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


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

1. Write a policy and procedure to routinely test steam sterilizers larger than 2 cubic feet, table-top steam sterilizers and flash sterilization cycles.
2. Write a policy and procedure for qualification testing of steam sterilizers larger than 2 cubic feet, table-top steam sterilizers and flash sterilization cycles.
3. Write a recall policy in response to a positive biological indicator.
4. Write a policy and procedure for periodic product quality assurance testing of routinely processed items.

Test Questions
True or False

1. Routine sterilizer efficacy monitoring requires the use of a biological indicator process challenge device (BI PCD) at least weekly, but preferably every day and in every load that contains implants that are quarantined until the BI is negative.
2. Routine BI monitoring of steam sterilizers larger than 2 cubic feet is done in an empty load using an AAMI 16-towel BI PCD or an equivalent commercial BI PCD.
3. In all steam sterilizers, routine BI monitoring needs to be done in each type of cycle that is available on the sterilizer.
4. The BI PCD for table-top sterilizers should be representative of the type of package or tray routinely processed, and the BI PCD should be placed in a full load for routine and qualification testing.
5. For routine BI testing in flash sterilization cycles, each type of tray or tray configuration should be tested with a BI.
6. Each day a test BI is incubated, a positive control BI from the same lot is incubated.
7. A recall is initiated when a BI is positive, and all medical devices processed since the last negative BI should be retrieved and reprocessed.
8. Three consecutive Bowie-Dick (BD) PCDs should be run to qualify a sterilizer when changes in the utilities connected to the sterilizer are made as a result of a water-main break, annual boiler maintenance, additional equipment loads and installation of new boilers.
9. Qualification testing of dynamic-air-removal sterilizers involves running three consecutive empty cycles with BD PCDs, followed by three consecutive empty cycles with BI PCDs.
10. Product testing using BIs and chemical indicators (CIs) inside each product should be done on each loaner instrument tray before it is put into routine use and after any changes are made in composition.

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 in-service 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 in-service 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.
It is important for the leadership of the healthcare facility to have this AAMI document to assist in making informed decisions.

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:

1. ANSI/AAMI ST46, *Steam sterilization and sterility assurance in health care facilities*
2. ANSI/AAMI ST42, *Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities*
3. ANSI/AAMI ST37, *Flash sterilization: Steam sterilization of patient care items for immediate use*
4. ANSI/AAMI ST35, *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings*
5. 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 *Managing Infection Control* inservice Part I, Condensation of the AAMI Steam Sterilization Recommended Practices Quality Control (Section 10) published in September 2006 discussed sections 10.1-10.6, pages 75-84 of the recommended practice. The main difference in those sections from the previous documents are:

- Two tables were added to summarize the essential elements of sterilization process monitoring.
- 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 General considerations under Section 10.5.3 Biological indicators, page 82.

The *Managing Infection Control* inservice Part II, Condensation of the AAMI Steam Sterilization Recommended Practices Quality Control (Section 10) discusses sections 10.7-10.11, pages 93-107. The main difference in these sections from the previous documents is the routine sterilizer efficacy monitoring and qualification testing are divided into sections:

- sterilizers larger than 2 cubic feet;
- table-top sterilizers;
- flash sterilization cycles.

Other significant points about the contents of ST79 are:

- 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.
- The frequency of usage of BIs has not changed.
- 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.
- 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 Part II inservice will highlight the monitoring recommended practices from 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), 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.

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 inservice, in addition to information about how to become a member of AAMI.
Routine sterilizer efficacy monitoring (Section 10.7, page 93)

Routine sterilizer efficacy monitoring is divided into sections based on the size of the sterilizer (larger than 2 cubic feet, table-top sterilizers and flash sterilization cycles). Routine testing with a BI PCD (BI challenge test pack or BI challenge test tray) should be done to ensure the steam sterilizer is effectively sterilizing medical devices.

General considerations (Section 10.7.1, page 85)

BI s should be used within a process challenge device (PCD) (challenge or test pack):

- to routinely monitor sterilizers at least weekly, but preferably every day that the sterilizer is in use
  - in each type of cycle 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

*If any of these cycles are programmed or used on one sterilizer, that cycle must be tested with a BI PCD at least weekly, preferably every day the sterilizer is used. To avoid testing cycles not used daily, write your policy and procedure to require testing with a BI PCD each day or each time the cycle is used.

Every load containing implants (10.6.1) should be monitored with a PCD containing a BI and a Class 5 integrating CI or an enzyme-only indicator. “The load should be quarantined until the results of the BI testing are available.” The 2006 Association of PeriOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Settings states:

- “Flash sterilization should not be used for implantable 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.”

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**Figure 1: Instructions to Prepare AAMI Routine 16-Towel BI PCD and to Use for Sterilizers Larger than 2 Cubic Feet**

**Components:**
1. One or more BIs (one or two test BIs and one control BI from the same lot) and CIs.
2. Sixteen clean, preconditioned (room temperature [20°C-23°C/68°F-73°F] and a relative humidity of at least 35% for two hours), reusable huck or absorbent surgical towels, in good condition, each approximately 16 inches x 26 inches (41 cm x 66 cm).

**Preparation:**
1. Fold each towel lengthwise into thirds and then fold widthwise in the middle. Stack towels one on top of another, with folds opposite each other, to form a stack that is approximately 9 inches wide, 9 inches long and 6 inches high (23 cm x 23 cm x 15 cm).
2. Place the BIs and CIs between the eighth and ninth towels in the approximate geometric center of the pack.
3. Tape the pack in a manner that will yield the pack approximately 6 inches (15 cm) high.
4. Label as a BI PCD.

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**Figure 2: Test Procedure and Acceptance Criteria for AAMI Routine 16-Towel BI PCD and Disposable BI PCDs for Sterilizers Larger than 2 Cubic Feet**

**Test Procedure:**
1. Place the BI PCD flat (AAMI 16-towel PCD or according to the manufacturer’s instructions) on a rack or shelf near the drain. Routine testing is done in a full load to test the effectiveness of the entire process (packaging, loading, correct cycle parameters, steam quality and utilities) and sterilizer qualification testing is done in an empty load to test the performance of just the sterilizer, steam quality and utilities. Do not place another pack on top of the BI PCD. This will create too great of a challenge.
2. Run the load according to the sterilizer manufacturer’s instructions.
3. At the end of the cycle, cool the BI PCD and BI according to the manufacturer’s instructions.
4. Read the CIs and record the results.
5. Incubate the test BIs and a positive control BI from the same lot each day a test BI is incubated.
6. Read and record the results.

**Acceptance Criteria:**
1. Negative BI results from all BIs in the load.
2. Appropriate reading from physical monitors.
3. Appropriate reading from the CIs.
“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.”

Routine biological monitoring of sterilizers larger than 2 cubic feet (Section 10.7.2, page 87)

Composition of the PCD (BI challenge test pack) (Section 10.7.2.1, pages 85-86)

Placement of the PCD (BI challenge test pack) (Section 10.7.2.2, page 86)

Test procedure (Section 10.7.2.3, page 87)

Acceptance criteria (Section 10.7.2.4, page 87)

The BI PCD used to test this size sterilizer is the AAMI routine 16-towel pack (see Figure 1 on page 82), or a commercially available BI PCD that is cleared by FDA for this intended use. The same test pack can be used for routine and sterilizer qualification testing. The same test procedure and acceptance criteria are used for the commercially available BI PCDs as for the AAMI prepared BI PCD (see Figure 2 on page 82). The BI PCD should be run in each type of cycle for which a sterilizer is designed (Section 10.7.1, page 85).

Routine biological monitoring of table-top sterilizers (Section 10.7.3, page 88)

Composition of the PCD (BI challenge test pack or BI challenge test tray) (Section 10.7.3.1, page 88)

Placement of the PCD (BI challenge test pack or BI challenge test tray) (Section 10.7.3.2, page 88)

Test procedure (Section 10.7.3.3, page 88)

Acceptance criteria (Section 10.7.3.4, page 88)

The BI PCD for table-top sterilizers should represent the same type of package or tray routinely processed through the sterilizer. Select the most difficult to sterilize from those most frequently processed. The BI PCD should contain one or more BIs and one or more CIs. The same BI PCD is used for routine and sterilizer qualification testing. The BI PCD should be run in each type of cycle for which the sterilizer is designed (Section 10.7.1, page 85). Table 1 shows appropriate BI PCDs for the loads commonly run in a table-top steam sterilizer. Figure 3 describes the test procedure and acceptance criteria for BI PCD testing of table-top steam sterilizers for routine and sterilizer qualification testing.

### Table 1: BI PCDs for Routine and Qualification Testing of Table-Top Steam Sterilizers

<table>
<thead>
<tr>
<th>Program/Load</th>
<th>Temperature</th>
<th>Time*</th>
<th>BI PCD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unwrapped instruments on a tray or glassware</td>
<td>270ºF-274ºF (132ºC-135ºC)</td>
<td>≥3 min</td>
<td>BI in unwrapped instrument tray or glassware</td>
</tr>
<tr>
<td>Wrapped trays of instruments, instruments in peel pouches</td>
<td>270ºF-274ºF (132ºC-135ºC)</td>
<td>≥5 min</td>
<td>BI in a wrapped tray or peel pouch and include porous items if applicable</td>
</tr>
<tr>
<td>Packs, wrapped</td>
<td>250ºF(121ºC)</td>
<td>≥30 min</td>
<td>BI in wrapped pack that is representative of the load, include porous items if appropriate</td>
</tr>
<tr>
<td>Liquids</td>
<td>250ºF(121ºC)</td>
<td>≥15 min</td>
<td>BI suspended above a test container of the liquid</td>
</tr>
</tbody>
</table>

*Check with the medical device or sterilizer manufacturer for correct times for the items being processed

### Figure 3: Test Procedure and Acceptance Criteria for BI Testing of Table-Top Steam Sterilizers

1. Choose the appropriate BI PCD (see Table 1) for each type of sterilization cycle (e.g., unwrapped instruments, wrapped instruments, packs) that will be used.
2. Place a BI and CI in the area of the PCD determined to create the greatest challenge to air removal and sterilant penetration.
3. Place the BI PCD in a full load for both routine and sterilizer qualification testing in the coldest area of the sterilizer chamber as determined by the table-top sterilizer manufacturer. Full load testing is done to create the greatest challenge to the limited amount of steam that is added to the chamber.
4. Run the sterilization cycle according to the sterilizer manufacturer’s instructions.
5. At the end of the cycle, cool the BI PCD and BI according to the manufacturer’s instructions.
6. Read and record the results of the CIs.
7. Incubate the test BIs and a positive control BI from the same lot each day a test BI is incubated.
8. Read and record the results.

**Acceptance Criteria:**

1. Negative BI results from all BIs in the load.
2. Appropriate reading from physical monitors.
3. Appropriate reading from the CIs.
Table 2: BI PCDs for Different Cycle/Tray Configurations for Routine Testing of a Flash Sterilization Cycle*#

<table>
<thead>
<tr>
<th>Type of Cycle</th>
<th>Type of Tray Configuration</th>
<th>BI PCD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity</td>
<td>Open surgical tray</td>
<td>BI in open surgical tray</td>
</tr>
<tr>
<td>Gravity</td>
<td>Wrapped surgical tray, with or without porous item (towel, foam pad, etc)</td>
<td>BI in wrapped surgical tray (include porous items if in patient care tray)</td>
</tr>
<tr>
<td>Gravity</td>
<td>Protective organizing case</td>
<td>BI in protective organizing case in area(s) that creates the greatest challenge to air removal and sterilant penetration</td>
</tr>
<tr>
<td>Gravity</td>
<td>Rigid sterilization container</td>
<td>BI in rigid sterilization container in area(s) that creates the greatest challenge to air removal and sterilant penetration</td>
</tr>
<tr>
<td>Dynamic air removal</td>
<td>Open surgical tray with or without porous item (towel, foam pad, etc)</td>
<td>BI in open surgical tray (include porous items if in patient care tray)</td>
</tr>
<tr>
<td>Dynamic air removal</td>
<td>Wrapped surgical tray, with or without porous item (towel, foam pad, etc)</td>
<td>BI in wrapped surgical tray (include porous items if in patient care tray)</td>
</tr>
<tr>
<td>Dynamic air removal</td>
<td>Protective organizing case</td>
<td>BI in protective organizing case in area(s) that creates the greatest challenge to air removal and sterilant penetration</td>
</tr>
<tr>
<td>Dynamic air removal</td>
<td>Rigid sterilization container</td>
<td>BI in rigid sterilization container in area(s) that creates the greatest challenge to air removal and sterilant penetration</td>
</tr>
</tbody>
</table>

*Sterilization times determined by medical device or sterilizer manufacturer.  
#Commercially available BI PCDs could be used if designed for the type of cycle, time and temperature, and if they create the same challenge as the type of tray configuration.

Note: Negative BI results from a cycle run with the open surgical tray indicate that the process is killing spores. If other tray configurations produce positive BI results this suggests that air is not being removed and that steam is not penetrating inside that other tray configuration. This could be a problem with the performance of the tray configuration or the cycle parameters chosen for processing that tray configuration.

Routine biological monitoring of flash sterilization cycles (Section 10.7.4, page 89)

Composition of the PCD (BI challenge test pack or BI challenge test tray) (Section 10.7.4.1, page 89)

Placement of the PCD (BI challenge test pack or BI challenge test tray) (Section 10.7.4.2, page 89)

Test procedure (Section 10.7.4.3, page 89)

Acceptance criteria (Section 10.7.4.4, page 89)

The BI PCD should be representative of the same type of tray that is routinely processed. Each type of tray configuration routinely processed should be tested because they each create a different challenge to air removal and steam penetration during the sterilization process:

- perforated, mesh-bottom, open surgical tray
- rigid sterilization container system
- protective organizing case
- single-wrapped surgical tray

One or more BIs and one or more CIs should be placed in the most challenging area of the PCD. The BI PCD should be run in each type of cycle for which a sterilizer is designed (Section 10.7.4.1).

Test Procedure:

1. Place the BI PCD flat or according to the manufacturer’s instructions in an empty chamber on a rack or shelf near the drain. Empty chamber testing creates the greatest challenge because it minimizes the effect of heat-up time on spore kill that occurs when a heavy metal mass is in the load. Do not place another tray on top of the BI PCD. This will create too great of a challenge.

2. Run the load according to the sterilizer manufacturer’s instructions.

3. At the end of the cycle, cool the BI PCD and BI according to the manufacturer’s instructions.

4. Read the CI and record the results.

5. Incubate the test BI and a positive control BI from the same lot each day a test vial is incubated.

6. Read and record the results.

Acceptance Criteria:

1. Negative BI results from all BIs in the load.
2. Appropriate reading from physical monitors.
3. Appropriate reading from the CIs.

Figure 4: Test Procedure and Acceptance Criteria for BI PCDs for Flash Sterilization Cycles
1. Immediately verbally report the positive BI results to the appropriate supervisor and infection control department so they can implement the institution’s recall policies and procedures and recall items before they contact the patient. If they determine that suspected nonsterile devices have been involved in patient use, follow-up surveillance of patients should be initiated as determined by the facility’s policies and procedures.

2. Immediately initiate a recall order for all medical devices processed in the sterilizer since the last cycle that showed a negative biological indicator, even if other monitoring tools indicated a successful sterilization process. Communicate the following information to the affected departments immediately:
   a. Why the medical devices are being recalled;
   b. Who authorized the recall;
   c. Who is responsible for reporting the results of the recall;
   d. Which medical devices are to be recalled (include load label information—sterilizer load, load number and processing date);
   e. To which persons or departments the order is addressed;
   f. The required method for recording the number and type of products recalled by location;
   g. Who, when and how to return the recalled medical devices to sterile processing.

3. Retrieve and reprocess all medical devices if it is determined the sterilization failure was not a result of operator error (e.g., selection of the incorrect cycle).

4. Take the sterilizer in question out of service.

5. If using spore strip BIs that require sterile transfer to a media, subculture the BI according to the manufacturer’s instructions. If using self-contained BIs, subculture if you suspect the BI was not correctly activated and incubated. “The load recall should not be delayed during this testing.”

6. Determine the reason for the sterilization failure.\(^4,5\)

7. Correct the identified problem.

8. Verify the correction by retesting the sterilizer(s) following the instructions for sterilization qualification testing beginning on page 92 of this inservice.

9. Follow with a written recall report of the recall order that includes:
   a. The circumstances that prompted the recall order;
   b. The total number of products intended to be recalled and the percentage actually recalled;
   c. Surveillance measures taken if affected devices could not be retrieved and have been in contact with patients;
   d. Verification that recalled items were reprocessed;
   e. Corrective action taken to prevent this situation from occurring again.

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**Figure 5: Positive Biological Indicators (BIs) Results-Action Steps to Take\(^1,3\)**
spore-bearing rods to demonstrate the presence of *Geobacillus stearothermophilus* spores and growth of organisms in culture media at 55°C-60°C (131°F-140°F).

**Routine Bowie-Dick testing of dynamic-air-removal sterilizers (Section 10.7.6, pages 91-93)**

- **General considerations (Section 10.7.6.1, page 91)**

- **Composition of the Bowie-Dick test pack (Section 10.7.6.2, page 91)**

- **Placement of the Bowie-Dick test pack (Section 10.7.6.3, page 92)**

- **Test procedure (Section 10.7.6.4, page 92)**

  The Bowie-Dick (BD) test is used in dynamic-air-removal sterilizers daily as a “rapid means” of detecting:
  - air leaks;
  - inadequate air removal;
  - inadequate steam penetration;
  - presence of noncondensable gases (i.e., air or gases from boiler additives).

If air is not removed from the chamber, the steam will drive the air back into the load, and air pockets will occur in the BD PCD or in packs within a full load. In addition, if noncondensable gases enter with the steam, this will inhibit steam penetration. The result in both situations is an ineffective sterilization process.

Dynamic-air-removal sterilizers include prevacum and steam-flush-pressure-pulse sterilizers. Follow the sterilizer manufacturer’s recommendations regarding the need to run a BD test in the steam-flush-pressure-pulse sterilizers. The BD is not used in gravity-displacement steam sterilizers.

In addition to daily testing, the BD test should be run during sterilizer qualification testing (Section 10.8, pages 94-95) in three consecutive empty cycles after three consecutive empty cycle testing with a BI PCD. Sterilizer qualification testing is performed after:
  - sterilizer installation;
  - sterilizer relocation;
  - sterilizer malfunctions;
  - sterilizer major repairs—“a major repair is a repair outside
the scope of normal maintenance. This includes weld repairs of the pressure vessel, replacement of the chamber door or 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 major repair. Changes to the utilities connected to the sterilizer such as those that result from a water-main break, annual boiler maintenance, additional equipment loads and installation of new boilers should be treated as major repairs;

- sterilization process failures.

During qualification testing the BD PCDs are run after the BI PCDs for this reason:

“In qualification testing, it is preferable to run the Bowie-Dick test cycles after the BI PCD test cycles because it is important to establish first that the sterilizer is capable of achieving biological kill so that the subsequent Bowie-Dick test cycles will be run under ‘best-case’ conditions. The results of later Bowie-Dick tests run during routine monitoring can then be compared to the results of the Bowie-Dick qualification testing, enabling the routine Bowie-Dick test results to be better interpreted. If during qualification testing, the Bowie-Dick test cycles are run first and then the sterilizer then fails biological testing, the Bowie-Dick test results will not necessarily reflect the air removal characteristics of a properly functioning sterilizer. Therefore, if the user chooses to run the Bowie-Dick test cycles first (rather than in the recommended test sequence) and the sterilizer then fails biological testing, the Bowie-Dick test cycles will have to be repeated after corrective action has been taken and the sterilizer is functioning properly according to the biological testing.”

A healthcare facility-prepared BD PCD (see Figure 6 on page 90) or a commercially available BD PCD that has been cleared by FDA as equivalent to this type of BD PCD can be used. The test procedure and acceptance criteria for either type of PCD is listed in Figure 7 on page 91.

Important points to remember when running the BD PCD to ensure accurate results:
Run at the same time each day “because standardization of the testing procedure reduces the opportunity for error.”

Run a shortened cycle (no dry time) first to properly preheat the sterilizer and purge air out of the lines, even if the sterilizer was never turned off to prevent “false failures.”

Run only one BD PCD in the load at a time because other packs in the load may trap a percentage of air and reduce the sensitivity of the test.

Run the test on a loading cart for proper placement and to avoid superheating of the BD PCD or excess moisture inside the pack.

Run the test pack for 3.5 to 4 minutes at 273°F (134°C) (drying cycle may be omitted) to avoid invalid results due to longer exposure times. “Even an extra minute could affect results.”

Use a cool cart each time you do qualification testing (three consecutive loads) “to prevent

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**Figure 6: Instructions to Prepare Bowie-Dick PCD**

**Components:**
1. Clean and preconditioned (room temperature [20°C-23°C/68°F-73°F] and a relative humidity of at least 35% for two hours) 100% cotton, surgical towels.

**Preparation:**
1. Fold towels to a size 9 inches (250 mm ± 20 mm) in one direction and 12 inches (300 mm ± 20 mm) in the other direction, and placed one above the other. The height of the BD PCDs should be between 10-11 inches (250 mm and 280 mm). The number of towels will vary depending on towel thickness and wear.
2. Place the BD test sheet in the center of the pack.
3. Wrap loosely with a two-ply fabric wrap made of 100% cotton with a thread count both warp and weft of 5.5 mm. Secure with steam indicator tape.
Figure 7: Test Procedures and Acceptance Criteria for Bowie-Dick PCDs

**Test Procedure:**
1. Run an empty chamber cycle right before you run the Bowie-Dick test to preheat the sterilizer and purge air out of the lines, even if the sterilizer was never turned off.
2. Run the test at the same time each day.
3. Place one test pack horizontally in the front, bottom section of the sterilizer rack, near the door over the drain, but not on the floor unless recommended by the BD PCD manufacturer.
4. Run the test pack for 3.5 to 4 minutes at 273°F (134°C). Drying cycle may be omitted.
5. Carefully open the BD PCD because it still may be hot.

**Acceptance Criteria:**
1. If the test sheet has a uniform color change, use the sterilizer.
2. If the test sheet has a nonuniform color change, retest the sterilizer.
3. If a second test sheet is run and has a uniform color change, use the sterilizer.
4. If the second test sheet has a nonuniform color change, don’t use the sterilizer until the problem is identified and corrected, and three consecutive BD test sheets show a uniform color change.
5. Read and record results

*A sterilizer malfunction is indicated if:

"Any unexpected color change, such as the center of the test sheet being paler or a different color than the edges (i.e., there is a nonuniform color change), indicates there was an air pocket present during the cycle due to sterilizer malfunction."*

#Compare the test sheet with the previous day's results and the BD results from the most recent sterilization qualification testing, which should show the most uniform BD test results.
superheating in the chamber (which can affect the test results) and more closely duplicates normal processing procedures.”

Qualification testing (Section 10.8, pages 93-98)

Qualification testing is divided into sections based on the size of the sterilizer (larger than 2 cubic feet, table-top sterilizers and flash sterilization cycles). Qualification testing with a BI PCD (BI challenge test pack or BI challenge test tray) is done to assess whether the sterilizer is functioning properly after an event has occurred that may affect sterilizer performance.

Changes to the utilities connected to the sterilizer should be treated as major repairs.

General considerations (Section 10.8.1, pages 93-94)

Sterilizer qualification testing using a BI PCD is performed after:
- sterilizer installation;
- sterilizer relocation;
- sterilizer malfunctions;
- sterilizer major repairs—“a major repair is a repair outside the scope of normal maintenance. This includes weld repairs of the pressure vessel, replacement of the chamber door or 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 major repair. Changes to the utilities connected to the sterilizer such as those that result from a water-main break, annual boiler maintenance, additional equipment loads and installation of new boilers should be treated as major repairs”;
- sterilization process failures.

Three consecutive empty cycles should be run with a BI PCD followed by three consecutive empty cycles with a BD PCD in dynamic-air removal sterilizers (see Routine Bowie-Dick testing of dynamic-air-removal sterilizers, Section 10.7.6, pages 91-93). For this testing, a cool loading cart should be used for each cycle “to prevent superheating in the chamber (which can affect the test results) and more closely duplicates normal processing procedures.”

The sterilizer can be released for routine use if all BI results are negative, physical monitor results are acceptable, all CIs reach their appropriate endpoint, and all BD test sheets should show a uniform color change.

Qualification testing of sterilizers larger than 2 cubic feet (Section 10.8.2, pages 94-95)

- Composition of the PCD (BI challenge test pack) (Section 10.8.2.1, page 94)
- Placement of the PCD (BI challenge test pack) (Section 10.8.2.2, page 94)
- Test procedure (Section 10.8.2.3, page 95)
- Acceptance criteria (Section 10.8.2.4, page 95)

The AAMI 16-towel BI PCD or a commercially available BI PCD of equivalent performance can be used. See Figure 1 on page 82 for how to prepare an AAMI 16-towel BI PCD. See Figure 2 on page 82 for test procedure and acceptance criteria. Remember this BI PCD is always run in three consecutive empty cycles, and each type of cycle for which a sterilizer is designed should be tested (Section 10.5.3.2, page 82):
- 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.

Qualification testing of table-top sterilizers (Section 10.8.2, page 96)

- Composition of the PCD (BI challenge test pack or BI challenge test tray) (Section 10.8.3.1, page 96)
- Placement of the PCD (BI challenge test pack or BI challenge test tray) (Section 10.8.3.2, page 96)
- Test procedure (Section 10.8.3.3, page 96)
- Acceptance criteria (Section 10.8.3.4, page 96)

The same BI PCDs are used for sterilizer qualification testing as for routine testing. The BI PC should be run in each type of cycle for which a sterilizer is designed (Section 10.5.3.2, page 82). Table 1, page 84 shows appropriate BI PCDs for the loads commonly run in a table-top steam sterilizer. Qualification testing is done in a fully loaded chamber as is routine testing. See Figure 3, page 84 for the test procedure and acceptance criteria for BI PCD testing of table-top steam sterilizers for sterilizer qualification and routine testing. All packages or trays processed during qualification testing should be quarantined until the BI results are negative.

Qualification testing of flash sterilization cycles (Section 10.8.4, pages 97-98)

- Composition of the PCD (BI challenge test tray) (Section 10.8.4.1, page 97)
- Placement of the PCD (BI challenge test tray) (Section 10.8.4.2, page 97)
- Test procedure (Section 10.8.4.3, page 97)
- Acceptance criteria (Section 10.8.4.4, page 98)
The BI PCD (BI challenge test tray) should be representative of the same type of tray that is routinely processed. Select only one of the following as the BI PCD:
- perforated, mesh-bottom, open surgical tray
- rigid sterilization container system
- protective organizing case
- single-wrapped surgical tray.

One or more BIs and one or more CIs should be placed in the most challenging area of the BI PCD. See Figure 4, page 86 for the test procedure and acceptance criteria for the BI PCD. This BI PCD is always run in three consecutive empty cycles. The BI PCD should be run in each type of cycle for which a sterilizer is designed (Section 10.5.3.2, page 82).

**Periodic product quality assurance testing of routinely processed items (Section 10.9, page 98)**

Product testing is recommended because the BI PCDs discussed in the other sections present a known challenge to the sterilization process that does not necessarily reflect the same challenge as items routinely processed. “Therefore, product testing is recommended as part of a complete quality assurance program to ensure the effectiveness of the sterilization process and to avoid wet packs.”

“Quality assurance testing of routinely processed items should be performed on an ongoing basis.” Routinely sterilized products should be tested periodically; and testing should also occur when “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 procedure should be performed on each loaner tray before it is put into routine use and whenever the contents change. Obtain in writing, from the medical device manufacturer, the sterilization cycle to use for the loaner instruments.7

Multiple BIs and CIs (Class 3, Class 4, Class 5 and/or enzyme-only indicators) should be placed within the product to be tested. The number of samples will depend on the size and configuration of the pack being tested. See Figure 8, page 94 for an example of placement of BIs and CIs inside a multilevel instrument container. BIs and CIs are placed inside each layer in multiple locations. The product test samples should be labeled and placed among other products in a full load. After the sterilization process, the test BIs should be retrieved, incubated along with a positive control BI, and the results recorded along with the CI results. A photo of the placement of the BIs and CIs for your records would assist in recording the results according to location of the BIs and CIs.

The packages should also be inspected for evidence of moisture. “If moisture is observed, steps should be taken to remedy the problem.” These include changing the packaging, adjusting the loading or decreasing the amount of metal in the load, selecting a longer sterilization and/or drying time, and adjusting the unloading and cooling procedure.

If any test results indicate a problem, an investigation should determine the cause, the problem corrected, and the products retested. “It might be necessary to change the configuration of the load and/or items within the package or to service the sterilizer.” Document in the sterilization records the test protocol, the initial test results, corrective actions taken, and the final test results.

Examples of product testing are:
- **Wrapped textile packs**
  - Place BIs and CIs between multiple layers of draping material or surgical towels.
Basin sets
Place BIs and CIs in locations where air would be trapped, such as between nested basins.

Instrument sets
Place BIs and CIs at each end of tray and among instruments.

Containment devices
Place BIs and CIs in each corner, the center, and any other areas recommended by the containment device manufacturer.

Multilayered instrument trays in containment devices
Place BIs and CIs in the locations deter-
mined by the product manufacturer to create the greatest challenge to the sterilization process.

- **Other types of items**
  Place BIs and CIs in the area of the load least accessible to steam penetration.

**Periodic product quality assurance testing of rigid sterilization container systems (Section 10.10, pages 99-106)**

“This section covers the responsibilities of manufacturers and users in matching rigid sterilization container systems and sterilization cycles.” This section will be discussed in a future *Managing Infection Control* inservice.

**Product recalls (Section 10.11, pages 106-107)**

- **General considerations (Section 10.11.1, page 106)**
- **Recall procedure (Section 10.11.2, page 107)**
- **Recall order (Section 10.11.3, page 107)**
- **Recall report (Section 10.11.4, page 107)**

“To ensure patient safety and compliance with the user facility reporting requirements of the Safe Medical Devices Act of 1990, the health care facility should establish recall procedures to expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions such as quarantine of the sterilizer, notification of physicians and affected clinical departments, and surveillance of patients.”1 See Figure 5, page 87 for steps to take for a recall.

**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 B1 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.

The important recommended practices in Sections 10.7 to 10.11 are:
- Routine sterilizer efficacy testing is done at least weekly, but preferably every day the sterilizer is used.
- Routine sterilizer efficacy testing is done in each type of cycle for which a sterilizer is designed and in table-top sterilizers and flash sterilization cycles; each type of packaging used is also tested with a BI.
- When a positive BI occurs, all medical devices processed since the last negative BI should be recalled.
- Qualification testing is performed after an event occurs that could affect the performance of the sterilizer.
- After a sterilization process failure, the sterilizer should be retested with BI PCDs in three consecutive empty cycles (except for table-top steam sterilizers where full loads are used) followed by three consecutive empty cycles with BD PCDs (in dynamic-air-removal sterilizers only) before it is placed back into routine use.
- Periodic product quality assurance testing of routinely processed items should be done because the BI PCDs used routinely do not necessarily reflect the same challenge as items routinely processed.

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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ANSWERS

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