Many thanks to the team at 3M Health Care for working with healthVIE.com to provide the following accredited course. IAHCSMM has awarded 1.5 contact points for completion of this continuing education lesson toward IAHCSMM recertification. The CBSPD has preapproved this inservice for 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 1 contact hour. This form is valid up to five (5) years from the date of publication. Instructions for submitting results are on page 92.

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

Load control monitoring is the process by which a load is monitored and released based on the result of a biological indicator (BI) in a process challenge device (PCD). Only a BI can detect the actual killing of microbial spores inside the sterilizer. (ANSI/AAMI ST79 Section 10.5.3.1)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 in each load allows quarantining of all loads pending BI results, especially those containing implants, and reduces variability and chance for errors. The advantages of using a BI PCD in each load for load control include:

- Reducing the risk and cost of healthcare-associated infections (HAIs) because you know the load is not released until the BI is negative;
- Providing a universal standard of patient care by treating all loads the same with the equal chance of identifying a sterilization process failure before the patient becomes involved;
- Reducing the cost and impact of a recall;
- To be certain all implants, including those in loaners, are appropriately monitored and quarantined until the BI is negative;
- Ensure every type of steam sterilization cycle used is monitored; and
- Ensure every type of packaging used in flash sterilization is monitored.

For monitoring of nonimplant loads, a Class 5 integrating indicator PCD may be used as load control by providing “additional information about the attainment of the critical parameters of the sterilization process.”(ANSI/AAMI ST79 Section 10.5.2.1 and 10.5.3.2)¹ Using this CI PCD does not provide the same value as using a BI PCD because the performance of Class 5 integrating CIs “do not contain spores and do not directly measure the lethality of a sterilization cycle.” (ANSI/AAMI ST79 Section 10.5.3.2)¹

This inservice will discuss:

- Process challenge devices;
- BI PCDs used for:
  - Routine release of nonimplant loads,
  - Routine release of implant loads,
  - Routine sterilizer efficacy monitoring;
- What to do when the load control monitoring device detects a problem.

Recommended practices from the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses 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.”¹

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)¹ The type of PCD used will depend upon the type of sterilization process, cycle, and parameters and the type of load being monitored. ANSI/AAMI ST79 Section 10.5.4 states a PCD for steam sterilization processes may include the following monitors:

- A BI;
- A BI and a Class 5 integrating indicator;
- A Class 5 integrating indicator.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 10.7.2.1 for steam sterilizers larger than 2 cubic feet and in ANSI/AAMI ST41 in Section 10.7.2 for ethylene oxide (EO) sterilizers.¹,² 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)³

The BI PCDs for table-top sterilizers (ANSI/AAMI Section 10.7.3) and flash steam sterilization cycles (ANSI/AAMI Section 10.7.4) are user-assembled and should be representative of the load.¹

Practical application

- 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 manufacturer of the BI PCD and CI PCD should be followed to ensure accurate results.

Let’s discuss the types of BI PCDs to use for routine load release of nonimplant and implant loads and for routine sterilizer efficacy monitoring.
Competency testing of employees ensures correct interpretation of monitoring tools.

Routine Load Release of Nonimplant loads

Routine release of nonimplant loads should be an active decision based on the evaluation of all available data. An experienced and knowledgeable person should make that decision at the end of the steam sterilization cycle after evaluating the:

- Physical monitors;
- External chemical indicators;
- Internal chemical indicators;
- A PCDs containing either a
  - BI,
  - BI and Class 5 integrating indicator,
  - Class 5 integrating indicator. (ANSI/AAMI ST79 Section 10.4)\(^1\)

The use of a PCD in each nonimplant load is optional based on the ANSI/AAMI ST79 recommended practices but the advantage of using a BI PCD in each load is discussed in the PCD section above. How will you determine that the sterilization process is effective if you do not monitor with a BI PCD?

For EO sterilizers the following should also be evaluated by an experienced and knowledgeable person:

- Physical monitors;
- External chemical indicators;
- Internal chemical indicators;
- BI PCDs containing a chemical indicator (CI) in each load. (ANSI/AAMI ST41 Section 10.4)\(^2\)

The AAMI recommendations for monitoring other gaseous chemical sterilization processes (e.g., hydrogen peroxide and ozone) include the use of physical monitors, chemical indicators and a PCD with a BI or a BI and a CI. (AAMI ST58 Section 9.5)\(^4\)

The user should also be appropriately trained and knowledgeable about the performance and interpretation of results of the physical, chemical and biological indicators, and competency should be assessed.

AORN recommends in the 2010 Perioperative Standards and Recommended Practices for Sterilization and Disinfection Recommendation XVI that the following be evaluated for all steam and low temperature sterilization processes (e.g., EO, hydrogen peroxide, and ozone):

- Physical monitors;
- External chemical indicators;
- Internal chemical indicators;
- BIs.\(^5\)

Practical application

- Use physical monitors, chemical and biological indicators to release nonimplant loads.
- Every load monitoring with a BI PCD and quarantining until the BI is negative ensures that improperly sterilized medical devices are not released for patient use.
- Competency testing of employees ensures correct interpretation of monitoring tools.

Routine Load Release of Implant Loads

Routine release of implant loads should also be an active decision based on the evaluation of all available data. An experienced and knowledgeable person should make that decision at the end of the steam sterilization cycle after evaluating the:

- Physical monitors;
- External chemical indicators;
- Internal chemical indicators;
- BI PCD containing a Class 5 integrating indicator. (ANSI/AAMI ST79 Section 10.4)\(^1\)

For loads run in EO the BI PCD should contain a Class 4 multivariable or Class 5 integrating CI. (ANSI/AAMI ST41 Section 10.4 and 10.5.2.2.2)\(^2\)

For hydrogen peroxide and ozone, the PCD may contain a BI or a BI and CI. (ANSI/AAMI ST58 9.5.4.1)\(^4\)

AAMI and AORN state that the load containing the implant should be quarantined until the results of the BI testing are available. (ANSI/AAMI ST79 Section 10.6.3, ANSI/AAMI ST41 Section 10.6.3, ANSI/AAMI ST58 Section 9.5.4.3, and AORN Sterilization XVI)\(^1,2,4,5\) This recommendation is based on reducing the patient risk associated with implants.

For steam sterilization ANSI/AAMI ST79 states in Section 10.6.3 in a documented emergency situation it may be necessary to release the implant based on the results of the Class 5 integrating indicator in the BI PCD.\(^1\) This information should be fully traceable to the patient. “Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.”(ANSI/AAMI ST79 Section 10.6.3)\(^1\) This is a patient safety issue.

When documented medical exceptions occur for low temperature sterilization and an early release is unavoidable, the release of the device before the BI is known should be documented. (ANSI/AAMI ST58 section 9.5.4.3)\(^2,4\)
Practical application

- Use physical monitors, chemical and biological indicators to release implant loads.
- Every implant load should be monitored with a BI PCD and quarantined until the BI is negative to ensure improperly sterilized items are not released for patient use.
- Competency testing of employees ensures correct interpretation of monitoring tools.

Routine Sterilizer Efficacy Monitoring

Routine sterilizer efficacy monitoring establishes a regular pattern of testing the efficacy of the sterilization process. All sterilizers should be routinely monitored using appropriate BI PCDs. If a BI PCD is used in each load this monitoring meets the recommended practice requirements for routine sterilizer efficacy monitoring and takes the guess work out of whether all implants, every type of steam sterilization cycle and every type of packaging used in flash sterilization is monitored with a BI. Every load monitoring with a BI PCD ensures consistency and detects operator errors which are the main reason for sterilization process failures. Let’s discuss the routine sterilizer efficacy monitoring requirements for each type of sterilization process.

STEAM STERILIZERS

Steam sterilizers should be monitored with a BI PCD weekly, preferably daily (each day the sterilizer is used). (ANSI/AAMI ST79 Section 10.4) ANSI/AAMI ST79 Section 10.7.1 states that if a steam sterilizer is designed to be used for multiple types of cycles then:
- each type of cycle should be routinely tested because each cycle creates a different challenge to air removal and steam penetration:
  - 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.

A note states that if you are running both a 4 and a 10 minute dynamic-air removal sterilizer at 132°C to 135°C [270°F to 275°F], than only the shortest sterilization time needs to be tested.

Steam sterilizers greater than 2 cubic feet

The BI PCD should be an AAMI 16 towel pack (routine 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, and in a full load to create the creates challenge to air removal and steam penetration. (ANSI/AAMI ST79 Section 10.7.2) See Table 1 for examples of BI PCDs for the load contents. Remember to also test each type of cycle used in a sterilizer as described under steam sterilizers above.

Figure 1. Instructions to Assemble and Run an AAMI Routine 16-Towel BI PCD (ANSI/AAMI Section 10.7.2)

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-inch by 26-inch (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-inch wide, 9-inch long, and 6-inch high (23 cm x 23 cm x 15 cm). (See AAMI Figure 10 on page 78.)
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-inch (15 cm) high.
4. Label as a BI PCD.

Test Procedure:
1. Place the test pack flat in a full chamber on a rack or shelf near the drain. (See AAMI Figure 11 on page 78)
2. Run the load according to the sterilizer manufacturers’ instructions.
3. At the end of the cycle, cool the test pack according to the BI manufacturers’ instructions.
4. Read the CI and record the results.
5. 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.
Table 1. BI PCDs for Routine Sterilizer Efficacy Monitoring of 270°F to 275°F (132°C to 135°C) Dynamic-Air-Removal or 250°F (121°C) Gravity Displacement Steam Sterilization Cycles*

<table>
<thead>
<tr>
<th>Type of Tray Configuration or Load</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>

* Check with the medical device or 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.

 Practical application

- Test each type of cycle used in a steam sterilizer with a BI PCD that is representative of that load.

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 2.) (ANSI/AAMI ST79 Section 10.7.3)¹ 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 edge if it is a small pack or flat if it is a tray or large pack in a full load which is normally the front of the sterilizer. Table 2 describes appropriate BI PCDs for the load contents. Remember to also test each type of cycle used in a sterilizer as described under steam sterilizers above.
The BI PCD will be user-assembled and consist of a BI and a Class 4 or 5 CI placed inside each tray configuration to be tested. See Figures 3 and 4 for examples. A biological indicator containing *Geobacillus stearothermophilus* spores is used. AORN recommends “Class 5 chemical integrating indicators should be used within each sterilizer container or tray.”(AORN IV.d.)

The BI PCD should be placed on the bottom shelf of the sterilizer, over the drain, in an empty load to create the greatest challenge to air removal and steam penetration. (ANSI/AAM ST79 Section 10.7.4)

Limiting the number of tray configurations used will minimize the amount of routine testing needed.

### Table 2. BI PCDs for Different Cycle/Tray Configurations for Flash Sterilization Cycles*

<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 or 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.

### Table 3. BI PCDs for Routine Sterilizer Efficacy Monitoring 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 or 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.

### Flash sterilization cycles

For routine biological monitoring of flash sterilization cycles ANSI/AAMI ST79 Section 10.7.4.1 states:

- each type of tray configuration in routine use should be tested because each creates 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.

The BI PCD will be user-assembled and consist of a BI and a Class 4 or 5 CI placed inside each tray configuration to be tested. See Figures 3 and 4 for examples. A biological indicator containing *Geobacillus stearothermophilus* spores is used. AORN recommends “Class 5 chemical integrating indicators should be used within each sterilizer container or tray.”(AORN IV.d.)

The BI PCD should be placed on the bottom shelf of the sterilizer, over the drain, in an empty load to create the greatest challenge to air removal and steam penetration. (ANSI/AAM ST79 Section 10.7.4)

Limiting the number of tray configurations used will minimize the amount of routine testing needed.

### Table 2. BI PCDs for Routine Sterilizer Efficacy Monitoring 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 or 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.
LOW TEMPERATURE STERILIZATION

Ethylene oxide sterilizers

The routine BI PCD recommended in Section 10.7 of ANSI/AAMI ST79 or a commercially available BI PCD equivalent should be use in each sterilization cycle. The BI PCD contains a BI with Bacillus atrophaeus spores and a Class 4 multi-variable or Class 5 integrating indicator. One BI PCD should be placed in the center of each load unless otherwise indicated by the sterilizer manufacturer because this creates the greatest challenge to humidity and EO penetration.

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 percent cotton.
4. A peel pouch or wrapper large enough to contain the test pack contents.

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

Practical application
- Test each type of cycle used in each steam sterilizer and each type of packaging used with a BI PCD that is representative of that load.
been folded lengthwise into thirds and then in thirds again to create nine layers.
3. Place these items inside one peel pouch or wrapper large enough to contain the test pack components.
4. Label as a BI PCD.

Test Procedure:
1. Place in the center of the load.
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. Read the CI and record the results.
4. 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.

AMMI Figure 3—Preparation of the PCD (routine BI test pack) (drawing not to scale)

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.

Reprinted from ANSI/AAMI ST79:2006 and A1 & A2 with permission of Association for the Advancement of Medical Instrumentation, Inc. © 2009 AAMI www.aami.org. All rights reserved. Further reproduction or distribution prohibited.
Ozone sterilizers

A BI PCD should be used at least daily, but preferably in every sterilization cycle. (ANSI/AAMI ST58 Section 9.4.4.3) 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 representative of the most difficult item to sterilize in the load being sterilized.”

Figure 12—Decision tree for conducting investigations of steam sterilization process failures

Reprinted from ANSI/AAMI ST79:2006 and A1 & A2 with permission of Association for the Advancement of Medical Instrumentation, Inc. © 2009 AAMI. www.aami.org. All rights reserved. Further reproduction or distribution prohibited.
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 towards 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.

**Practical application**

- Test each ozone load with a BI PCD.

### What to Do When the Load Control Monitoring Detects a Problem

When the BI PCD, or CI PCD, or other CIs, or physical monitors detect a sterilization process failure a healthcare facility needs to take action. ANSI/AAMI ST79 provides a decision tree (see Figure 12) for conducting investigations of steam sterilization process failures for steam sterilizers but the same process used in this decision tree could be used for low temperature sterilization processes. (ANSI/AAMI ST79 Section10.7.5)\(^1\) In addition see Table 8 for a checklist for identifying reasons for steam sterilization process failures. (ANSI/AAMI ST79 Section10.7.5)\(^1\)

If any of the monitoring tools identify a sterilization process failure the load is quarantined, the sterilizer is removed from service, and an investigation of the cause is initiated. (ANSI/AAMI ST79 section 10.7.5.1) The action steps say in ANSI/AAMI ST79 section 10.7.5.1 for steam sterilizers:

\"b\) If it is determined that the sterilization failure was not the result of operator error (e.g., selecting the incorrect cycle), items processed in that sterilizer since the last negative BI results should be considered nonsterile. They should be retrieved, if possible, and reprocessed. The sterilizer in question should be taken out of service.\"\(^2\)

The same response should occur when any monitoring products used in hydrogen peroxide or ozone sterilizers indicate a sterilization process failure. The qualification testing to be done to place the sterilizers back into use will depend on whether there was a minor or major repair of the sterilizer or utilities. This subject will be addressed in a future inservice. More information on product recall can be found in the Product Recall Update published November 2009 in *Managing Infection Control* (now called healthVIE.com).

**Table 8—Checklist for identifying reasons for steam sterilization process failures**

<table>
<thead>
<tr>
<th>OPERATOR ERRORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect use and interpretation of monitoring tools</td>
</tr>
<tr>
<td>- Incorrect physical monitors for the load</td>
</tr>
<tr>
<td>- Incorrect use of BI or BI PCD</td>
</tr>
<tr>
<td>- Incorrect selection of BI or BI PCD for the load</td>
</tr>
<tr>
<td>- Incorrect placement of BI PCD in the load (e.g., another pack was placed on top of the PCD)</td>
</tr>
<tr>
<td>- Incorrect incubation of BI</td>
</tr>
<tr>
<td>- Misinterpretation of BI result</td>
</tr>
<tr>
<td>- Incorrect documentation of BI result</td>
</tr>
<tr>
<td>- Incorrect use of Class 5 integrating CI PCD</td>
</tr>
<tr>
<td>- Incorrect selection of CI PCD for the load</td>
</tr>
<tr>
<td>- Incorrect placement of CI PCD in the load (e.g., another pack was placed on top of the PCD)</td>
</tr>
<tr>
<td>- Misinterpretation of Class 5 integrating CI result</td>
</tr>
<tr>
<td>- Incorrect documentation of Class 5 integrating CI result</td>
</tr>
<tr>
<td>- Incorrect use of internal CI</td>
</tr>
<tr>
<td>- Incorrect selection of internal CI for the load</td>
</tr>
<tr>
<td>- Misinterpretation of internal CI result</td>
</tr>
<tr>
<td>- Incorrect documentation of internal CI results</td>
</tr>
<tr>
<td>- Incorrect storage of any CIs or BIs</td>
</tr>
<tr>
<td>- Failure to check physical monitors for functionality before running cycle</td>
</tr>
</tbody>
</table>

\*continued on page 90*
Use of broken media ampoule or ampoule with missing spore strip
Use of BI PCD or CI PCD that is missing the BI or CI
Use of defective CI (e.g., a CI that is expired, faded, shows a partial color change because of incorrect storage, or has been previously exposed to the sterilant)

**Selection of incorrect cycle for load contents**
(containment device or medical device manufacturer’s instructions for use not followed)
Use of inappropriate packaging materials or packaging technique

- Incorrect packaging or containment device for the cycle parameters
- Incorrect preparation of containment device for use (e.g., incorrect filters, valves, or bottom tray)
- Use of a paper-plastic pouch, woven or nonwoven wrapper, or towel in a 270°F to 275°F (132°C to 135°C) gravity-displacement cycle
- Use of a tray that does not allow air removal and steam penetration
- Use of a wrapper that is too large for the application
- Placement of a folded paper–plastic pouch inside another paper-plastic pouch
- Placement of a paper-plastic pouch inside a wrapped set or containment device without verification of adequate air removal and steam penetration by product testing
- Incorrect placement of basins in set (i.e., basins are not aligned in the same direction)
- Failure to use nonlinting absorbent material between nested basins
- Preparation of textile packs that are too dense to sterilize with the cycle parameters chosen
- Inadequate preconditioning of packaging materials (i.e., not holding package materials at 68°F to 73°F (20°C to 23°C) for 2 hours before use)

**Incorrect loading of sterilizer**
- Stacking of containment devices if not recommended by manufacturer
- Stacking of perforated instrument trays
- Incorrect placement of instrument trays (i.e., not laying instrument trays flat or parallel to the shelf)

- Incorrect placement of paper-plastic pouches (e.g., placing pouches flat instead of on edge; not allowing sufficient space between pouches; not placing pouches with plastic sides facing one direction)
- Incorrect placement of basins (i.e., not placing basins on their sides so that water can drain)
- Incorrect placement of textile packs (i.e., not placing them on edge)
- Placement of packages too close together, impeding air removal and sterilant penetration in the load

**STERILIZER OR UTILITIES MALFUNCTIONS**

**Poor steam quality or quantity**
- Wet steam
  - Improper insulation of steam lines
  - Malfunction of trap in steam line or no trap in steam line
  - Malfunction of drain check valve or no drain check valve
  - Steam contact with a cold load
  - Too much water in steam produced at boiler
- Superheated steam
  - Improper heatup of chamber
  - Desiccated packaging materials (e.g., towels)
  - Steam pressure too low for the temperature
  - Excessive reduction of steam pressure too close to sterilizer
  - Faulty steam control valve or pressure reducer control valve
- Other steam problems
  - Variations in steam pressure because of clogged filter, poorly engineered piping, or excessive demands
  - Out-of-calibration pressure gauges and controllers
  - Clogged steam lines
  - Clogged steam supply strainer
  - Clogged chamber drain line, strainer, or chamber drain screen
  - Malfunction of valves

**Incomplete air removal**
- Inadequate vacuum or vacuum depth or other air removal system
- Clogged chamber drain line, strainer, or chamber drain screen
- Clogged vent lines
Leak caused by faulty door gasket
Leak in other areas of chamber
Plugged, faulty or incorrectly adjusted control valves
Low steam pressure
High water temperature
Inadequate water supply pressure
Clogged water supply strainer
Trapping of air by the load
Incorrect cycle parameters for the load

Inadequate cycle temperature
Out-of-calibration temperature gauge
Long heatup time for large loads (i.e., heat lag)
Clogged chamber drain line, strainer, or chamber drain screen
Variations in steam pressure because of clogged filter, poorly engineered piping, or excessive demands on steam supply

Presence of noncondensable gases in steam line and load
Inadequate steam supply pressure
Clogged steam supply strainer

Insufficient time at temperature
Out-of-calibration control timer
Inappropriate cycle parameters for the load being processed
Come-up time of less than 1.5 minutes in a 270°F to 275°F (132°C to 135°C) gravity-displacement cycle
Oversized load

Summary
Load control monitoring is a process in which a load is monitored and released based on the result of a BI PCD. 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. Competency testing of employees also ensures correct interpretation of the monitoring tools used to release nonimplant and implant loads and to routinely monitor the efficacy of the sterilization process. Using a self-contained BI with a one-, three- or four-hour readout for load control allows quarantining of all loads pending BI results which reduces the risk and cost of healthcare-associated infections because loads are not released until the BI is negative. This is about improving patient safety.

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. 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.

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

Sterile Process and Distribution CEU Information
CEU Applicant Name ________________________________
Address_________________________________________________________
City____________________ State________ Zip Code ________________

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.

IAHCSMM has awarded 1.5 Contact Points for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CE Application Form
This inservice is approved by the California Board of Registered Nurses, CEP 5770 for 1 contact hour. This form is valid up to five (5) years from the date of publication.
1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. KEEP A COPY FOR YOUR RECORDS.
6. Submit this form and the answer sheet to:
   TKMK Media, LLC
   healthVIE.com
   PO Box 25310, Scottsdale, AZ 85255-9998
7. For questions, contact craig@firstaccessmedia.com.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of healthVIE.com's receipt of the application.

Application
Please print or type.

Name______________________________________________________________
Mailing Address_____________________________________________________
City, State, Country, Zip____________________________________________
Daytime phone (                    )_______________________________________
Position/Title_______________________________________________________
Social Security or Nursing License Number _____________________________
Date application submitted _________________________________________
Signature __________________________________________________________

Offer expires June 2015

On a scale of 1-5, 5 being Excellent and 1 being Poor, please rate this program for the following:
1) Overall content _______________________
2) Met written objectives ________________
3) Usability of content ________________

Copyright©2010/TKMK Media L.L.C./All Rights Reseved. Reprint with permission from TKMK Media L.L.C.