Sterilizer Qualification Testing Using Process Challenge Devices

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Objectives
After completion of this self-study activity, the learner will be able to:
1. Explain what a process challenge device is.
2. Explain what sterilizer qualification testing is.
3. Identify the correct biological indicator process challenge devices (BI PCDs) to use for sterilization qualification testing in steam and low temperature sterilization processes.
4. Develop policies and procedures for using biological indicator process challenge devices for sterilizer qualification testing for steam and low temperature sterilization processes.

Test Questions
1. A process challenge device (PCD) is designed to create a challenge to the sterilization process that represents the most difficult item routinely processed.
   A. True    B. False

2. Qualification testing of steam sterilizers is performed after the sterilizer is installed or relocated, after malfunctions and sterilization process failures if there is a major repair.
   A. True    B. False

3. Qualification testing of steam sterilizers requires the use of one biological indicator PCD in three consecutive empty cycles in sterilizers greater than 2 cubic feet and flash sterilization cycles.
   A. True    B. False

4. Qualification testing of steam sterilizers also requires the use of one Bowie-Dick test pack in three consecutive empty cycles in prevacuum steam sterilizers greater than 2 cubic feet and in prevacuum flash sterilization cycles.
   A. True    B. False

5. Qualification testing of table-top steam sterilizers requires the use of one BI PCD in three consecutive full cycles and quarantining the load contents until the BI is negative.
   A. True    B. False

6. Qualification testing in steam sterilizers requires that all types of cycles used be tested (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], and flash with single wrapper or other packaging).
   A. True    B. False

7. The BI PCD used in flash sterilization cycles is user-assembled and made by placing a BI and a chemical indicator (CI) in a type of tray configuration normally used such as a perforated, mesh-bottom, open surgical tray or a rigid sterilization container.
   A. True    B. False

8. After an investigation reveals that a sterilization process failure in an ethylene oxide sterilizer was not a result of a sterilizer malfunction, sterilizer qualification testing is performed using one AAMI routine BI PCD or a commercially available equivalent BI PCD in three consecutive full cycles and quarantining the load which is quanrantied until the biological indicator is negative.
   A. True    B. False

9. After an investigation reveals that a sterilization process failure in an ethylene oxide sterilizer was a result of a sterilizer malfunction, sterilizer qualification testing is performed using one AAMI routine BI PCD or a commercially available equivalent BI PCD in three consecutive full cycles and quarantining the load which is quanrantied until the biological indicator is negative.
   A. True    B. False

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cycles in a load similar in composition and density to the load exhibiting the failure with all patient care items being quarantined until the BI is negative.

A. True  B. False

10. For hydrogen peroxide and ozone sterilizers perform qualification testing according to the sterilizer manufacturer's instructions for use.

A. True  B. False

Introduction
Sterilization qualification testing is testing the sterilizer with a biological indicator (BI) in a process challenge device (PCD) after events occur which could affect the ability of the sterilizer to perform.

Only a BI can detect the actual killing of microbial spores inside the sterilizer. (ANSI/AAMI ST79 Section 10.5.3.1) If all spores die inside the BI, you have assurance that other infectious organisms have also died inside the sterilizer. Using a self-contained biological indicator with a one-, three- or four-hour readout in a BI PCD for this testing will decrease the time needed to put the sterilizer into routine use.

This inservice will discuss:
- Process challenge devices;
- Sterilizer qualification testing for steam sterilizers; and
- Sterilizer qualification testing for low temperature sterilization processes.

Recommended practices from the Association for the Advancement of Medical Instrumentation (AAMI) were used to prepare this inservice.

Process Challenge Devices
ANSI/AAMI ST79 defines in Section 2.100 a process challenge device (PCD):

"Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process."

This PCD should provide "a challenge that is equal to or greater than the challenge posed by the most difficult item routinely processed." (ANSI/AAMI ST79 Section 10.5.4) The type of PCD used will depend upon the type of sterilization process, cycle, and parameters used. Table 6 in Section 10.4 of ANSI/AAMI ST79 states that for steam sterilizer qualification testing a PCD containing a BI is used and it may also contain a CI (chemical indicator). A Class 4 multi-variable or Class 5 integrating CI would provide more information than a Class 3 single-variable CI. (ANSI/AAMI ST79 Section 10.5.2.1)

A PCD may be user-assembled or a commercially available, disposable, pre-assembled pack. These commercially available BI PCDs should be FDA cleared and their performance should be comparable to the published standard user-assembled or reference BI PCD described in ANSI/AAMI ST79 in Section 10.8.2 for steam sterilizers larger than 2 cubic feet and in ANSI/AAMI ST41 in Section 10.7.2 and 10.8.2 for ethylene oxide (EO) sterilizers. Presently there are no published standard user-assembled or reference BI PCDs for hydrogen peroxide or ozone sterilization. (AAMI TIR31 Section 6.4 and 6.5)

The BI PCDs for table-top sterilizers (ANSI/AAMI Section 10.8.3) and flash steam sterilization cycles (ANSI/AAMI Section 10.8.4) are user-assembled and should be representative of the load.

Practical application
- Only a BI PCD which may also contain a CI should be used for sterilizer qualification testing.
- All BI PCDs should contain the appropriate BI and CI for the sterilization process and cycle being tested.
- All BI PCDs should be representative of the load contents and create a challenge equal to or greater than the most difficult item processed.
- The instructions for use from the sterilizer and BI PCD manufacturer should be followed to ensure accurate results.

Sterilizer Qualification Testing for Steam Sterilizers
Sterilizer qualification testing using a BI PCD is performed after:
- sterilizer installation and relocation to assess the sterilizer performance in the environment in which it will be used; and
- sterilizer malfunctions and sterilization process failures if there is a major repair of the sterilizer or utilities to ensure the sterilizer is performing to specifications;
- 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. (ANSI/AAMI ST79 Section 10.8.1)

ANSI/AAMI ST79 Section 10.8.1 states if a steam sterilizer is designed to be used for multiple types of cycles than:
Each type of cycle used should be tested to ensure all cycles are working before the sterilizer is placed into routine use:
- gravity-displacement at 132°C to 135°C [270°F to 275°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 you are running both a four and a 10 minute dynamic-air removal sterilizer at 132°C to 135°C [270°F to 275°F], then only the shortest sterilization time needs to be tested. (ANSI/AAMI ST79 Section 10.8.1) This information applies to steam sterilizers larger than 2 cubic feet, table-top sterilizers and flash sterilization cycles. Each type of cycle needs to be tested because it creates a different challenge to air removal and steam penetration.

For dynamic-air-removal sterilizers Bowie-Dick testing is also performed. The release of the steam sterilizer for routine use after sterilizer qualification testing should be an active decision based on the evaluation of all available data. An experienced and knowledgeable person should make that decision based on the results of the physical monitors, BI PCDs, and the Bowie-Dick tests, if applicable.

A BI PCD should be run after a sterilizer is installed, relocated, and after malfunction or sterilization process failure that require a major repair.

A BI PCD should be run in each type of cycle used.

Use the results of the physical monitors, BI PCDs, and Bowie-Dick tests, if applicable, to release the sterilizer for routine use.

**STEAM STERILIZERS GREATER THAN 2 CUBIC FEET**

The BI PCD should be an AAMI 16 towel pack (BI challenge test pack) (see Figure 1) or a commercially available BI PCD of equivalent performance. A biological indicator containing *Geobacillus stearothermophilus* spores is used. The CI should be either a Class 4 multi-variable or a Class 5 integrating indicator. One BI PCD is placed on the bottom shelf of the sterilizer, over the drain in an empty sterilizer to assess the performance of the sterilizer and utilities. (ANSI/AAMI ST79 Section 10.8.2.2) Run three consecutive empty test cycles. An empty cycle is the greatest challenge for assessing the ability of the sterilizer and utilities to function in your facility without adding the challenge of a load. The ability of a sterilizer to process a load is assessed during routine sterilizer efficacy testing. Remember to also test each type of cycle used in a sterilizer greater than 2 cubic feet as described under qualification testing for steam sterilizers above. See Table 1 for examples of BI PCDs to use for sterilizer qualification testing based on the load contents.

For dynamic-air-removal sterilizers (e.g., prevacuum), Bowie-Dick test packs are run to detect air leaks, inadequate air removal, inadequate steam penetration, and the presence of noncondensable gases (e.g., air or gas from boiler additives). (ANSI/AAMI ST79 Section 10.7.6.1) See Figure 2 for instructions for assembling and running a Bowie-Dick Test Pack. A commercially available, disposable Bowie-Dick test pack may be used if cleared by the FDA to be equivalent in performance to the AAMI Bowie-Dick test pack.

**Figure 1. Instructions to Assemble and Run an AAMI 16-Towel Challenge BI PCD for Sterilizers Greater than 2 Cubic Feet (ANSI/AAMI Section 10.8.2, pack composition Section 10.7.2.1)**

**Components:**
1. One or more BIs (one or two test vials and one control vial from the same lot) and one Class 4 or Class 5 CI.
2. Sixteen clean, preconditioned, reusable huck or absorbent surgical towels, in good condition, each approximately 16 in x 26 in (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 in wide, 9 in long, and 6 in high (23 cm x 23 cm x 15 cm). (See AAMI Figure 10.)
2. Place the BIs and CI between the eighth and ninth towels in the approximate geometric center of the pack. One additional BI from the lot used for testing should be left unexposed to the sterilant and used as a positive control.
3. Tape the pack in a manner that will yield the pack approximately 6 in (15 cm) high.
4. Label as a BI PCD.

**Test Procedure:**
1. Place the test pack flat in an empty chamber on a rack or shelf near the drain. (See AAMI Figure 15.)
2. Run the load according to the sterilizer manufacturers’ instructions.

Practical application
- A BI PCD should be run after a sterilizer is installed, relocated, and after malfunction or sterilization process failure that require a major repair.
- A BI PCD should be run in each type of cycle used.
- Use the results of the physical monitors, BI PCDs, and Bowie-Dick tests, if applicable, to release the sterilizer for routine use.

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3. Repeat this test two more times for a total of three consecutive empty cycles.

4. At the end of the cycle, cool the test pack according to the BI manufacturer’s instructions.

5. Read the CI and record the results.

6. Incubate the BI test vial and a control vial from the same lot each day a test vial is incubated in each incubator or auto-reader. Read and record the results. Repeat this test for a total of three consecutive empty cycles for each sterilization cycle for which the sterilizer is designed for use.

7. Place the sterilizer into routine use if all the physical monitors are correct, the BIs are negative, and the BD test sheets show a uniform color change or pass. (See Figure 2.)

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**Table 1. BI PCDs for Sterilizer Qualification Testing of 270°F to 275°F (132°C to 135°C) Dynamic-Air-Removal or 250°F (121°C) Gravity Displacement Steam Sterilization Cycles for Sterilizers Greater than 2 cubic Feet***

<table>
<thead>
<tr>
<th>Type of Tray</th>
<th>BI PCD**</th>
</tr>
</thead>
<tbody>
<tr>
<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) or an AAMI 16-towel BI PCD or commercially available BI PCD of equivalent performance if appropriate for cycle parameters</td>
</tr>
<tr>
<td>Mixed wrapped load</td>
<td>Bi in AAMI 16-towel PCD or commercially available BI PCD of equivalent performance</td>
</tr>
<tr>
<td>Protective organizing case</td>
<td>Bi in protective organizing case in area(s) that create the greatest challenge to air removal and sterilant penetration or an AAMI 16-towel PCD or commercially available BI PCD of equivalent performance if shown in product testing to be appropriate</td>
</tr>
<tr>
<td>Rigid sterilization container</td>
<td>Bi in rigid sterilization container in area(s) that create the greatest challenge to air removal and sterilant penetration or an AAMI 16-towel PCD or commercially available BI PCD of equivalent performance if shown in product testing to be appropriate</td>
</tr>
</tbody>
</table>

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**Figure 2. Instructions to Assemble and Run an AAMI Bowie-Dick Test Pack (ANSI/AAMI ST79 Section 10.7.6)**

**Components:**
1. 100% cotton surgical towels.
2. Commercially available Bowie-Dick-type test sheet.
3. A single two-ply fabric wrap made of 100% cotton with a thread count both warp and weft of 5.5 mm.

**Preparation:**
1. Fold each towel to a size 9 inches (250 mm ± 20 mm) in one direction and 12 inches (300 mm ± 20 mm) in the other direction. Place one above the other to

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

**Check with the sterilizer and biological indicator manufacturer to make sure you are using the correct BI for the cycles being tested.

***Perforated or mesh-bottom tray.

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a height between 10 and 11 inches (250 and 280 mm). The numbers of towels needed will depend upon the towel thickness and wear and will vary from test to test. The height of the test pack should be between 10 and 11 inches (250 and 280 mm).

2. Place the Bowie-Dick-type test sheet in the center of the pack.
3. Loosely apply the wrap and secure with tape. (See AAMI Figure 13.)

Test Procedure:
1. Run an empty chamber cycle right before you run the Bowie-Dick (BD) test to preheat the sterilizer and purge air out of the lines, even if the sterilizer was never turned off. This is not necessary if the tests are run right after the BI PCD test.
2. Place one BD test pack horizontally in the front, bottom section of the sterilizer rack or loading cart, near the door over the drain, but not on the floor unless recommended by the test pack manufacturer. (See AAMI Figure 14.)
3. Run the test pack for 3.5 to 4 minutes at 270-275°F (132-135°C). Dry time may be omitted.
4. Repeat this test two more times for a total of three consecutive empty cycles.
5. If the test sheets have a uniform color change, place the sterilizer into routine use.
6. If the test sheets do not have a uniform color change or pass result, do not place the sterilizer into routine use until the problem is identified.

TABLE-TOP STEAM STERILIZERS

The BI PCD will be user-assembled and should be representative of the same type of package or tray to be routinely processed and the most difficult to sterilize. (See Figure 3.) (ANSI/AAMI ST79 Section 10.8.3) A biological indicator containing *Geobacillus stearothermophilus* spores is used. The CI should be either a Class 4 multi-variable or Class 5 integrating indicator. One BI PCD is placed on edge if it is a small pack or flat if it is a tray or large pack in a full load in the most challenging location which is normally the front of the sterilizer. Run three consecutive full test cycles. All packages or trays processed during qualification testing should be quarantined until the BI results are negative. Table-top sterilizers have a water reservoir which creates a limited amount of steam so sterilizer qualification testing is done in a full load because this is the greatest challenge to steam penetration in a table-top sterilizer. (ANSI/AAMI ST79 Section 10.8.3.2) Remember to also test each type of cycle used in a table-top sterilizer as described under qualification testing for steam sterilizers above. Table 2 on page 80 describes appropriate BI PCDs for the load contents.
Table 2. BI PCDs for Sterilizer 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 perforated instrument tray*** or glassware</td>
<td>270°F-274°F (132°C-135°C)</td>
<td>≥3 min</td>
<td>BI in unwrapped perforated instrument tray or glassware</td>
</tr>
<tr>
<td>Wrapped trays of instruments, instruments in peel pouches</td>
<td>270°F-274°F (132°C-135°C)</td>
<td>≥4 min</td>
<td>BI in a wrapped tray or peel pouch and include porous items (e.g., towel, foam pad, etc) if applicable</td>
</tr>
<tr>
<td>Packs, wrapped</td>
<td>250°F (121°C)</td>
<td>≥30 min</td>
<td>BI in wrapped pack that is representative of the load, include porous items if appropriate</td>
</tr>
</tbody>
</table>

*Check with the medical device and sterilizer manufacturer for correct times for the items being processed.
**Check with the sterilizer and biological indicator manufacturer to make sure you are using the correct BI for the cycles being tested.
***Perforated or mesh-bottom trays

Table 3. BI PCDs for Different Cycle/Tray Configurations for Flash Sterilization Cycles*

<table>
<thead>
<tr>
<th>Type of Cycle</th>
<th>Type of Tray Configuration</th>
<th>BI PCD**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity Open surgical tray***</td>
<td>BI in open surgical tray</td>
<td></td>
</tr>
<tr>
<td>Gravity 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>
<td></td>
</tr>
<tr>
<td>Gravity Protective organizing case</td>
<td>BI in protective organizing case in area(s) that create the greatest challenge to air removal and sterilant penetration</td>
<td></td>
</tr>
<tr>
<td>Gravity Rigid sterilization container</td>
<td>BI in rigid sterilization container in area(s) that create the greatest challenge to air removal and sterilant penetration</td>
<td></td>
</tr>
<tr>
<td>Dynamic-air-removal 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>
<td></td>
</tr>
<tr>
<td>Dynamic-air-removal 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>
<td></td>
</tr>
<tr>
<td>Dynamic-air-removal Protective organizing case</td>
<td>BI in protective organizing case in area(s) that create the greatest challenge to air removal and sterilant penetration</td>
<td></td>
</tr>
<tr>
<td>Dynamic-air-removal Rigid sterilization container</td>
<td>BI in rigid sterilization container in area(s) that create the greatest challenge to air removal and sterilant penetration</td>
<td></td>
</tr>
</tbody>
</table>

*Check with the medical device and sterilizer manufacturer for correct times for the items being processed.
**Check with the sterilizer and biological indicator manufacturer to make sure you are using the correct BI for the cycles being tested.
***Perforated or mesh-bottom trays

FLASH STERILIZATION CYCLES

The BI PCD will be user-assembled and should be representative of the tray configurations routinely used. For sterilizer qualification testing not every tray configuration used routinely needs to be tested as is required in routine sterilizer efficacy monitoring. So choose the tray configuration used most often or that creates the greatest challenge. These include:

- perforated, mesh-bottom, open surgical tray;
- rigid sterilization container system;
- protective organizing case; and
- single-wrapped surgical tray. (ANSI/AAMI ST79 Section 10.7.4.1)

A biological indicator containing *Geobacillus stearothermophilus* spores is used. The CI should be either a Class 4 multi-variable or Class 5 integrating indicator. The BI PCD should be placed on the bottom shelf of the sterilizer, over the drain, in an empty load. The empty load minimizes the heat-up time which minimizes the lethality of the process and creates a greater challenge to the BI. (ANSI/AAMI Section 10.8.4) Run three consecutive empty test cycles. Remember to also test each type of cycle used for flash sterilization as described under qualification testing for steam sterilizers above. Table 3 describes appropriate BI PCDs for the load contents.
For dynamic-air-removal sterilizers (e.g., prevacuum) used for flash sterilization, a Bowie-Dick testing is also performed. See Figure 2 and AAMI Figure 13 and 14 for information about this testing. (ANSI/AAMI ST79 Section 10.7.6.1)

Figure 4. BI PCDs for flash sterilization in gravity sterilizers

Figure 5. BI PCDs for flash sterilization in dynamic-air removal sterilizers

Practical application
- Test each type of cycle used in flash steam sterilization with a BI PCD that is representative of a tray configuration routinely used.
- Run one BI PCD in three consecutive empty cycles.
- For prevacuum sterilizers also run one BD test pack in three consecutive empty cycles.
- Release the sterilizer for routine use if the physical monitors are correct, the BIs are negative, and the BD tests show a pass.

Sterilizer Qualification Testing for Low Temperature Sterilization Processes
For ethylene oxide sterilizer qualification testing BI PCDs are used after:
- sterilizer installation, relocation and major design to assess the sterilizer performance in the environment in which it will be used;
- sterilizer malfunctions;
- sterilization process failures;
- sterilizer major repairs to ensure the sterilizer is performing to specifications after the correction of a malfunction or process failure:
  - a major repair is a repair outside the scope of normal maintenance such as replacing the chamber door or upgrading controls. Normal preventive maintenance, such as replacing gaskets, is not considered a major repair. Significant changes to the utilities connected to the sterilizer which could affect the ability of the sterilizer to meet the sterilizer manufacturers’ utility requirements such as utility line sizes, maximum and minimum pressures, dynamic flow requirements, and a specific electrical supply which operates in a specified range of that value would be considered a major repair. Adding additional equipment loads may also affect the utilities. (ANSI/AAMI ST41 Section 10.8.1)

For hydrogen peroxide and ozone sterilizer qualification testing should be performed:
- During installation;
- After major relocation;
- After sterilizer malfunctions;
- After sterilization process failures; and
- Any major repairs of the sterilizer. (AAMI TIR31Section 6.4.5 and 6.5.5 and ANSI/AAMI ST58 Section 9.5.4.3 and 9.5.4.4)

The release of low temperature sterilizers for routine use after sterilizer qualification testing should be an active decision based on the evaluation of all available data. An experienced and knowledgeable person should make that decision based on the results of the physical monitors and the BI PCDs.

ETHYLENE OXIDE STERILIZERS
The type and number of BI PCDs used will depend on the type of qualification testing being done. Either the routine BI PCD described in Section 10.7.2 of ANSI/AAMI ST41 (or a commercially available BI PCD of equivalent performance) or the challenge BI PCD described in Section 10.8.2 should be used. A biological indicator containing Bacillus atrophaeus spores is used. The CI should be either a Class 4 multi-variable or Class 5 integrating indicator.
Qualification testing after sterilizer installation or relocation

Use one or more challenge BI PCDs. See Figure 6 for instructions to assemble an AAMI challenge BI PCD and AAMI Figures 4, 5, and 6 for the components of the challenge BI PCD. The challenge BI PCD should be run in three consecutive cycles in a simulated load. (ANSI/AAMI ST41 Section 10.8.1) \( ^2 \) “A simulated load should contain additional PCDs without BIs, not patient care items.” (ANSI/AAMI ST41 Section 10.8) \( ^2 \) The simulated load was chosen so that patient care items would be available for use and to control costs. 

- For a sterilizer having a chamber volume of 8.8 cubic feet, place the BI PCD in the front center of the basket by the door and add six simulated packs for a total of seven.
- For a sterilizer having a chamber volume of 5 cubic feet, place the BI PCD in the front center of the basket by the door and add four simulated packs for a total of five.
- For a sterilizer having a chamber volume of 4 cubic feet, place the BI PCD in the front center of the basket by the door and add three simulated packs for a total of four. (ANSI/AAMI ST41 Section 10.8.3) \( ^1 \)

Qualification testing after major redesign

This sophisticated testing will require the assistance of the sterilizer manufacturer or other service provider who did this testing when the sterilizer was originally designed. One or more challenge BI PCDs (see Figure 6 for instructions to assemble an AAMI challenge BI PCD and AAMI Figures 4, 5, and 6 for the components of the challenge BI PCD) should be run in three consecutive half-cycles in a simulated load. (ANSI/AAMI ST41 Section 10.8.1) \( ^2 \) In addition, one or more challenge BI PCDs should be run in three consecutive full-exposure cycles in an otherwise empty sterilizer. For a sterilizer chamber that is 8.8 cubic feet or less, place one BI PCD in the front center of the basket by the door.

To create the simulated load for the half-cycle testing:

- For a sterilizer having a chamber volume of 8.8 cubic feet, add six simulated packs for a total of seven.
- For a sterilizer having a chamber volume of 5 cubic feet, add four simulated packs for a total of five.
- For a sterilizer having a chamber volume of 4 cubic feet, add three simulated packs for a total of four. (ANSI/AAMI ST41 Section 10.8.3) \( ^1 \)

Figure 6. Instructions to Assemble an AAMI Challenge BI PCD (ANSI/AAMI ST41 Section 10.8.2) \( ^2 \)

Components:
1. Four clean, freshly laundered, preconditioned surgical towels (woven, 100% cotton absorbent approximately 18 inches by 30 inches).
2. Two BIs for testing and one control BI from the same lot and one Class 4 or Class 5 CI.
3. Two plastic syringes (approximately 20 cc).
4. One adult plastic airway (See AAMI Figure 5).
5. One 10-inch-long section of latex tubing with an internal diameter of 3/16 inch and a wall thickness of 1/16 inch (see AAMI Figure 5). PVC tubing may be used if latex tubing is not available.
6. Two clean, approximately 24-inch by 24-inch woven or nonwoven wrappers.

All components should be held at room temperature \([18^\circ C \text{ to } 24^\circ C (65^\circ F \text{ to } 75^\circ F)]\) and a relative humidity of 35% for at least 2 hours prior to making the BI PCD.

Preparation:
1. Fold each towel in thirds and then in half to create six layers per towel and stacked one on top of another.
2. Place each BI, according to the BI manufacturers’ instructions, inside separate plastic syringes of sufficient size that the plunger diaphragm does not touch the BI when the plunger is inserted into the barrel of the syringe. If there is a plastic protective tip guard on the syringe, remove it (see AAMI Figure 4). One additional BI from the lot used for testing should be left unexposed to the sterilant and used as a positive control.
3. Place the syringes with the BI, the latex tubing, plastic airway and CIs between the folds of the clean surgical towel (see AAMI Figure 6).
4. Double wrap the items and secure with tape.
5. Label as a BI PCD.

Test Procedure:
1. Place the BI PCD in sterilizer according to the type of testing being performed.
2. Upon completion of the cycle, the BI PCD should be handled according to the healthcare facility’s protocol for minimizing worker exposure to EO (see sterilizer and BI PCD manufacturers’ instructions).
3. Incubate the BI test vials and a control vial from the same lot each day a test vial is incubated in each incubator or auto-reader. Read and record the results.

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4. Place the sterilizer into routine use if all the physical monitors are correct, the CIs have reached their endpoint response and BIs are negative.

**AAMI Figure 4—Placement of BI in syringe**

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**AAMI Figure 5—Some components of the PCD (challenge BI test pack)**

Oral airway 10-inch latex tubing Chemical indicator Two 24 x 24-inch wrappers

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

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**Qualification testing after sterilizer malfunctions and major repairs or a sterilization process failure**

If the physical monitors indicate any malfunctions and it cannot be corrected immediately, the cycle should be terminated, aerated, and considered not sterile. (ANSI/AAMI ST41 Section 10.6.4)² The root cause should be identified and the sterilization process failure corrected. Sterilization process failures can occur in a normally functioning sterilizer as a result of:

- poor sterilant quality;
- operator error;
- improper utilities (steam and water); and
- other factors. (ANSI/AAMI ST41 Section 10.6.4)²

“The same investigative procedure should be followed at the completion of the cycle if external CIs or the monitor in a BI PCD indicates a questionable cycle.” (ANSI/AAMI ST41 Section 10.6.4)²

**Investigation reveals sterilizer did not malfunction (ANSI/AAMI ST41 Section 10.6.4)²**

Place a routine BI PCD (see Figure 6 for instructions to assemble an AAMI Routine BI PCD and AAMI Figure 3 for more information) or a commercially available equivalent BI PCD in one cycle in a load similar in composition and density to the load exhibiting the sterilization process failure. Place the routine BI in the center of the load unless otherwise indicated by the sterilizer manufacturer. Quarantine the load until the BI is negative. If the BI is positive, remove the sterilizer from use until it can be serviced. If a sterilizer malfunction is not identified then investigate to determine if the:

- items in the load were packaged correctly;
- sterilizer was loaded correctly; and
- correct cycle was run for the load.

**Investigation reveals the sterilizer has malfunctioned (ANSI/AAMI ST41 Section 10.6.4)²**

Correct the problem. If the problem is a result of a major repair to the sterilizer or utilities (see Sterilizer qualification testing for low temperature sterilization processes on page 82 for a description of a major repair), one routine BI PCD (see Figure 7 for instructions to assemble an AAMI Routine BI PCD and AAMI Figure 3 for more information) or a commercially available equivalent BI PCD should be run in three consecutive cycles in a load similar in composition and density to the load exhibiting the sterilization process failure. The patient care items should be quarantined until the BI is negative.
Figure 7. Instructions to Assemble an AAMI Routine BI PCD (ANSI/AAMI ST41 Section 10.7)²

Components:
1. Two BIs (one test vial and one control vial from the same lot) and one Class 4 or Class 5 CI. (See AAMI Figure 3.)
2. One plastic syringe (approximately 20 cc).
3. A clean surgical towel, woven, 100% cotton.
4. A peel pouch or wrapper large enough to contain the test pack contents.

All components should be held at room temperature [18°C to 24°C (65°F to 75°F)] and a relative humidity of 35% for at least 2 hours prior to making the BI PCD.

Preparation:
1. Place one BI, according to the BI manufacturers’ instructions, inside a plastic syringe of sufficient size that the plunger diaphragm does not touch the BI when the plunger is inserted into the barrel of the syringe. If there is a plastic protective tip guard on the syringe, remove it. One additional BI from the lot used for testing should be left unexposed to the sterilant and used as a positive control.
2. Place the syringe with the BI and the CI between the folds of the clean surgical towel, which has been folded lengthwise into thirds and then in thirds again to create nine layers.

continued on page 90

NOTE 1—Place the BI in the syringe according to the BI manufacturer’s instructions. The correct orientation of the BI in the syringe ensures that any vent in the BI faces toward the needle end of the syringe. (Paper strip BIs may be used in any orientation.)

NOTE 2—A CI should be placed in the folds of the towel.

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3. Place these items inside one peel pouch or wrapper large enough to contain the test pack components and seal.
4. Label as a BI PCD.

Test Procedure:
1. Place the BI PCD in the sterilizer according to the type of testing being performed.
2. Upon completion of the cycle, the BI PCD should be handled according to the healthcare facility’s protocol for minimizing worker exposure to EO (see sterilizer and BI PCD manufacturers’ instructions).
3. Incubate the BI test vials and a control vial from the same lot each day a test vial is incubated in each incubator or auto-reader. Read and record the results.
4. Place the sterilizer into routine use if all the physical monitors are correct, the CIs have reached their endpoint response and BIs are negative.

Hydrogen peroxide sterilizers
A BI PCD for the hydrogen peroxide sterilization process consists of a BI containing *Geobacillus stearothermophilus* spores and a CI. “The BI PCD should create a challenge to the sterilization process that is representative of the most difficult item to sterilize in the load being processed.” (ANSI/AAMI TIR30 Section 6.5.2)³

Commercial BI PCD kits are available. These kits are specific to the sterilizer model so ensure you are using the correct kit for the sterilizer being monitored. (ANSI/AAMI TIR30 Section 6.4)³ A healthcare facility prepared BI PCD should include a BI and CI in a package or tray routinely processed that is representative of the most difficult to sterilize item in the load being processed. (ANSI/AAMI TIR31 Section 6.4.4.2)³ Consult with the sterilizer manufacturer for material selection, assembly of, and placement of the BI PCD for sterilizer qualification testing.

Ozone sterilizers
A BI PCD for the ozone sterilization process consists of a biological indicator containing *Geobacillus stearothermophilus* spores and a CI. “The BI PCD should provide a challenge to the sterilization process that is equal to or greater than the challenge posed by the most difficult item routinely processed.” (ANSI/AAMI TIR30 Section 6.5.2)³

The manufacturer recommends the preparation of a syringe pack. The BI is placed with the cap toward the opening or bevel of the syringe with the tip removed. The syringe containing the BI and a CI (outside of the syringe) is placed inside a peel pouch. Contact the sterilizer manufacturer for further information about the material selection, assembly of, and placement of the BI PCD for sterilizer qualification testing.

Practical application
- Perform sterilizer qualification testing according to the sterilizer manufacturers’ instructions for use.

Summary
Sterilizer qualification testing is testing the sterilizer with a biological indicator (BI) in a process challenge device (PCD) after events occur which could affect the ability of the sterilizer to perform. This ensures that the sterilizer and utilities are performing before the sterilizer is placed into routine use. The BI PCD should contain the appropriate BI and CI for the process being monitored and create a challenge equal to or greater than the challenge posed by the most difficult item routinely processed. Follow the AAMI recommended practices for sterilizer qualification testing and the instructions for use from the BI PCD and sterilizer manufacturer to ensure the appropriate testing is being performed.

References
Martha Young, BS, MS, CSPDT, is president of Martha L. Young LLC, providing SAVVY sterilization solutions to healthcare manufacturers and facilities and a consultant for 3M. She recently retired from the 3M Infection Prevention Division, St. Paul, Minn. after 31 years and has more than 28 years of experience in the specialty area of sterilization and disinfection. Ms. Young has lectured around the world, has numerous publications on infection prevention with an emphasis on how to improve the performance of the sterilization process, and is a technical advisor for healthVIE.com (formerly Managing Infection Control) and writes a quarterly column for OR Manager. She is a member of IAHCSMM, AORN (Past Professional/Practice Issues Chair for AORN Specialty Assembly for Sterilization Processing and Materials Management from 2006-2010), APIC and a certified Central Sterile Processing and Distribution Technician. Additionally, Ms. Young is a member of several AAMI working groups developing recommended practices. In 2007 HPN acknowledged her as one of the “30 Pros Worth Knowing” who are the most influential in healthcare sterile processing. Ms. Young can be reached at marthalyoung1@aol.com.

### Sterile Process and Distribution CEU Information

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The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1.5 contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until recertification is required. **DO NOT SEND LESSON OR TEST TO CBSPD.**

For additional information regarding Certification contact: CBSPD, 148 Main St., Lebanon, NJ, 08833 or call 908-236-0530 or 800-555-9765 or visit the Web site at www.sterileprocessing.org.

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### ANSWERS

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