Quality Control of Table-Top Steam Sterilizers

by Martha Young, BS, MS, CSPDT

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

True or False

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.
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.
3. Follow the device manufacturer's reprocessing instructions if the sterilization times are longer than the sterilizer manufacturer's minimum recommended sterilization times.
4. An internal chemical indicator inside the pack that has reached its endpoint does not indicate that the sterilant penetrated the pack.
5. If the external or internal chemical indicator has not reached its endpoint, do not release the tray or package for use.
6. If a table-top steam sterilizer is designed to be used for multiple types of modes or cycles (e.g., 270ºF-274ºF/ 132ºC-135ºC unwrapped instruments, 270ºF-274ºF/132ºC-135ºC wrapped instruments or peel pouches, 250ºF/121ºC wrapped packs, 250ºF/121ºC liquids), then each sterilization mode or cycle should be routinely tested with a biological indicator process challenge device (BI PCD).
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.
8. It is not necessary to incubate a control biological indicator each day a test biological indicator is run and incubated.
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.
10. When a positive biological indicator occurs, recall all items processed since the last negative biological indicator.

Many thanks to the team at 3M Health Care for working with Managing Infection Control *to provide the following accredited course. IAHCSMM has awarded one and one-half (1.5) contact points for completion of this continuing education lesson toward IAHCSMM recertification. The CBSPD has preapproved this inservice for one and one-half (1.5) contact hours for a period of five (5) years from the date of publication, and to be used only once in a recertification period. This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication. Instructions for submitting results are on page 97.*

Managing Infection Control *and 3M Health Care will be working collaboratively to provide continuing education courses in monthly editions of* Managing Infection Control.

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 the inservice with the same title published in July 2005. 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 recommended practices of the Association for the Advancement of Medical Instrumentation (AAMI), whose goal is to promote sterility assurance and assist healthcare personnel in the proper use of steam sterilization process equipment.

The AAMI *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, ANSI/AAMI ST79:2006, defines a

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table-top steam sterilizer as: "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."

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."[1] Quality control includes:

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

Develop Policies, Procedures and Staff Training

ANSI/AAMI ST79 states that: "Policies and procedures provide guidelines for maintaining control and determining methods of improving processes and products." Develop policies and procedures as required by the Joint Commission (JCAHO) based on the most stringent current scientific knowledge; accepted practice guidelines; and applicable laws, rules and regulation.

Ensure that policies and procedures are consistent throughout the healthcare network. For table-top steam sterilizers the most stringent recommended practice is published in ANSI/AAMI ST79:2006.

ANSI/AAMI ST79:2006 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 and monitor 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;
- 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.

Before the Sterilizer Is Put into Routine Use

Prior to routine use of the sterilizer, work with the information provided by the manufacturer of the sterilizer and any 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., 270ºF-274ºF/132ºC-135ºC unwrapped instruments, 270ºF-274ºF/132ºC-135ºC wrapped instruments or peel pouches, 250ºF/121ºC wrapped packs, 250ºF/121ºC liquids) should be tested. 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 considered the most difficult to sterilizer and includes items that are routinely processed. Table 1 lists the 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 containing wrapped packs.

Figure 1. Examples of BI PCDs

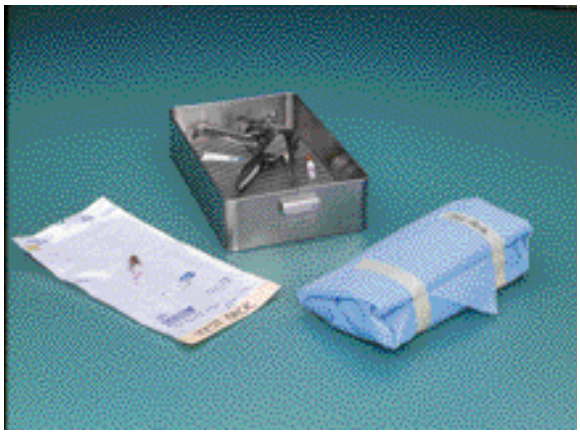


Table 1: BI PCDs for Qualification and Routine Sterilizer Efficacy Testing of Table-Top Steam Sterilizers

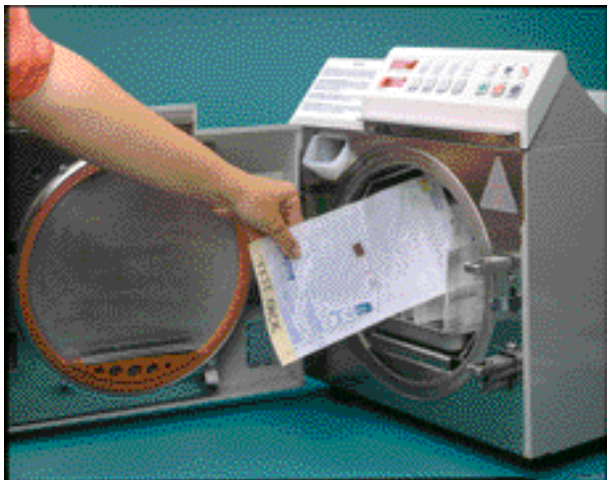
Program/Load	Temperature	Time*	BI PCD (Challenge or Test Pack)
Unwrapped instruments on a tray or glassware	270ºF-274ºF (132ºC-135ºC)	≥3 min	BI in unwrapped instrument tray or glassware
Wrapped trays of instruments, instruments in peel pouches	270ºF-274ºF (132ºC-135ºC)	≥5 min	BI in a wrapped tray or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

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

A biological indicator consisting of *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 biological indicator 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 biological indicator manufacturer to make sure the correct biological indicator is being used for the cycles being tested. Place a chemical indicator (CI) that is either a Class 4 multi-variable or a Class 5 integrating indicator next to the BI. See Table 2 on p.90 for more information about the classes of CIs.

Qualification testing with a BI PCD is done in a fully loaded chamber. This creates the greatest challenge for the limited amount of sterilant that enters the chamber of a table-top sterilizer.[1] Place the BI PCD on its edge, if it is a small pack, or flat if it is a tray or large pack, in the coldest area of the sterilizer chamber as determined by the sterilizer manufacturer. This creates the most severe challenge to the sterilizer. Normally this is "the center of the load towards the front of the chamber."[1]

Figure 2. Placement of BI PCD in load



Run a 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.[1] 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. See Figure 2 for placement of the BI PCD.

Each day that a test vial (processed vial) is 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:

- spores are viable;
- media can promote growth of the test spores; and
- the incubator is operating at the proper temperature.[1]

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 prevacuum), also run a Bowie-Dick-type test pack (BD PCD). Run the BD PCD in three consecutive empty cycles, one right after the other. The BD PCD evaluates the ability of the sterilizer to remove air, and also steam penetration before the sterilizer is used routinely. The BD PCD should be of a size appropriate for the chamber

being tested and equivalent to the performance of the defined AAMI Bowie-Dick towel test pack.[2] The cycle should be run for 3-1/2 to 4 minutes at 270ºF/132ºC. The BD test sheets should show a uniform color change (the color in the center should be the same as the color at the outer edges) for the sterilizer to be released for routine use.

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

- relocation,
- malfunctions,
- major repairs, and
- sterilization process failures.

ANSI/AAMI ST79 defines a major repair as: "... a repair outside the scope of normal maintenance, such as weld repairs of the pressure vessel; replacement of the chamber door, vacuum pump or a 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 a major repair."[1]

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

Figure 3. Sterilizer Qualification Testing of Table-Top Steam Sterilizers[1,2]

1. Choose the appropriate BI Process Challenge Device (PCD) (see Table 1) for each type of sterilization mode or cycle (e.g., 270ºF-274ºF/132ºC-135ºC unwrapped instruments, 270ºF-274ºF/ 132ºC-135ºC wrapped instruments or peel pouches, 250ºF/ 121ºC wrapped packs, 250ºF/121ºC liquids) 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.
4. Run one of the sterilization modes or cycles.*
5. Read and record the results of the CIs.
6. Quarantine the load contents.
7. Incubate the BI test and control vials. Read and record the results
8. Repeat this test for a total of three consecutive full cycles for each sterilization mode or cycle used.
9. If it is a dynamic-air-removal sterilizer, run a BD PCD in three consecutive empty cycles for 3-1/2 to 4 minutes at 270ºF/ 132ºC. All the test sheets must show a uniform color indicating a pass.
10. If all the CIs reach their endpoint response, the BIs are negative and the BD tests show a pass, release the sterilizer for routine use.
11. 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. The BD testing would require three more cycles.*

A complete sterilization monitoring program includes not only physical monitors, but also chemical and biological indicators.

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 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 cannot 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 p. 96 whenever changes are made in packaging, product or load configuration, or materials.[1]

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.[1] If there is no drying phase on the sterilizer, check with the manufacturer of the sterilizer for instructions on how to dry the load.

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."[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.

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.

Physical monitors include time, temperature and pressure recorders such as chart displays, digital printouts and gauge readings. The printout should be reviewed for correct conditions, and this review should be documented by initialing and dating the printout. The sterilizer and cycle number should be identified if more than one sterilizer is available or more than one load is run per day. These physical monitors should be checked for functionality prior to the beginning of a cycle, the cycle conditions verified by reading, and the printout marked by the operator at the end of the cycle for correct cycle information and saved as part of recordkeeping. Sterilizers without recording devices should not be used.[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 sterilizer should be retested (see *Sterilizer Qualification Testing at Time of Installation*).

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.

Bowie-Dick Testing (Equipment Control)

If the table-top sterilizer does not have a dynamic-air-removal system (i.e, vacuum-assisted or prevacuum), then Bowie-Dick testing is not required.

If the table-top sterilizer has a dynamic-air removal system (ie., vacuum-assisted or prevacuum), a Bowie-Dick test pack

Table 2: Chemical Indicator Classes and Practical Application[1,3]

Class	ISO 11140-1: 2005 Definition	Practical Application
Class 1: Process Indicators	"Process indicators 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. They shall be designed to react to one or more of the critical process variables."	Indicator tapes, indicator labels and load cards are examples of externally visible Chemical Indicators that are Process Indicators used for exposure control.
Class 2: Indicators for use in Specific Tests	"Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards."	Bowie-Dick type tests are specific tests used for equipment control to evaluate the sterilizer performance.
Class 3: Single Variable Indicators	"A single variable indicator shall be designed to react to one of the critical variables and is intended to indicate exposure to a sterilization process at a stated value (SV) of the chosen variable."	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 for exposure control monitoring. This temperature tube would be used to determine that a specific temperature was reached at a specific location in the sterilizer chamber.
Class 4: Multi-variable Indicators	"A multi-variable indicator shall be designed to react to two or more of the critical variables and is intended to indicate exposure to a sterilization cycle at SVs of the chosen variable."	Multi-variable Chemical Indicators are used for pack control. These internal Chemical Indicators are usually paper strips printed with a Chemical Indicator.
Class 5: Integrating Indicators	"Integrating indicators shall be designed to react to all critical variables. The SVs are generated to be equivalent to, or exceed the performance requirements given in the ISO 11138 series for BIs."	Integrating Indicators are the most precise of the internal Chemical Indicators. Integrating Indicators are used for pack control monitoring. They can 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 challenge test pack or Process Challenge Device (PCD). These indicators must now have SVs at 121ºC, 135ºC, and at least one more temperature in between. Also, the SV at 121ºC MUST be greater than 16.5 minutes to ensure performance is comparable to BIs in saturated steam.
Class 6: Emulating Indicators	"Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process."	Emulating Indicators can be used as internal Chemical Indicators for pack control. Emulating Indicators are specified for specific sterilization cycles which means an end user will need to inventory a different Class 6 Emulating Indicator for each sterilization cycle time and temperature (i.e., 3 min, 5 min, 10 min, 18 min, 40 min, etc) run in the facility. The response of a Class 6 Emulating Indicator does not necessarily correlate to a Biological Indicator, so the indicator cannot be used as an additional monitoring tool to release loads that do not contain implants. (See Class 5 definition) The use of Class 6 Emulating Indicators is presently not covered in any AAMI health-care facilities user documents.

(BD PCD) should be run each day in an empty chamber to evaluate the efficacy of air removal, and steam penetration before the sterilizer is used routinely. As stated in the *Sterilizer Qualification Testing at Time of Installation* section, the Bowie-Dick-type test pack should be of a size appropriate for the chamber being tested and equivalent to the performance of the defined AAMI Bowie-Dick towel test pack. The cycle should be run for 3-1/2 to 4 minutes at 270ºF/132ºC. The Bowie-Dick test sheets should show a uniform color change (the color in the center should be the same as the color at the outer edges) for the sterilizer to be released for use that day.

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. The CI should be placed in that area of the package, tray or container system considered to be least accessible to steam penetration. This location might or might not be the center of the package, tray or container system."[1]

Check with the medical device manufacturer for information about where to place the CI in the package, tray or container that would be the least accessible area to steam penetration. The CI should be a Class 4 multi-variable indicator or a Class 5 integrating indicator.[1] See Table 2 on p. 90 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 endpoint, suggesting inadequate steam sterilization processing, do not use the package.[1] Before deciding to recall the entire load, check the sterilizer physical monitoring

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.

information and 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.

External Chemical Indicators (Exposure Control)—Exposure control identifies processed medical devices from unprocessed medical devices at a glance. ANSI/AAMI ST79 recommended practice states that an external chemical indicator should be placed on the outside of each package unless the internal chemical indicator is visible (e.g., peel pouches, open perforated surgical trays). "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."[1]

An external chemical indicator should be a Class 1 indicator. 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.

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 devices that provide a direct measure of the lethality of the process."[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:

1. 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)
   - 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
2. To monitor every load containing implants. "The load should be quarantined until the results of the BI testing are available."[1]

**Each cycle programmed or used for an individual sterilizer must be tested with a BI PCD at least weekly, preferably every day the sterilizer is used. To avoid testing cycles not used daily, your policy and procedure should be written to test with a BI PCD each day or each time the cycle is used. See Figure 4 for how to perform the routine sterilizer efficacy testing.*

Figure 4. BI Routine Sterilizer Efficacy Testing of Table-Top Steam Sterilizers[1]

1. Choose the appropriate BI Process Challenge Device (PCD) (see Table 1) for each type of sterilization mode or cycle (e.g., 270ºF-274ºF/132ºC-135ºC unwrapped instruments, 270ºF-274ºF/132ºC-135ºC wrapped instruments or peel pouches, 250ºF/121ºC wrapped packs, 250ºF/121ºC liquids) 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.
4. Run the sterilization cycle.
5. Read and record the results of the CIs.
6. Incubate the BI test and control vials. Read and record the results.
7. Release the load if the monitoring results are correct.

Using a self-contained biological indicator with a one or three-hour readout for routine sterilizer efficacy testing 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 nonsterile medical device. This also minimizes costs.[4] Check with the sterilizer and biological indicator manufacturer to make sure you are using the correct BI for the cycles being tested.

Routine Load Release For Nonimplant Loads

The following monitoring should be done routinely for each load before it is released for use to ensure that the sterilization process was effective:

- Physically monitor each load.
- Label every package with an external process indicator.
- Place an internal CI inside each package.
- If desired, place a PCD containing a BI and/or a Class 5 integrating CI in the chamber to monitor loads not containing implants.
- 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 present.

Release Criteria for Implants

A BI PCD containing a Class 5 integrating chemical indicator should be used in each load containing an implant.[1] The load should be quarantined until the BI is negative to improve patient safety. The following monitoring should be done:
- Physically monitor each load.
- Label every package with an external process indicator.
- Place an internal CI inside each package.
- Monitor with a PCD containing a BI and/or a Class 5 integrating CI or an enzyme-only indicator.
- 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 present.

For further information on monitoring of implants, see "Condensation of the AAMI Steam Sterilization Recommended Practices, Quality Control (Section 10), Part 1, Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2006)" published in *Managing Infection Control*, September 2006.[5]

Recordkeeping

Recordkeeping documents 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" to enable 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. In addition this label allows traceability of the reprocessed medical device to the patient on whom it is used or in whom it is implanted. The "lot control identifier" should include the sterilizer number, the date of sterilization and the cycle number.[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). 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 states that sterilization records should be recorded and maintained for each load to ensure real-time monitoring of the process,

that cycle parameters have been met, and to assist with recalls and establish accountability.[1] The information for each sterilization cycle includes:

- lot number;
- contents of load;
- exposure time and temperature if not on a recording chart;
- operator identification;
- results of BI testing;
- results of the Bowie-Dick testing;
- results of chemical indicator (CI) in the PCD (BI challenge test pack, BI challenge test tray, CI challenge test pack);
- any reports of inconclusive or nonresponsive CIs in the load.

"Sterilizer records should be retained according to the policy and procedure established by the individual healthcare facility."[1]

Recall

If a positive BI is obtained, immediately phone or messenger the appropriate supervisor and infection control department. This notification should be followed by a written report. As stated in ANSI/AAMI ST79: "If it is determined that the sterilization failure was not the result of operator error (e.g., selection of the incorrect cycle), items processed in that sterilizer since the last negative BI results should be considered unsterile. They should be retrieved, if possible, and reprocessed (see 10.11). The sterilizer in question should be taken out of service."[1]

Use of a self-contained biological indicator with a one or three-hour readout allows the sterilizer to be placed back into routine use in the shortest amount of time.

Remember that a sterilization process failure could be the result of:

- a sterilizer failure:
  - not enough water in the reservoir;
  - incorrect time at temperature;
- incorrect packaging (too dense);
- incorrect loading:

- too large a load;
- incorrect placement of items (peel pouches not placed on side with paper side facing one way);

▸ selecting the wrong cycle parameters for the load (e.g., running a wrapped pack in the unwrapped cycle).

Eighty-five percent of sterilization process failures are due to human error. Ten percent are due to equipment malfunctions, and five percent are due to utility problems.[6]

To retest the table-top steam sterilizer, run a BI PCD in three consecutive full chamber cycles. For dynamic-air-removal sterilizers, a Bowie-Dick PCD should be run in three consecutive empty-chamber cycles. The testing protocol is discussed in detail in the *Sterilizer Qualification Testing at Time of Installation* section and in Figure 3.

Until the results of retesting are satisfactory (three cycles with negative BIs and three cycles with acceptable color change in the Bowie-Dick test sheet indicator), the performance of the sterilizer should remain questionable, and the sterilizer should not be put back into routine use.

The more often the sterilization process is monitored with a self-contained biological indicator with a one- or three-hour readout, the sooner the results are obtained, and 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.

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. Product testing ensures the effectiveness of the sterilization process and helps to avoid wet packs.

"Quality assurance testing of routinely processed items should be performed on an ongoing basis." Routinely sterilized products should be tested periodically, and testing should also occur when "major changes are made in packaging, wraps or load configuration,

such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper."[1]

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

The packages should also be inspected for evidence of moisture. "If moisture is observed, steps should be taken to remedy the problem."[1] 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."[1] Document in the sterilization records the test protocol, the initial test results, corrective actions taken, and the final test results.

Figure 5. Periodic Product Quality Assurance Testing of Routinely Processed Items[1]

1. Follow medical device manufacturer's instructions for processing the device.
2. Place CIs and BIs in the areas of the product determined to be the least accessible to steam penetration.
3. Label as a test.
4. Place in a standard load.
5. Run the cycle.
6. Retrieve CIs and BIs.
7. Read and record the results of the CIs.
8. Incubate the BI test and control vials. Read and record the results.
9. Place the product into routine use if the monitoring results are correct, and there is no evidence of moisture.

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:

1. development of policies and procedures and staff training;
2. sterilizer qualification testing;
3. 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;
   - recordkeeping;
4. recall; and
5. periodic product quality assurance testing of routinely processed items.

Up-to-date policies and procedures based on recommended practices, staff training, 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 improves patient outcomes.

Ordering Information

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ANSI/AAMI ST79:2006, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

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References

1. The Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79:2006.
2. The Association for the Advancement of Medical Instrumentation. Table-top steam sterilizers, ANSI/AAMI ST55:2004.
3. The Association for the Advancement of Medical Instrumentation. Sterilization of health care products-Chemical indicators-Part 1: General requirements, ANSI/AAMI/ ISO 11140-1:2005.

4. Ross, Edwin. Using Biological Monitoring to Reduce Infection, Risk, and Costs. Surgical Services Management. Vol. 4, No. 7, July 1986, p. 249.
5. Young, Martha. Condensation of the AAMI Steam Sterilization Recommended Practices, Quality Control (Section 10), Part 1, Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2006) published in Managing Infection Control, September, 2006.
6. Hancock, Charles. Person communications, 2006.

Martha Young, BS, MS, CSPDT, is a senior international technical service specialist in 3M Medical Products, St. Paul, Minn. She has more than 25 years of experience in the area of sterilization and disinfection. Young lectures around the world and has numerous publications on infection prevention with an emphasis on improving the performance of the sterilization process. She is a member of IAHCSMM, ASHCSP, AORN (Professional/Practice Issues Chair for AORN speciality assembly for Sterile Processing Materials Management) and APIC, and is a certified Central Sterile Processing and Distribution Technician. In addition she is a member of several AAMI working group committees that are developing recommended practices.

ANSWERS

1. T	6. T
2. F	7. T
3. T	8. F
4. F	9. T
5. T	10. T

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