3M’s Sterilization Tech Line FAQs
Sandra Velte, BA, CSPDT

May 2013
Objectives

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

1. Describe the procedure for routine sterilizer efficacy testing of steam sterilizers larger than 2 cubic feet, immediate-use (IUSS) steam sterilization cycles, and table-top steam sterilizers.
2. Describe the procedure for running the Bowie-Dick test.
3. Describe steps to take in the event of a positive biological indicator (BI) or failed internal chemical indicator.
4. Discuss guidelines and recommended practices for sterilization record keeping.

Test Questions

1. The Bowie-Dick test should be run in an otherwise empty chamber.
   A. True   B. False

2. The Bowie-Dick test should be run in a cold sterilizer chamber, without running a warm-up cycle first.
   A. True   B. False

3. According to the Association for the Advancement of Medical Instrumentation Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79), routine testing with a biological indicator process challenge device (BI PCD) is done in an empty chamber for sterilizers greater than 2 cubic feet and table-top sterilizers.
   A. True   B. False

4. According to AAMI ST79, routine testing with a BI PCD is done in a full chamber for immediate-use steam sterilization (IUSS) cycles.
   A. True   B. False

5. Commercially available BI PCDs are an option for monitoring table-top and IUSS cycles.
   A. True   B. False

6. Biological and chemical indicators directly measure the lethality of a sterilization cycle.
   A. True   B. False

7. To save time, the Bowie-Dick test and the BI PCD can be run at the same time.
   A. True   B. False

8. Sterilizer maintenance and repairs should be documented in a paper or electronic record keeping system.
   A. True   B. False

9. Sterilization records should be kept for seven years.
   A. True   B. False

10. The Association for the Advancement of Medical Instrumentation Ethylene oxide sterilization in health care facilities: Safety and effectiveness (ANSI/AAMI ST41) document recommends the use of a BI PCD in every other ethylene oxide sterilization cycle.
    A. True   B. False
Introduction

Have you ever wondered if the policies and procedures at your facility are in compliance with the most current guidelines and recommended practices from the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN)? Have you ever had a debate in your department about the proper way to monitor a certain sterilization cycle? Have you ever experienced a sterilization process failure and wished you had someone to help you troubleshoot the cause? Well, you are not alone. Every year, the 3M Sterilization Tech Line receives over 2500 calls on a variety of topics related to 3M sterilization products, recommended practices from AAMI and AORN, troubleshooting, and many others. This self-study, in-service article covers some of the most frequently asked questions from 2012.

QUESTION 1

In a prevacuum steam sterilizer, why do we need to run an empty-chamber, warm-up cycle before we run the Bowie-Dick test?

ANSWER 1

First, insufficient air removal in a dynamic-air-removal steam sterilizer, particularly in a prevacuum cycle, can defeat sterilization and result in non-sterile supplies, if undetected. Effective removal of air is critical to steam penetration and sterilization. The Bowie-Dick test is used to evaluate the efficacy of air removal and steam penetration in prevacuum steam sterilizers.

An improperly heated sterilizer could yield false Bowie-Dick test failures. A sterilizer that is tested from a “cold start” — that is, after the sterilizer has been turned on and before a load is processed — might fail the Bowie-Dick test. Therefore, it is recommended to first preheat the sterilizer to operating temperature by running an empty-chamber, warm-up cycle.

A Bowie-Dick test is a sensitive and rapid means of detecting residual air in the sterilizer chamber caused by air leaks, inadequate vacuum, inadequate steam penetration, and noncondensable gases in the steam supply. Noncondensable gases are air or other gases caused by boiler additives that can enter the chamber with the steam and inhibit proper steam penetration of the items in the load. If a sterilizer has an inadequate vacuum, air leak, or poor steam quality, air pockets may form inside the sterilizer and compromise sterility by allowing air pockets to form throughout the load.

A Bowie-Dick test is run every day, before the first processed load. If the sterilizer is used continuously, the test may be performed at any time, but should be performed at the same time every day.\(^{1}\)

QUESTION 2

Can we run the Bowie-Dick test for longer than the recommended 3.5–4 minutes?

ANSWER 2

No. The recommended exposure time for the Bowie-Dick test is 3.5 minutes. However, if a sterilizer cannot be set for half-minute increments, a 4-minute exposure time can be used. The exposure time should never exceed 4 minutes because even an extra minute could affect the results.

If longer exposure times are used, the sensitivity of the test is reduced and there is a risk of getting a false passing result. In other words, the Bowie-Dick test sheet could show a passing result even in the presence of an air pocket. Therefore, if the exposure time is longer than 4 minutes the test is considered invalid and the results are meaningless.\(^{1}\)

Since dry time does not have an affect on the outcome of the Bowie-Dick test results, it may be omitted to save time. A typical Bowie-Dick test cycle has only one minute of dry time.

The Bowie-Dick test should be placed on the bottom shelf, over the drain in an otherwise empty chamber. Be sure to follow the specific written instructions for use (IFU) from the manufacturer of the Bowie-Dick test you are using (see Figure 1).

Figure 1. Bowie-Dick test pack on bottom shelf over drain
QUESTION 3
To save time, can we run the biological indicator process challenge pack (BI PCD) along with the Bowie-Dick test?

ANSWER 3
No. The Bowie-Dick test should be run in an otherwise empty chamber to maximize the potential for detecting any residual air in the sterilizer chamber. The Bowie-Dick test pack should be the only item on the sterilizer cart because other packs in the chamber could entrain a percentage of the air and reduce the sensitivity of the test. (ANSI/AAMI ST79, Section 10.7.6)

On the other hand, routine sterilizer efficacy testing with a BI PCD in sterilizers larger than 2 cubic feet is conducted in a full load. A fully loaded chamber is the most challenging configuration for a sterilizer larger than 2 cubic feet because all of the air must be removed from the load to ensure adequate steam penetration into every pack. (ANSI/AAMI ST79, Section 10.7.2.2)

The BI PCD should be placed on the bottom shelf, over the drain and the load built around it (see Figure 2). Be sure to follow the specific written IFU from the manufacturer of the BI PCD you are using.

QUESTION 4
In the operating room, sometimes we need to run an immediate-use steam sterilization (IUSS) cycle. Should we run a gravity-displacement or prevacuum cycle?

ANSWER 4
When deciding which steam sterilization cycle to use, start by referring to the medical device manufacturer’s written IFU, which should identify the specific methods of cleaning, packaging and sterilization that have been validated by the manufacturer.

For IUSS cycles, it is recommended to use a containment device to ensure aseptic transfer from the sterilizer to the point of use. (ANSI/AAMI ST79, Section 8.6.2.1) Some container manufacturers specify exposure times longer than the times recommended by the sterilizer and medical device manufacturer, so you will need to reconcile any differences between the manufacturers of the sterilizer, the packaging material and the medical device. (ANSI/AAMI ST79, Section 8.6.1)

For example, you might have a medical device that requires a standard 4 minute 270°F prevacuum cycle, but the container you are using for IUSS requires a minimum of 5 minutes of exposure in a 270°F prevacuum cycle. In this case, you would run the longer 5 minute cycle required by the container manufacturer to ensure that adequate steam sterilization conditions are achieved inside the container.

AAMI ST79 now states for sterilization for immediate-use that unless a device manufacturer specifically recommends the use of gravity-displacement cycles, dynamic-air-removal cycles should be the cycle of choice. (ANSI/AAMI ST79, Section 8.6.1) And, the sterilizer manufacturer’s and device manufacturer’s written IFU should always be followed.

The medical device manufacturer’s written IFU should be provided with new medical devices upon purchase and with each set of loaner instruments. IFU can also be received by calling the manufacturer to request a copy or sometimes downloaded from the medical device manufacturer’s website. A system should be in place to keep IFU up-to-date.

There are a couple of ways you can collect medical device manufacturer’s IFU:
- Build your own library of documents, which can be quite time consuming, or
- Subscribe to an online database.

The oneSource Document Site founded by a company called Best Practice Professionals, Inc., provides “one stop shopping” for health care facilities looking for medical device manufacturer’s written IFU. A facility pays an annual subscription rate for this service. For more information, visit their website at www.oneSOURCEDocs.com.
QUESTION 5
What is a Process Challenge Device?

ANSWER 5
A Process Challenge Device, or PCD, is an item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process. Whenever you challenge a sterilization process you use a process challenge device that is representative of the load and that provides the greatest challenge to the load. (ANSI/AAMI ST79, Section 2.103, 10.5.4)

This can sometimes be confusing, so let’s take a closer look.

A process challenge device can contain any of the following monitoring tools:
- Biological Indicator
- Class 5 Integrating Indicator
- Biological Indicator and Class 5 Integrating Indicator
- Class 6 Emulating Indicator

The PCD you use will depend on the type of testing that is being performed and could be a user-assembled challenge test pack or test tray, or an FDA-cleared, commercially available PCD.

User-assembled PCDs include the AAMI 16-towel pack or a challenge test pack or tray. (ANSI/AAMI ST79, Section 10.5.4)

Similarly, there are no commercially available PCDs for IUSS cycles, so you need to make your own representative PCD. For example, in a table-top steam sterilizer, loads often consist of all peel pouches. Therefore, placing the BI inside of a peel pouch would be an appropriate BI PCD, as this would provide a challenge equivalent to the items being processed in the load. (ANSI/AAMI ST79, Section 10.7.3)

Figure 3. Biological indicator process challenge device (BI PCD) for testing immediate-use steam sterilizer (IUSS) 270°F/132°C prevacuum steam cycles that process rigid sterilization containers

Figure 4. Biological indicator process challenge device (BI PCD) placed in an empty load for testing immediate-use steam sterilizer (IUSS) 270°F/132°C prevacuum steam cycles that process rigid sterilization containers

Figure 5. Biological indicator process challenge device (BI PCD) for testing table-top sterilizers
In contrast, terminal loads that are processed in large steam sterilizers (i.e., sterilizers greater than 2 cubic feet) usually consist of mixed items (wrapped sets, towel packs, rigid containers, etc.). In this case, you might choose to use a commercially-available, FDA-cleared PCD that is representative of the load and provides the greatest challenge for the load. As discussed above, the BI PCD is run in a full load (see Figure 2). (ANSI/AAMI ST79, Section 10.7.2)\(^1\)

**QUESTION 6**

How do we test our immediate-Use Steam Sterilizer (IUSS)?

**ANSWER 6**

For all types of steam sterilizers, ANSI/AAMI ST79 recommends that routine sterilizer efficacy testing be performed with a biological indicator process challenge device (BI PCD) at least weekly, but preferably every day the sterilizer is used. If the sterilizer is prevacuum, a daily Bowie-Dick test is also recommended, which is run before the BI PCD test cycle.

If the IUSS sterilizer is used for multiple types of cycles, such as gravity-displacement and prevacuum, each sterilization mode should be tested separately. Additionally, each type of tray configuration in routine use for IUSS cycles should be tested separately.

If a sterilizer runs the same type of cycle (e.g., 270°F prevacuum for both 4 and 10 minutes) and the same type of packaging is used, then only the shortest, most challenging cycle needs to be routinely tested with a BI PCD (i.e., the 4 minute cycle).

For routine sterilizer efficacy testing of IUSS cycles, you need to make your own representative PCD (see Figure 3). For example, if you use a rigid container system for IUSS you would place a biological and chemical indicator inside the empty container and run it on the bottom shelf over the drain (see Figure 4). This testing is conducted in the morning before you start processing for the day. (ANSI/AAMI ST79, Section 10.7.1 & 10.7.4)\(^1\)

**QUESTION 7**

We had a positive biological indicator (BI). The cycle printout showed that the parameters of time and temperature were met, and the control BI was positive like it should be. What else should we look for?

**ANSWER 7**

That is a good question. Investigating steam sterilization process failures often involves an extensive conversation and sometimes multiple conversations to help figure out the problem.

There is a variety of sterilization monitoring tools available to help ensure the probability of sterility of a processed load. Each monitoring device has advantages as well as limitations.

With physical monitors, such as the sterilizer cycle printouts, the temperature that is recorded on the printout tape is the temperature taken at one location in the sterilizer, which is generally located near the drain. However, that same temperature may not have been achieved throughout the sterilizer chamber or inside all the packs in the load. To know whether steam penetrated to the inside of the packs, you rely on internal chemical indicators.

For load control, BI PCDs are used. Biological indicators provide evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological indicator PCDs are placed in the most difficult area in the sterilizer for the sterilant to penetrate.

A good way to start your investigation is to refer to the ANSI/AAMI ST79 Table 8 Checklist, found in Section 10, for a list of some of the more common reasons for sterilization process failures. Things like overloading the sterilizer, or running the incorrect cycle for the load, having poor steam quality or quantity, and sterilizer equipment issues are all areas to investigate. While human error, or operator error, is attributed to many BI failures, the one thing you don’t want to do is automatically write off the problem as an “operator error” without doing an investigation to prove that the problem was caused by human error. (ANSI/AAMI ST79, Section 10 & Table 8, on following page)\(^1\)

Monitoring tools tell us when things are going well. But their real value is to tell us when there’s a problem, or when something has gone wrong with the sterilization process. The next time you are investigating a sterilization process failure, feel free to call the 3M Sterilization Tech Line for troubleshooting assistance (1-800-441-1922 option 2).
### Table 8: Checklist for identifying reasons for steam sterilization process failures

<table>
<thead>
<tr>
<th>Operator errors</th>
<th>Sterilizer or utility malfunctions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect use and interpretation of monitoring tools</td>
<td>Poor steam quality or quantity</td>
</tr>
<tr>
<td>• Incorrect physical monitors for the load</td>
<td>• Wet steam</td>
</tr>
<tr>
<td>• Incorrect use of BI or BI PCD</td>
<td></td>
</tr>
<tr>
<td>– Incorrect selection of BI or BI PCD for the load</td>
<td></td>
</tr>
<tr>
<td>– Incorrect placement of BI PCD in the load (e.g., another pack was placed on top of the PCD)</td>
<td></td>
</tr>
<tr>
<td>– Incorrect incubation of BI</td>
<td></td>
</tr>
<tr>
<td>– Misinterpretation of BI result</td>
<td></td>
</tr>
<tr>
<td>– Incorrect documentation of BI result</td>
<td></td>
</tr>
<tr>
<td>• Incorrect use of Class 5 integrating CI PCD or Class 6 emulating CI PCD</td>
<td></td>
</tr>
<tr>
<td>– Incorrect selection of CI PCD for the load.</td>
<td></td>
</tr>
<tr>
<td>– Incorrect placement of CI PCD in the load (e.g., another pack was placed on top of the PCD)</td>
<td></td>
</tr>
<tr>
<td>– Misinterpretation of Class 5 integrating CI result or Class 6 emulating CI result</td>
<td></td>
</tr>
<tr>
<td>– Incorrect documentation of Class 5 integrating CI result or Class 6 emulating CI result</td>
<td></td>
</tr>
<tr>
<td>• Incorrect use of internal CI</td>
<td></td>
</tr>
<tr>
<td>– Incorrect selection of internal CI for the load</td>
<td></td>
</tr>
<tr>
<td>– Misinterpretation of internal CI result</td>
<td></td>
</tr>
<tr>
<td>– Incorrect documentation of internal CI results</td>
<td></td>
</tr>
<tr>
<td>• Incorrect storage of any CIs or BiFs</td>
<td></td>
</tr>
<tr>
<td>• Failure to check physical monitors for functionality before running cycle</td>
<td></td>
</tr>
<tr>
<td>• Use of broken media ampoule or ampoule with missing spore strip</td>
<td></td>
</tr>
<tr>
<td>• 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)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Selection of incorrect cycle for load contents (containment device or medical device manufacturer’s written IFU not followed)</th>
<th>Incomplete air removal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of inappropriate packaging materials or packaging technique</td>
<td></td>
</tr>
<tr>
<td>• Incorrect packaging or containment device for the cycle parameters</td>
<td>• Inadequate vacuum or vacuum depth or other air removal system</td>
</tr>
<tr>
<td>• Incorrect preparation of containment device for use (e.g., incorrect filters, valves, or bottom tray)</td>
<td></td>
</tr>
<tr>
<td>• 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</td>
<td></td>
</tr>
<tr>
<td>• Use of a tray that does not allow air removal and steam penetration</td>
<td></td>
</tr>
<tr>
<td>• Use of a wrapper that is too large for the application</td>
<td></td>
</tr>
<tr>
<td>• Placement of a folded paper–plastic pouch inside another paper–plastic pouch</td>
<td></td>
</tr>
<tr>
<td>• 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</td>
<td></td>
</tr>
<tr>
<td>• Incorrect placement of basins in set (i.e., basins are not aligned in the same direction)</td>
<td></td>
</tr>
<tr>
<td>• Failure to use nonlinting absorbent material between nested basins</td>
<td></td>
</tr>
<tr>
<td>• Preparation of textile packs that are too dense to sterilize with the cycle parameters chosen</td>
<td></td>
</tr>
<tr>
<td>• 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)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incorrect loading of sterilizer</th>
<th>Inadequate cycle temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Stacking of containment devices if not recommended by manufacturer</td>
<td>• Out-of-calibration temperature gauge</td>
</tr>
<tr>
<td>• Stacking of perforated instrument trays</td>
<td></td>
</tr>
<tr>
<td>• Incorrect placement of instrument trays (i.e., not laying instrument trays flat or parallel to the shelf)</td>
<td></td>
</tr>
<tr>
<td>• 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)</td>
<td></td>
</tr>
<tr>
<td>• Incorrect placement of basins (i.e., not placing basins on their sides so that water can drain)</td>
<td></td>
</tr>
<tr>
<td>• Incorrect placement of textile packs (i.e., not placing them on edge)</td>
<td></td>
</tr>
<tr>
<td>• Placement of packages too close together, impeding air removal and sterilant penetration in the load</td>
<td></td>
</tr>
</tbody>
</table>

QUESTION 8
We just purchased rigid sterilization containers. Where should we place the internal chemical indicators?

ANSWER 8
ANSI/AAMI ST79 recommends that the internal chemical indicator be placed in the area that is least accessible to steam penetration. For containment devices, the container manufacturer’s IFU should be consulted. (ANSI/AAMI ST79, Section 10.5.2.2.2)1

AORN provides more specific guidance on placement of internal chemical indicators in rigid sterilization containers. For example, AORN recommends placing internal chemical indicators in two opposite corners on each level. So for containers with multiple levels, there will be two internal chemical indicators on each level in opposing diagonal corners. (AORN, RP: Packaging Systems, IX)2

QUESTION 9
We had a chemical integrator fail in a pack that was processed in our main sterile processing department. Why would we have a failure in only one pack?

ANSWER 9
Internal CIs should be used within each package, tray, or rigid sterilization container system to be sterilized. Internal pack monitoring verifies that the sterilant penetrated to the point of placement in the pack and confirms that specific exposure conditions were met. (ANSI/AAMI ST79, Section 10.5.2.2.2)1

By placing an internal chemical indicator inside every pack, you can detect local problems that sometimes occur due to human error, sterilizer malfunction, or sterilant quality problems. Sometimes the sterilant may not penetrate an individual pack or packs. Failures inside packs can be caused by a number of things, such as an air pocket, a small leak in the vacuum system, not enough sterilant, or poor quality steam. Additionally, the pack itself may have been wrapped too densely, or the load could have been packed too tightly for the sterilant to penetrate. Even if the BI result is negative, the sterilant may not always penetrate each individual pack in the load.

QUESTION 10
If we open a package from a load that has a non-responding or failed internal chemical indicator, what action should we take with the rest of the load?

ANSWER 10
Internal chemical indicators are retrieved and read at the point of use. The contents of a package with a non-responding or failed chemical indicator result should not be used; rather, the package should be returned for reprocessing.

AAMI ST79 states that other packages in the load should be quarantined until the biological indicator result is available. If no BI results are available, then a decision will need to be made whether to recall the load based on physical monitors and other CI results. (ANSI/AAMI ST79, Section 10.5.2.2.2)1

Some facilities choose to open and forfeit a couple of the more dense packs from that same load to see if indicators in those packs passed.

QUESTION 11
What information from my steam sterilization cycles do I need to keep?

ANSWER 11
For each sterilization load, the following information should be recorded:

- lot number
- date and time of the cycle
- load contents
- exposure time and temperature
- initials of the operator
- biological and chemical indicator results, including Bowie-Dick testing

Records of sterilizer maintenance, calibration, and repair are also required. (ANSI/AAMI ST79, Section 10.3.2)1

For IUSS cycles, AORN recommends to also record the name of the patient receiving the device and the reason the item needed to be sterilized by IUSS. (AORN, RP: Sterilization, VII.g.1)3
**QUESTION 12**

How should we keep, or store these sterilization records?

**ANSWER 12**

Documentation can be accomplished with the use of a paper or electronic record keeping system, or a combination of both. With a paper system, envelopes can be used to store sterilizer items, such as cycle printout tapes and Bowie-Dick test sheets. Load record cards and log books are other examples of paper record keeping tools.

It is not so important the method used to collect the information as having complete and accurate records, and a system that will allow for easy retrieval of data. Electronic documentation offers certain advantages, such as the ability to access past records instantaneously, as all load information is in one location (see Figure 7).

**Figure 7. Electronic record keeping system**

The length of time that records must be retained varies throughout the country. Each healthcare facility is responsible for determining its record-retention policy based on state and local regulations, legal considerations, and its individual situation. Consult with your Risk Manager to find out how long sterilization records need to be maintained at your facility. (ANSI/AAMI ST79, Section 10.3.2)1

---

**QUESTION 13**

How often should we run a biological indicator in our ethylene oxide (EO) sterilizer?

**ANSWER 13**

According to ANSI/AAMI ST41, every ethylene oxide sterilization cycle should be routinely monitored with a BI PCD.

As you probably know, a BI is a test system containing viable microorganisms that provides a defined resistance to a specified sterilization process. The spore that provides resistance to the ethylene oxide process is *Bacillus atrophaeus*. (ANSI/AAMI ST41, Section 10.5.3.1 & 10.6.1)4

As with steam sterilization, the BI PCD can be either a user-assembled challenge pack, or a commercially available, FDA-cleared preassembled test pack.

**QUESTION 14:**

How long should we aerate our Ethylene Oxide (EO) loads?

**ANSWER 14:**

The ability of EO to penetrate into complex devices and long lumens, without breaking down, makes it an excellent low temperature sterilant. However, devices that are sterilized by ethylene oxide must be adequately airdried to remove residual EO prior to patient use.

Aeration time depends on many variables, including the composition of the device; its wrapping material; aeration process variables, such as temperature; and the intended application of the device. For example, will the device be used externally or is it an implantable? All of these variables will influence permissible residual EO levels.

Refer to the medical device manufacturer’s IFU for aeration time and temperature recommendations. The manufacturer is required to conduct studies to determine the necessary aeration time and is responsible for providing this information to you.

For general guidance on aeration, you can consult ANSI/AAMI ST41. PVC, or polyvinyl chloride, is a polymer that is very difficult to aerate and default aeration times based on the aeration of PVC are provided in the ANSI/AAMI ST41 EO document. (ANSI/AAMI ST41, Section 8.8.4)4
Summary

- To avoid false fail results, an empty-chamber warm-up cycle is recommended before running the Bowie-Dick test. To ensure accurate results, the Bowie-Dick test is run in an otherwise empty chamber. Exposure time is 3.5–4 minutes, no longer.
- In sterilizers greater than 2 cubic feet and table-top sterilizers, routine testing with a BI PCD is conducted in a fully loaded chamber. On the other hand, IUSS cycles are tested with the containment device or other packaging configuration (BI PCD) but no instruments in an empty load. Each type of tray configuration used should be tested separately.
- The Bowie-Dick test and the BI PCD are placed in the most challenging location in the sterilizer chamber, which is generally the bottom shelf over the drain.
- When choosing which type of cycle to use (gravity vs. prevacuum) follow the validated instructions for use from the manufacturer of the medical device, sterilizer, and packaging.
- To ensure easy access to current manufacturer’s IFU, build your own library or subscribe to an online database, such as oneSOURCEdocs.com.
- A PCD, or process challenge device, is another term for test pack or challenge pack. A PCD is representative of the load and creates the greatest challenge. A PCD can contain a BI, a BI and Class 5 integrating indicator, a Class 5 integrating indicator, or a Class 6 emulating indicator. A PCD can be user-assembled or commercially available.
- Monitoring tools such as physical monitors, chemical and biological indicators, and PCDs are used to indicate when something has gone wrong. Use the Table 8 Checklist in ANSI/AAMI ST79 when investigating a sterilization process failure.
- Biological indicators are the only monitoring tool that directly measures the lethality of a sterilization cycle.
- Each item to be sterilized should contain at least one internal CI that is placed in the location that is least accessible to steam penetration. AORN recommends placing two CIs in opposite corners on each level of a rigid sterilization container. Internal CIs detect local problems that can occur due to loading or wrapping errors, inadequate air removal or steam penetration, poor steam quality, or sterilizer malfunction. A package with a failed internal CI should not be used, but returned for reprocessing. The load should be quarantined until the BI result is known. If no BI result is available, the decision to recall the load or not needs to be made based on the physical monitors and other CI results.
- Pertinent information from each sterilization cycle should be documented and kept in a paper or electronic record keeping system. Sterilizer repair and maintenance records should also be kept. Each facility needs to develop its own records retention policy.
- A BI PCD is run with every load in an EO sterilizer. The length of aeration time required for a particular medical device is determined by the manufacturer.
- The next time you have a question, please feel free to call us at 1-800-441-1922 option 2.

References

### Sandra Velte, BA

Sandra Velte, BA, is one of the voices at the end of the 1-800-441-1922 3M Healthcare Techline for Sterilization Assurance products (option 2). In this role, she answers technical questions about 3M products, troubleshoots sterilization process failures, and provides information related to sterilization best practices. Sandra is a member of the Minnesota Healthcare Central Service Members Association (MHCSMA) and the International Association of Healthcare Central Service Material Management (IAHCSMM) and is a certified Central Sterile Processing and Distribution Technician.

### Answers

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>A</td>
</tr>
<tr>
<td>2.</td>
<td>B</td>
</tr>
<tr>
<td>3.</td>
<td>B</td>
</tr>
<tr>
<td>4.</td>
<td>B</td>
</tr>
<tr>
<td>5.</td>
<td>B</td>
</tr>
<tr>
<td>6.</td>
<td>B</td>
</tr>
<tr>
<td>7.</td>
<td>B</td>
</tr>
<tr>
<td>8.</td>
<td>A</td>
</tr>
<tr>
<td>9.</td>
<td>B</td>
</tr>
<tr>
<td>10.</td>
<td>B</td>
</tr>
</tbody>
</table>
Sterile Process and Distribution CE Information

CE Applicant Name: ____________________________  City: ____________________________
Address: ____________________________________  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 re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, Inc. 148 Main St., Lebanon, NJ, 08833 or call 908-236-0530 or 1-800-555-9765 or visit the website at www.sterileprocessing.org.

IAHCSMM has awarded 1.5 approved 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:
   3M Infection Prevention
   Attn: HC4160
   RR Donnelly Fulfillment Services
   585 Hale Avenue North
   Oakdale, MN 55128-9935

7. For questions please call the 3M Healthcare helpline: 1-800-228-3957.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of RR Donnelly's receipt of the application.

Application  Please print clearly or type.

Name: __________________________________________
Mailing Address: __________________________________
City: ____________________________  State: ____________________________  Zip Code: ____________________________
Country: ____________________________
Daytime phone: (_________)  Position/Title: ____________________________
Social Security or Nursing License Number: ____________________________
Date application submitted: ____________________________
Signature: ____________________________

Offer expires May 2018

3M Infection Prevention Division
3M Health Care
2510 Conway Avenue
St. Paul, MN 55144-1000
U.S.A.
1 800 228-3957
www.3M.com/infectionprevention