Quality Control of Table-top Steam Sterilizers Update

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Objectives

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

1. Develop policies and procedures for sterilizer qualification testing.
2. Develop policies and procedures for routine use of the sterilizer.
3. Develop policies and procedures for a recall.
4. Develop policies and procedures for product testing.

Test Questions

1. A biological indicator process challenge device (BI PCD) for a table-top steam sterilizer is a challenge or test pack that is representative of the same type of package or tray that is considered the most difficult to sterilize and includes items that are routinely processed.
   A. True  B. False

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2. Sterilizer qualification testing (e.g., testing when sterilizer is installed, relocated, after malfunctions, major repairs and sterilization process failures) is done in three consecutive empty loads.
   A. True  B. False

3. Follow the device manufacturer’s reprocessing instructions if the sterilization times are longer than the sterilizer manufacturer’s minimum recommended sterilization times.
   A. True  B. False

4. An internal chemical indicator inside the pack that has reached its endpoint does not indicate that the sterilant penetrated the pack.
   A. True  B. False

5. If the external or internal chemical indicator has not reached its endpoint, do not release the tray or package for use.
   A. True  B. False

6. If a table-top steam sterilizer is designed to be used for multiple types of modes or cycles (e.g., 270°F-274°F/132°C-135°C unwrapped instruments, 270°F-274°F/132°C-135°C wrapped instruments or peel pouches, or 250°F/121°C wrapped packs), then each sterilization mode or cycle should be routinely tested with a biological indicator process challenge device (BI PCD).
   A. True  B. False
7. Each load containing implantable devices should be monitored with a biological indicator process challenge device (BI PCD) and quarantined until the results of the BI are available.
   A. True  B. False

8. It is not necessary to incubate a control biological indicator each day a test biological indicator is run and incubated.
   A. True  B. False

9. The more often the sterilization process is monitored with a BI and the sooner the results are obtained, the greater the chance of detecting a sterilization process failure earlier, thus reducing the risk of a potential infection to the patient and the cost of recall.
   A. True  B. False

10. A positive biological indicator initiates a recall of all medical devices processed since the last load showing a negative biological indicator if the cause of the failure is immediately identified (usually operator error) and confined to one load.
    A. True  B. False

**Introduction**

This inservice provides an overview of quality control for table-top steam sterilizers located in office-based, ambulatory-care medical, surgical, and dental offices and replaces and updates the inservice Quality Control of Table-Top Steam Sterilizers published in July, 2007. Proper sterilization of medical devices in these settings is just as important as the sterilization of medical devices being done in large healthcare facilities. The information in this inservice is based on the Association for the Advancement of Medical Instrumentation (AAMI) recommended practices whose goal is to promote sterility assurance and assist healthcare personnel in the proper use of steam sterilization process equipment.


> "Compact steam sterilizer that has a chamber volume of not more than 2 cubic feet and that generates its own steam when distilled or deionized water is added by the user.” (ANSI/AAMI ST79 Section 2.129)\(^1\)

No matter the size or location of a steam sterilizer, “quality control involves continuous supervision of personnel performance and work practices and ongoing verification of adherence to established policies and procedures.” (ANSI/AAMI ST79 Section 10.1)\(^1\)

Quality control includes:

- development of policies and procedures, staff training and competency testing;
- sterilizer qualification testing;
- routine use of the sterilizer;
- selecting the correct cycle and drying time for the load contents;
- steam generation;
- monitoring with physical, chemical and biological indicators;
- routine load release for nonimplants;
- release criteria for implants;
- record keeping;
- recall; and
- periodic product quality assurance testing of routinely processed items.

**Develop Policies, Procedures and Staff Training**

Policies and procedures provide guidelines for maintaining control and determining methods of improving processes and products. These policies and procedures should also be developed based on:

- Federal, state and local regulations;
- Recommendations of the Centers for Disease Control and Prevention;
- National voluntary standards and recommended practices (i.e., AAMI, AORN); and
- Device/equipment manufacturers’ recommendations. (ANSI/AAMI ST79 Section 11.2)\(^1\)

The Joint Commission says:

- “The hospital considers clinical practice guidelines when designing or improving processes.” (LD.04.04.07) (Joint Commission, p. 127)
- “The hospital provides care, treatment, and services in accordance with licensure requirements, laws and regulations.” (LD.04.01.01)(Joint Commission, p, 114)
- “Patients with comparable needs receive the same standard of care, treatment, and services throughout the hospital.” (LD.04.03.07)(Joint Commission, p. 118)\(^2\)

Ensure that policies and procedures are consistent throughout the healthcare network.

The importance of following evidence-based standards and professional organization guidelines is also stated in the National Patient Safety Goals of the Joint Commission (NPSG.07.05.01) for January 1, 2010. The goal is to reduce the risk of surgical site infections by aligning policies and practices with evidence-based standards and/or professional organization guidelines. (Joint Commission, p. 237)\(^2\)

ANSI/AAMI ST79 states “Education and training decrease the possibility of operator error during preparation and sterilization processing and help ensure that personnel are conversant with the latest data and techniques.”
Train, monitor and perform competency testing of personnel to ensure they are following policies and procedures. Critical thinking skills are necessary to:

- understand the science behind the policies and procedures;
- avoid human errors; and
- improve the outcome of the sterilization process.

Continuous training and competency assessments help to minimize or eliminate human errors, which are the major contributor to sterilization process failures. Support ongoing continuing education and certification of employees to recognize the importance of their role in improving patient safety and properly performing the steps of the sterilization process.

**Practical Application**
- Use current device/equipment manufacturers’ recommendations, federal, state, and local regulations, voluntary standards and recommended practices to keep policies and procedures up-to-date.

**Before the Sterilizer is Put into Routine Use**

Prior to routine use of the sterilizer, work with the information provided by the manufacturer and in-house maintenance staff (if available) to ensure that the table-top steam sterilizer is installed correctly and has the correct utilities to function consistently and properly.

**STERILIZER QUALIFICATION TESTING AT TIME OF INSTALLATION**

Verify that the sterilizer is functioning correctly and ready for routine use by testing it with a biological indicator process challenge device (BI PCD) (previously referred to as a BI challenge or test pack). Each type of sterilization mode or cycle used (e.g., 270°F-274°F/132°C-135°C unwrapped instruments, 270°F-274°F 132°C-135°C wrapped instruments or peel pouches, or 250°F/121°C wrapped packs) should be tested. (ANSI/AAMI ST79 Section 10.8.1.1) Since there are no universally accepted standardized PCDs for table-top steam sterilizers, the BI PCD should be representative of the same type of package or tray that is routinely processed. The package should be selected from those most frequently processed and contain the items normally present during routine sterilization. (ANSI/AAMI ST79 Section 10.8.3.1). Table 1 lists some examples of BI PCDs that are appropriate for commonly used sterilizer modes or cycles. See Figure 1 which shows from right to left a BI PCD for sterilizer modes or cycles containing; instruments in a peel pouch, unwrapped instruments, and wrapped packs.

A biological indicator containing *Geobacillus stearothermophilus* spores is placed in the BI PCD in the most challenging area for the sterilant to penetrate. For example, in a wrapped pack containing absorbent material the BI should be placed in the geometric center. Use of a self-contained BI with a one- or three-hour readout allows the sterilizer to be placed into routine use in the shortest amount of time. Check with both the sterilizer and BI manufacturer to make sure the correct BI is being used for the cycles being tested. Place a chemical indicator (CI) next to the BI. See Table 2 for more information about the Classes of CIs.

**Table 1. BI PCDs for Sterilizer Qualification Testing and 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 (Challenge or Test Pack)</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 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.*
Choose the appropriate BI Process Challenge Device (PCD) (see Table 1) for each type of sterilization mode or cycle (e.g., 270°F-274°F/132°C-135°C unwrapped instruments, 270°F-274°F/132°C-135°C wrapped instruments or peel pouches, 250ºF/121ºC wrapped packs, 250ºF/121ºC) that will be used.

Place a BI and CI in the area of the PCD determined to create the greatest challenge to air removal and sterilant penetration.

Place the BI PCD in a full load in the coldest area of the sterilizer chamber as determined by the sterilizer manufacturer. Normally this is “the center of the load towards the front of the chamber.”

Run one of the sterilization modes or cycles.

Read and record the results of the CIs.

Quarantine the load contents.

Incubate the BI test and control vials. Read and record the results when available.

Repeat this test for a total of three consecutive full cycles for each sterilization mode or cycle used.*

If it is a dynamic-air-removal sterilizer, run a Bowie-Dick test pack in three consecutive empty cycles according to the sterilizer manufacturer’s instructions for use. All the test sheets must show a uniform color indicating a pass.

If all the CIs in the BI PCDs reach their endpoint response, the BIs are negative and the Bowie-Dick tests show a pass, release the sterilizer for routine use.

Release the quarantined loads for use.

*Run three consecutive cycles for each sterilization mode or cycle used. Up to 12 cycles could be tested with BI PCDs if all four sterilization modes are routinely used. If required, the Bowie-Dick testing would require three more cycles.

This creates the most severe challenge to the sterilizer. Normally this is “the center of the load towards the front of the chamber.”

Run one BI PCD in three consecutive full cycles, one right after the other, according to the sterilizer manufacturer’s instructions to ensure consistent performance of the sterilizer.

At the end of each cycle, remove the CI from the PCD and record the results. Remove the BI from the PCD and incubate according to manufacturer’s instructions. Quarantine the rest of the loads until the BI results are known.

Each day test vials (processed vials) are incubated, incubate at least one BI from the same lot that has not been exposed to the sterilization process as a control. The control is used to verify that:

- the spores are viable;
- the media can promote growth of the test spores; and
- the incubator is operating at the proper temperature.

The control must be positive for the test results to be valid. If the control is negative the test results are invalid, and the reason should be identified, corrected and testing repeated.

Read the results of the BIs at the end of the incubation time. Record all testing results.

When the test BIs are all negative and the control is positive, the sterilizer is ready to be placed into routine use and the quarantined loads can be released.

If the table-top steam sterilizer has a dynamic-air-removal system (i.e., vacuum-assisted or pre-vacuum), check with the sterilizer manufacturer about the proper procedure for running a Bowie-Dick test pack.

The same qualification testing should be performed after an event occurs that may affect the performance of the sterilizers. These events include:

- sterilizer relocation;
- sterilizer malfunctions;
sterilizer major repairs;
• A major repair is a repair outside the scope of normal maintenance. This includes weld repairs of the pressure vessel, replacement of the chamber door or major piping assembly, or rebuilds or upgrades of controls. Normal preventive maintenance, such as the rebuilding of solenoid valves or the replacement of gaskets, is not considered major repair. Changes to the utilities connected to the sterilizer such as those that result from a water-main break, annual boiler maintenance, additional equipment loads and installation of new boilers should be treated as major repairs.
• and, sterilization process failures. (ANSI/ AAMI ST79 Section 10.8.1)

See Figure 3 on page 74 for how to perform the sterilizer qualification testing.

Practical Application
• Perform sterilizer qualification testing on a table-top sterilizer at time of installation, after relocation, malfunctions, and major repairs and after sterilization process failures.
• Prepare a BI PCD that is representative of the same type of package or tray that is considered the most difficult to sterilize and is routinely and most frequently processed.
• Place the BI PCD in the center of a full load and quarantine the load until the BI results are available.

Routine Use of the Sterilizer
Now that the sterilizer qualification testing is complete, routine use of the sterilizer begins.

SELECT THE CORRECT CYCLE AND DRYING TIME FOR THE LOAD CONTENTS
Check with the medical device manufacturer (MDM) for reprocessing instructions. If the MDM’s recommended cycle is longer than the cycle recommended by the sterilizer manufacturer’s written instructions, follow the medical device manufacturer’s instructions. If the sterilizer timer can not be extended to meet the MDM’s instructions for use, the medical device cannot be processed in the table-top steam sterilizer. Make sure to choose the correct cycle for each medical device and packaging materials being used. If the correct cycle is not run, the medical devices will not be properly sterilized. Be sure to also perform the Periodic Product Quality Assurance Testing of Routinely Processed Items as described on page 84 whenever changes are made in packaging, product or load configuration, or materials.

In table-top steam sterilizers, residual moisture is trapped in the chamber. To achieve drying, it is necessary to vent the moisture to the atmosphere. Follow the sterilizer manufacturer’s drying instructions. These instructions typically are to open the door approximately one-half inch at the end of the cycle to allow moisture to escape, then initiate the drying cycle, which typically operates with the door open. A minimum of 10 minutes is recommended. (ANSI/AAMI ST79 Section 8.8.2) If there is no drying phase on the sterilizer, check with the manufacturer of the sterilizer for instructions on how to dry the load.

Practical Application
• Run the correct cycle and drying time for the load contents to ensure the medical devices are safe for the patient to use.

STEAM GENERATION
Table-top steam sterilizers generate their own steam. Follow sterilizer manufacturer’s instructions regarding water purity requirements, filling, draining, and general maintenance of the system. “Distilled or deionized water is generally recommended to help prevent the buildup of minerals in the steam generating system and to ensure the purity of the steam generated for sterilization.” (ANSI/ AAMI ST79 Section 3.3.4.1) Each day before the sterilizer is used, check to make sure there is enough water in the sterilizer reservoir for the number of loads to be processed.

Practical Application
• Each day make sure there is enough distilled or deionized water in the table-top sterilizer to sterilize the number of loads to be processed or the medical devices will not be safe for patient use.

PHYSICAL MONITORING (EQUIPMENT CONTROL)
Equipment control consists of monitoring the sterilizer prior to and during daily use to determine if the sterilizer is operating to the set conditions of time, temperature, pressure, air removal, moisture conditioning, and sterilant exposure. Physical monitoring provides real-time assessment that the sterilization conditions were achieved, a permanent record of those results and the first indication of a failed sterilization process. (ANSI/AAMI ST79 10.5.1) See Figure 4 on page 78 for an example of table-top sterilizer with a printer or recording device.
BOWIE-DICK TESTING (EQUIPMENT CONTROL)

If the table-top sterilizer does not have a dynamic-air-removal system (i.e., vacuum-assisted or pre-vacuum), then Bowie-Dick testing is not required. If the table-top sterilizer has a dynamic-air removal system (i.e., vacuum-assisted or pre-vacuum), a Bowie-Dick test pack (BD PCD) should be run each day in an empty chamber to detect air leaks, inadequate air removal, inadequate steam penetration, and noncondensible gases (e.g., air or gas from boiler additives). (ANSI/AAMI ST79 Section 10.7.6.1)

**Practical Application**
- Check with the table-top sterilizer manufacturer to determine if a Bowie-Dick test is required and if so, how to run it.

CHEMICAL INDICATORS (CIS)

Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer.

Internal Chemical Indicators (Pack Control)

Pack control uses internal chemical indicators to monitor the conditions inside individual packs to determine that the sterilant has penetrated to the location of the medical devices. ANSI/AAMI ST79 states:

> “An internal CI should be used within each package, tray, or rigid sterilization container system to be sterilized. This internal CI may be a single-variable indicator (Class 3 CI), multi-variable indicator (Class 4), or integrating indicator (Class 5). The class of CI chosen will depend upon how many critical process variables are to be monitored and how much information is desired about the sterilization process. The CI should be placed in that area of the package, tray, or containment device (rigid sterilization container system, instrument case, cassette, or organizing tray) considered to be least accessible to steam penetration; for a containment device, the manufacturer’s instructions for placement of the CI should be consulted. This location might or might not be the center of the package, tray, or containment device. Internal CIs should be used in the routine monitoring of items sterilized.” (ANSI/AAMI ST79 Section 10.5.2.2)

See Table 2 on page 79 for more information about the classes of CIs and their usage.

Personnel should be trained on how to interpret the results of each internal chemical indicator. When the package is opened, if the internal chemical indicator has not reached its appropriate

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Physical monitors include time, temperature, and pressure recorders such as chart displays, digital printouts and gauge readings. These physical monitors should be checked for functionality prior to the beginning of a cycle. If more than one sterilizer is available or more than one load is run per day, the sterilizer and cycle number should be identified on each package. After the cycle is complete, the cycle conditions should be verified by the operator who reads and initial the physical monitors for each cycle. The cycle printout or other physical monitors should be saved as part of record keeping. (ANSI/AAMI ST79 Section 10.5.1)•1 “Sterilizers that do not have recording devices should not be used.” (ANSI/AAMI ST79 Section 10.5.1)•1

If the physical monitoring shows a sterilizer malfunction or suspicious operation that cannot be corrected immediately then the cycle should be terminated and the load should be considered unsterile. The sterilizer should be removed from service and the malfunction corrected. The type of testing required before the sterilizer is placed into uses is discussed in Recall on page 82.

Physical monitoring will not detect loading and packaging problems that can interfere with steam sterilization because these monitors only measure the chamber temperature and not the temperature inside each package. That is why a complete sterilization monitoring program includes not only physical monitors, but also chemical and biological indicators.

**Practical Application**
- Verify by reading and initially the printout at the end of the cycle that the cycle conditions were correct for the load contents.
endpoints, suggesting inadequate steam sterilization processing, do not use the package. (ANSI/AAMI ST79 Section 10.5.2.2.2) Before deciding to recall the entire load, check the sterilizer physical monitoring information, results of internal chemical indicators in a select group of other packs from that load and quarantine the load if biological indicator results will be available.

### Practical Application

- Place a Class 4 multi-variable or Class 5 integrating indicator inside each package, peel pouch, tray or rigid sterilization container in the area determined to be the least accessible to steam penetration.
- Do not use the package if the internal CI has not reached an acceptable endpoint.

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#### Table 2. Chemical Indicator Classes and Practical Application (ANSI/AAMI ST79 Section 10.5.2.2.2)

<table>
<thead>
<tr>
<th>CLASS</th>
<th>DEFINITION</th>
<th>PRACTICAL APPLICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1: Process Indicators</td>
<td>“are intended for use with individual units, (e.g., packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. These indicators are also referred to as external CIs.”</td>
<td>Indicator tapes, indicator labels, and load cards are examples of external chemical indicators.</td>
</tr>
<tr>
<td>Class 2: Indicators for use in Specific Tests</td>
<td>“are intended for use in specific test procedures (e.g., the Bowie-Dick tests) as defined in relevant sterilizer/sterilization standards.”</td>
<td>Bowie-Dick tests are specific tests used to evaluate the sterilizer performance.</td>
</tr>
<tr>
<td>Class 3: Single-variable Indicators</td>
<td>“are designed to react to one of the critical variables* and intended to indicate exposure to a sterilization process at a stated value** of the chosen variable.”</td>
<td>An example of a single-variable indicator is a temperature tube that contains a chemical pellet that melts at a specific temperature. Single-variable indicators may be used for pack control monitoring but would not provide as much information as a Class 4 or Class 5 Chemical Indicator. Single-variable Indicators may also be used to determine that a specific temperature was reached at a specific location in the sterilizer chamber.</td>
</tr>
<tr>
<td>Class 4: Multi-variable Indicators</td>
<td>“are designed to react to two or more of the critical variables and intended to indicate exposure to a sterilization cycle at stated values** of the chosen variables.”</td>
<td>Multi-variable indicators are used as internal chemical indicators and are usually paper strips printed with a chemical indicator.</td>
</tr>
<tr>
<td>Class 5: Integrating Indicators</td>
<td>“are designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs”</td>
<td>Integrating indicators are used as internal chemical indicators. They may also be used as an additional monitoring tool to release loads that do not contain implants. For this additional monitoring the Class 5 integrating indicator must be used in the appropriate process challenge device (PCD).</td>
</tr>
<tr>
<td>Class 6: Emulating Indicators</td>
<td>“are cycle verification indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specific sterilization process.”</td>
<td>ANSI/AAMI ST79:2006, A1:2008, A2:2009 recommended practice “does not cover the use and application of Class 6 emulating indicators.”</td>
</tr>
</tbody>
</table>

*Critical variables*: “parameters identified as being essential to the sterilization process (and requiring monitoring).” (ISO definition 3.2)

**Stated value (SV)**: “value or values of a critical variable at which the indicator is designed to reach its endpoint as defined by the manufacturer.” (ISO definition 3.12) For example, a Class 5 Integrating Indicator with a stated value of 2.1 minutes at 135°C should reach its endpoint when tested at 135°C for 2.1 minutes in a resistometer. It will probably reach its endpoint sooner in a table-top sterilizer because of the come-up time.
External Chemical Indicators (Exposure Control)

Exposure control identifies processed medical devices from unprocessed medical devices at a glance. An external chemical indicator (Class 1) should be placed on the outside of each hospital assembled package or rigid sterilization container system unless the internal chemical indicator is visible (e.g., peel pouches, open perforated surgical trays). (ANSI/AAMI ST79 10.5.2.2.1)1 “The purpose of an external CI is to differentiate between processed and unprocessed items, not to establish whether the parameters for adequate sterilization were met.” (ANSI/AAMI ST79 10.5.2.2.1)1

After unloading the sterilizer, check the external indicator for each package. Do not release the tray or package for use if the chemical indicator has not reached its endpoint response.

CLASS 5 INTEGRATING INDICATORS FOR LOAD CONTROL

In addition to using a Class 5 integrating indicator as an internal CI, a Class 5 integrating indicator may be used in a process challenge device (PCD) that is representative of the load to monitor loads not containing implants to supplement the results of physical monitors and Class 1 process indicators. (ANSI/AAMI ST79 Section 10.5.4)2

If the Class 5 integrating indicator used for load control has not reached its acceptable endpoint, do not use the load, but reprocess.

**Practical Application**

- Class 5 integrating indicators in an appropriate PCD may be used to monitor nonimplant loads.

**BIOLOGICAL INDICATORS (LOAD CONTROL)**

Load control is the process by which a load is monitored and released based on the result of a BI in a process challenge device (PCD), commonly referred to as a test pack. “Biological indicators are the only sterilization process monitoring device that provides a direct measure of the lethality of the process.” (ANSI/AAMI ST79 10.5.3.1)1 Biological indicators should be incubated in accordance with the manufacturer’s instructions and facility policy and procedures.

ANSI/AAMI ST79 states that biological indicators should be used in PCDs:

- to routinely monitor sterilizers at least weekly, but preferably every day that the sterilizer is in use:
  - in each type of cycle for which a sterilizer is designed to be used
    - gravity-displacement at 132°C to 135°C [270°F to 275°F]
  - 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 (ANSI/AAMI ST79 10.5.3.2)1

- to monitor every load containing implants. (ANSI/AMI ST79 10.5.3.2)1 “The load should be quarantined until the results of the BI testing are available.” (ANSI/AAMI ST79 10.6.3)1

For example, if you run any of the above listed cycles routinely you need to run a BI PCD in each of those cycles weekly, preferably daily. The exception is “If you run the same type of cycle (e.g., dynamic-air-removal at 132°C to 135°C [270°F to 275°F] for different exposure times (e.g., 4 minutes and 10 minutes), then only the shortest cycle time needs to be tested.” (ANSI/AAMI ST79 10.5.3.2)1 See Figure 5 for how to perform routine sterilizer efficacy monitoring.

Using a self-contained biological indicator with a one- or three-hour readout for routine sterilizer efficacy monitoring in each load allows quarantining of all loads pending BI results, especially those containing implants. This helps eliminate recalls and reduces the risk to the patient and healthcare facility due to the use of a non-sterile medical device. This also minimizes costs.4 Check with the sterilizer and biological

**Figure 5. BI Routine Sterilizer Efficacy Monitoring of Table-Top Steam Sterilizers (ANSI/AAMI ST79 10.7.3)1**

1. Choose the appropriate BI Process Challenge Device (PCD) (see Table 1) for each type of sterilization mode or cycle (e.g., 270°F-274°F/132°C-135°C unwrapped instruments, 270°F-274°F/132°C-135°C wrapped instruments or peel pouches, 250°F/121°C wrapped packs, 250°F/121°C) that will be used.

2. Place a BI and CI in the area of the PCD determined to create the greatest challenge to air removal and sterilant penetration.

3. Place the BI PCD in a full load in the coldest area of the sterilizer chamber as determined by the sterilizer manufacturer. Normally this is “the center of the load towards the front of the chamber.”

4. Run the sterilization cycle.

5. Read and record the results of the Cls.

6. Incubate the BI test and control vials. Read and record the results when available.

7. Release the load if the monitoring results are correct.
indicator manufacturer to make sure you are using the correct BI for the cycles being tested.

**Practical Application**
- Monitor every load with a one- or three-hour readout BI to provide the same standard of care for all the “products” you process.

**ROUTINE LOAD RELEASE FOR NONIMPLANT LOADS**

The following monitoring should be done routinely for each load of nonimplants before it is released for use to ensure that the sterilization process was effective.
- read and initial physical monitors for each load;
- label every package with an external process indicator (Class 1);
- place an internal CI inside each package (Class 3, 4 or 5);
- if desired, place a PCD in the chamber containing
  - a BI,
  - a BI and a Class 5 integrating CI,
  - a Class 5 integrating CI;
- evaluate all quality control measures and data at the conclusion of the sterilization cycle (this should be done by an experienced, knowledgeable person);
- release loads only if the criteria for release are met. 
(ANSI/AAMI ST79 Section 10.5.4, 10.6.2)

**Practical Application**
- Monitor every load containing implants with a BI and a Class 5 integrating indicator PCD with a one or three-hour readout BI to provide the same standard of care for all the “products” you process.

**RELEASE CRITERIA FOR IMPLANTS**

A BI PCD containing a Class 5 integrating chemical indicator should be used in each load containing an implant. 
(ANSI/AAMI ST79 Section 10.5.4) The load “should be quarantined until the results of the BI testing are available.” 
(ANSI/AAMI ST79 10.6.3)

The following monitoring should be done:
- read and initial physically monitors for each load;
- label every package with an external process indicator (Class 1);
- place an internal CI inside each package (Class 3, 4, or 5);
- monitor with a PCD containing a BI and a Class 5 integrating CI;
- evaluate all quality control measures and data at the conclusion of the sterilization cycle (this should be done by an experienced, knowledgeable person);
- quarantine implant until BI is negative;
- release loads only if the criteria for release are met. 
(ANSI/AAMI ST79 Section 10.5.4, 10.6.3)

**DOCUMENTATION**

Documentation establishes accountability by documenting what materials have been processed and provides monitoring control evidence for those items. In the event of a sterilization process failure, good records will help you trace each package backward through the levels of monitoring control to the sterilization event itself.

Each item or pack should be labeled with a “lot control identifier” that designates the sterilizer identification number or code, the date of sterilization, and the cycle number (cycle run of the sterilizer). (ANSI/AAMI ST79 Section 10.3.1) Lot identification enables retrieval of items in the event of a recall, to trace problems such as wet packs to their source and to facilitate proper stock rotation. (ANSI/AAMI ST79 Section 10.3.1) In addition this label allows full traceability of the reprocessed medical device to the patient on whom it is used or in whom it is implanted. (ANSI/AAMI ST79 Section 10.3.1)

An expiration date or statement (e.g., “contents sterile unless package is damaged or opened”) on each item is important for stock rotation (e.g., use of “oldest” items first). (ANSI/AAMI ST79 Section 10.3.3) Each item should be inspected and not used if damaged or opened.

If the medical device is unwrapped the same information should be part of the load record:
- sterilizer identification and cycle number;
- contents of load;
- time and temperature of exposure phase of cycle;
- signature or identification of operator;
- date and time of cycle. (ANSI/AAMI ST79 Section 10.3.1)

Sterilization records should be recorded and maintained for each load to ensure real-time monitoring of the process, that cycle parameters have been met, to assist with recalls and establish accountability. (ANSI/AAMI ST79 Section 10.3.2) The information for each sterilization cycle includes:
- lot number;
- contents of load, including quantity, department and a specific description of the items (e.g., towel packs, type/name of instrument sets);
A recall back to the last negative BI should be initiated if the failure is not immediately identified. The action steps now state:

“b) If the cause of failure is immediately identified (usually operator error) and confined to one load or one item in the load (i.e., an item with a nonresponsive internal CI), the cause of the failure should be corrected and the load should be reprocessed. If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed (see 10.11). The sterilizer in question should be taken out of service for further investigation of root causes. See Figure 12 and Table 8 for guidance on how to conduct this investigation.” (ANSI/AAMI ST79 Section 10.7.5.1)\(^1\)

The recall order should be immediately communicated to affected departments and include:

- a) a list of all items processed back to the last negative BI;
- b) lot numbers of items to be recalled;
- c) identification of persons or departments to whom the order is addressed;
- d) information required to be recorded in terms of kind and quantity of products recalled; and
- e) specific action to be taken by the persons receiving the order such as returning or destroying products. (ANSI/AAMI ST79 Section 10.11.3)\(^1\)

The root cause of the sterilization process can be determined using the checklist from Table 8. Eighty-five percent of sterilization process failures are due to operator error. Ten percent are due to equipment malfunctions and 5 percent are due to utility problems.\(^5\)

The decision tree (Figure 12 on page 84) states that if the failure can be attributed to a sterilizer/utilities malfunction that requires a major repair then qualification testing should be done before the sterilizer is put back into routine use (see section on Sterilizer Qualification Testing at Time of Installation on page 73).
Figure 12 also states that if the failure can be attributed to a cause other than a sterilizer/utilities malfunction or if the failure cannot be attributed to a cause other than a sterilizer/utilities malfunction and the repair is minor then the sterilizer can be returned to service without conducting qualification testing.

Follow with a written report of the recall order that includes:

a) the circumstances that prompted the recall order;

b) corrective action(s) taken to prevent recurrence;

c) the total number of products intended to be recalled and the percentage actually recalled; and

d) verification that recalled items were reprocessed or destroyed, as appropriate. (ANSI/AAMI ST79 Section 10.11.4)

### Practical Application

- Recall all loads back to the last negative BI if a physical monitor, CI or BI failure occurs and an operator error is not immediately identified.
- If an operator error is immediately identified, correct the cause and reprocess the load.

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

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Periodic Product Quality Assurance Testing of Routinely Processed Items

This type of testing is done because the BI PCDs used may not reflect the same challenge as all items routinely processed. (ANSI/AAMI ST79 10.9) Product testing ensures the effectiveness of the sterilization process and helps to avoid wet packs.

Routinely sterilized products should be tested periodically and testing should also occur when “major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper.” (ANSI/AAMI ST79 10.9) This testing should also be done before rigid containers are placed into routine use.” (ANSI/AAMI ST79 10.10)

Multiple BIs and CIs (Class 3, Class 4, Class 5) should be placed within the product to be tested. The number of samples will depend on the size and configuration of the pack being tested. The product test samples should be labeled and placed among other products in a full load. After the sterilization process, the product testing samples should be opened, the test BIs should be retrieved and incubated along with a positive control BI from the same lot, and the results recorded along with the CI results. A photo of the placement of the BIs and CIs for your records would assist in recording the results according to location of the BIs and CIs.

The packages should also be inspected for evidence of moisture. “If moisture is observed, steps should be taken to remedy the problem.” (ANSI/AAMI ST79 Section 10.9) These include changing the packaging, adjusting the loading or decreasing the amount of metal in the load, selecting a longer sterilization and/or drying time, and adjusting the unloading and cooling procedure.

If any test results indicate a problem, an investigation should determine the cause, the problem should be corrected, and the products retested. “It might be necessary to change the configuration of the load and/or items within the package or to service the sterilizer.” (ANSI/AAMI ST79 Section 10.9) Product use should be discontinued until the problem is resolved.” (ANSI/AAMI ST79 Section 10.9) Document in the sterilization records the test protocol, the initial test results, corrective actions taken, and the final test results.

Summary

Monitoring of the table-top steam sterilization process is as complex and important as monitoring the larger steam sterilization processes used in healthcare facilities. Follow the AAMI recommended practices related to:

- development of policies and procedures and staff training;
- sterilizer qualification testing;
- routine use of the sterilizer;
- selecting the correct cycle and drying time for the load contents;
- steam generation;
- monitoring with physical, chemical and biological indicators;
- routine load release for nonimplants;
- release criteria for implants;
- documentation;
- recall; and
- periodic product quality assurance testing of routinely processed items.

Up-to-date policies and procedures based on recommended practices, staff training, competency testing, certification, and critical thinking skills help to ensure that the table-top steam sterilization process being used by your facility produces a sterile medical device that is safe for patient use.

Ordering Information

ANSI/AAMI ST79:2006, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
1. Order code: ST79 or ST79-PDF
2. Available in an attractive binder featuring sturdy metal rings, ledger-weight pages, and a laminated tab for each section for easy navigation. AAMI will issue revised pages that can be substituted into the binder when changes are made.
3. Also available in PDF format and as part of AAMI’s electronic CD and subscription products.
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4. Mail: AAMI, Customer Service Center, 1100 N. Glebe Road, Suite 220, Arlington, VA 22201-5762

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continued on page 91
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>
<tr>
<td>- Use of broken media ampoule or ampoule with missing spore strip</td>
</tr>
<tr>
<td>- Use of BI PCD or CI PCD that is missing the BI or CI</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>
</tr>
<tr>
<td>Selection of incorrect cycle for load contents (containment device or medical device manufacturer’s instructions for use not followed)</td>
</tr>
<tr>
<td>Use of inappropriate packaging materials or packaging technique</td>
</tr>
<tr>
<td>- Incorrect packaging or containment device for the cycle parameters</td>
</tr>
<tr>
<td>- Incorrect preparation of containment device for use (e.g., incorrect filters, valves, or bottom tray)</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>
</tr>
<tr>
<td>- Use of a tray that does not allow air removal and steam penetration</td>
</tr>
<tr>
<td>- Use of a wrapper that is too large for the application</td>
</tr>
<tr>
<td>- Placement of a folded paper–plastic pouch inside another paper–plastic pouch</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>
</tr>
<tr>
<td>- Incorrect placement of basins in set (i.e., basins are not aligned in the same direction)</td>
</tr>
<tr>
<td>- Failure to use nonlinting absorbent material between nested basins</td>
</tr>
<tr>
<td>- Preparation of textile packs that are too dense to sterilize with the cycle parameters chosen</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>
</tr>
<tr>
<td>Incorrect loading of sterilizer</td>
</tr>
<tr>
<td>- Stacking of containment devices if not recommended by manufacturer</td>
</tr>
<tr>
<td>- Stacking of perforated instrument trays</td>
</tr>
<tr>
<td>- Incorrect placement of instrument trays (i.e., not laying instrument trays flat or parallel to the shelf)</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>
</tr>
<tr>
<td>- Incorrect placement of basins (i.e., not placing basins on their sides so that water can drain)</td>
</tr>
<tr>
<td>- Incorrect placement of textile packs (i.e., not placing them on edge)</td>
</tr>
<tr>
<td>- Placement of packages too close together, impeding air removal and sterilant penetration in the load</td>
</tr>
</tbody>
</table>
Table 8. Checklist for identifying reasons for steam sterilization process failures (continued)

<table>
<thead>
<tr>
<th>Poor steam quality or quantity</th>
<th>Incomplete air removal</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Wet steam</td>
<td>• Inadequate vacuum or vacuum depth or other air removal system</td>
</tr>
<tr>
<td>- Improper insulation of steam lines</td>
<td>• Clogged chamber drain line, strainer, or chamber drain screen</td>
</tr>
<tr>
<td>- Malfunction of trap in steam line or no trap in steam line</td>
<td>• Clogged vent lines</td>
</tr>
<tr>
<td>- Malfunction of drain check valve or no drain check valve</td>
<td>• Leak caused by faulty door gasket</td>
</tr>
<tr>
<td>- Steam contact with a cold load</td>
<td>• Leak in other areas of chamber</td>
</tr>
<tr>
<td>- Too much water in steam produced at boiler</td>
<td>• Plugged, faulty or incorrectly adjusted control valves</td>
</tr>
<tr>
<td>• Superheated steam</td>
<td>• Low steam pressure</td>
</tr>
<tr>
<td>- Improper heatup of chamber</td>
<td>• High water temperature</td>
</tr>
<tr>
<td>- Desiccated packaging materials (e.g., towels)</td>
<td>• Inadequate water supply pressure</td>
</tr>
<tr>
<td>- Steam pressure too low for the temperature</td>
<td>• Clogged water supply strainer</td>
</tr>
<tr>
<td>- Excessive reduction of steam pressure too close to sterilizer</td>
<td>• Trapping of air by the load</td>
</tr>
<tr>
<td>- Faulty steam control valve or pressure reducer control valve</td>
<td>• Incorrect cycle parameters for the load</td>
</tr>
<tr>
<td>• Other steam problems</td>
<td></td>
</tr>
<tr>
<td>- Variations in steam pressure because of clogged filter,</td>
<td></td>
</tr>
<tr>
<td>poorly engineered piping, or excessive demands</td>
<td></td>
</tr>
<tr>
<td>- Out-of-calibration pressure gauges and controllers</td>
<td></td>
</tr>
<tr>
<td>- Clogged steam lines</td>
<td></td>
</tr>
<tr>
<td>- Clogged steam supply strainer</td>
<td></td>
</tr>
<tr>
<td>- Clogged chamber drain line, strainer, or chamber drain screen</td>
<td></td>
</tr>
<tr>
<td>- Malfunction of valves</td>
<td></td>
</tr>
</tbody>
</table>

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

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References

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2) Met written objectives ______________
3) Usability of content ________________

<01/10>

ANSWERS

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

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 IAHCSSMM, AORN (Professional Practice Issues Chair for AORN Specialty Assembly for Sterilization Processing and Materials Management), APIC and a certified Central Sterile Processing and Distribution Technician. Additional, 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.