be followed.

“Biological indicators are the only sterilization process monitoring device that provides a direct measure of the lethality of the process. Various types of BIs are available, each with different response characteristics and incubation requirements. To provide useful information about the lethality of the sterilization process, the appropriate BI must be chosen for the steam sterilization cycle being run and the BI must be used correctly (in accordance with the manufacturer’s instructions).”

In addition to the ST79 reference about BIs with enzyme-based early-readout, the manufacturer’s instructions for the BI with enzyme-based early-readout state: “The final negative Rapid Readout Biological Indicator reading is made at 1 or 3 hours in Attest 190/290 Auto-readers. After the final reading is obtained the processed Rapid Readout
Biological Indicator may be discarded. The processed Rapid Readout Biological Indicator and the positive control may also be further incubated at 60°C for a visual pH color change.

“Each facility must establish the final readout time in its policy and procedures. The policy should be based on manufacturers’ instructions for use, scientific knowledge, current recommended practices, applicable compliance requirements, medical supply inventory levels and the risk to the patient if the medical device is not sterile.”

**Using biological indicators (Section 10.5.3.2, page 82)**

The usage of BIs has not changed. BIs should be used within a PCD (user assembled or commercially available, disposable or preassembled):

- to routinely monitor sterilizers at least weekly, but preferably every day that the sterilizer is in use (10.7)
  - in each type of cycle for which a sterilizer is designed to be used*
    - gravity-displacement at 132°C to 135°C [270°F to 275°F]
    - gravity-displacement at 121°C [250°F]

- dynamic-air removal at 132°C to 135°C [270°F to 275°F]
- flash at 132°C to 135°C [270°F to 275°F]
- flash with single wrapper or other packaging

- for sterilizer qualification test after (10.8)
  - installation
  - relocation
  - malfunctions
  - major repairs
  - sterilization process failures

- to monitor every load containing implants (10.6.1)

BIs should also be used for periodic quality assurance testing of representative samples of actual products being sterilized (10.9 and 10.10).

*Each cycle programmed or used for an individual sterilizer must be tested with a BI PCD at least weekly, preferably every day the sterilizer is used. To avoid testing cycles not
used daily, your policy and procedure should be written to test with a BI PCD each day or each time the cycle is used.

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. In addition, Garner and Favero (1985) and CDC (2003a) recommend routine biological monitoring of sterilizer efficacy. 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.”

Process challenge devices (PCDs) (Section 10.5.4, pages 82-83)

A PCD is the 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. Depending upon the application in sterilization process monitoring, the PCD may contain a (an):

a) BI,
b) BI and a Class 5 integrating CI,
c) BI and an enzyme-only indicator,
d) Class 5 integrating CI, or
3) enzyme-only indicator.”

PCDs used for routine sterilizer efficacy (weekly, preferably every day the sterilizer is used), and qualification testing should contain a BI and may contain one or more CIs. PCDs used for the release of loads containing implantable devices should contain a BI, and either a Class 5 integrating CI or an enzyme-only indicator.

PCDs used for the routine release of loads containing nonimplantable items (testing of loads between routine sterilizer efficacy testing) may contain a:

a) BI (BI challenge test pack);
b) BI and either a Class 5 integrating CI or an enzyme-only indicator (BI challenge test pack); or
c) Class 5 integrating CI or an 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 recommended practices.
Routine load release (Section 10.6, pages 83-85)

Process monitoring devices (Section 10.6.1, page 84)
This section repeats information from previous sections:
- Physically monitor each load.
- Label every package with an external process indicator.
- Every package should contain an internal CI.
- If desired, a PCD containing a BI, or either a Class 5 integrating CI or an enzyme-only indicator may be placed in the chamber to monitor loads not containing implants.
- Implants should be monitored with a PCD containing a BI and a Class 5 integrating CI or an enzyme-only indicator.

Release criteria for nonimplant loads (Section 10.6.2, page 84)
All quality control measures and data need to be evaluated by an experienced, knowledgeable person at the conclusion of the sterilization cycle. Loads that do not meet the criteria for release should be stopped at this point.

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Release criteria for implants (Section 10.6.3, page 84)

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. “The load should be quarantined until the results of the BI testing are available” (CDC, 2003a).

“When medical exceptions dictate (e.g., the need for trauma-related orthopedic screw-plate sets), it could be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented. (See Annex L for examples of an implant log and exception form.) It is critical that 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. For example, ongoing periodic reviews of the exception forms and implant logs could reveal consistent patterns of events that are causing emergency release and that could be corrected.”

Premature release of implants before the BI result is available is unacceptable and should be the exception, not the rule. Each exception should be documented using an implant exception form. This form (see Annex L, page 93) requires providing the following information each time an implant is prematurely released:

Name of:

- Implant prematurely released,
- Patient,
- Surgeon.
- Reason for premature release; and
- What could have prevented premature release of the implant.
The 2006 Association of PeriOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Settings has a more stringent standard.

“Flash sterilization should not be used for implantable devices. Implants are foreign bodies and they increase the risk of surgical site infections. Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices.  

When an implantable device is sterilized at a health care facility, a biological indicator should be run with the load and the implant should be quarantined until the results of the biological indicator are known. If an emergency situation makes flash sterilization unavoidable, a rapid-action biological monitoring device should be used along with a class 5 chemical integrator. The implant should not be released until the rapid-action indicator provides a negative result. After the rapid-action negative result is obtained, the implant can be released for use in the immediate situation. If the implant is not used, it cannot be saved as sterile for future use. Resterilization of the device is required. If the biological indicator is later determined to have a positive result, the surgeon should be notified as soon as the results are known.”

Recent scientific studies have demonstrated that failures, due to marginal cycle conditions created by either inadequate air removal or superheated steam conditions, were not detected equally by chemical and biological indicators. Under these common failure conditions all BIs tested, which included spore strips, self-contained BIs and Rapid Readout BIs, demonstrated failures. Integrating indicators failed to detect these same failure conditions in side-by-side testing. The conclusions reached were that only biological indicators consistently detected all of the sterilization process failure conditions evaluated and that both the fluorescent readout and visual readings detected these failure conditions.

For the safety of the patient, implants should not be released until the BI is negative because of the risk associated with the implantation of a nonsterile device.

Sterilization process failures (Section 10.6.3, page 84)

A sterilizer cycle should be terminated, the load considered nonsterile, and the sterilizer removed from service if the physical monitoring, external CIs or the BI PCD indicates a malfunction or suspicious operation. “Sterilization process failures can occur in a normally functioning sterilizer as a result of poor steam quality, operator error, or other factors.” The cause of the sterilizer failure needs to be identified and the sterilizer retested before it is placed into use. Testing is further defined in Qualification testing (section 10.8, pages 93-94), which will be discussed in next month’s inservice.

After a major repair, three consecutive BI PCDs should be run, one right after the other, on the bottom rack over the drain in an empty sterilizer, except for table-top sterilizers where full loads should be used. In addition, three consecutive Bowie-Dick (BD) PCDs should be run, one right after the other, on the bottom rack over the drain in an empty sterilizer in dynamic-air-removal sterilizers.

“A major repair is a repair outside the scope of normal maintenance, such as weld repairs of the pressure vessel; replacement of the chamber door, vacuum pump, or a major piping assembly; or rebuilds or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves or the replacement of gaskets, is not considered a major repair.”
Summary

The AAMI Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2006) is the primary resource for steam sterilization and should be part of every healthcare facility’s library. The important recommended practices in Sections 10.1 to 10.6 are:

- Documentation and traceability of medical devices used on patients, especially implants, is needed for accountability to the patient and surgeon of the sterility of a reprocessed device.
- Sterilization process monitoring includes:
  - Monitoring every package and load;
  - Routine monitoring of sterilizer efficacy;
  - Qualification testing of the sterilizer;
  - Periodic product quality assurance testing.
- Sterilization process monitoring uses physical monitors, BIs and CIs, all of which are indispensable.
- Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule:
  - Emergency situations that require premature release of implants should be defined in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management.
  - An exception form must be filled out for each prematurely released implant.
- BIs with enzyme-based early-readout capability can be used for release of implants, routine sterilizer efficacy testing, qualification testing and product testing without the need to further incubate, unless required by the BI manufacturer’s instructions for use or the facility policy and procedures.
- Class 5 integrating chemical indicators and enzyme-only indicators are not a replacement for BIs.
- After a sterilization process failure, the sterilizer should be retested with BI PCDs and BD PCDs before it is placed back into routine use.

Sections 10.7 to 10.11 (Routine sterilizer efficacy monitoring, Routine Bowie-Dick testing of dynamic-air-removal sterilizers, Qualification testing, Periodic product quality assurance testing of routinely processed items, and Recall) will be reviewed in Part 2, in next month’s inservice.

Ordering Information

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.
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References

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For additional information regarding Certification contact: CBSPD, 2 Industrial Park Road, Suite 3, Alpha, NJ 08865 or call 908-454-9555 or visit www.sterileprocessing.org.

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