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Learning Objectives

1. Identify the four stages of reprocessing instruments and medical supplies that must be accomplished in order to have an effective sterilization process.

2. List the steps involved for conducting an investigation of a sterilization process failure.

3. Identify reasons for steam sterilization process failures.

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Steam sterilization process failures and recalls: Taking the correct actions

by Rose Seavey, RN, BS, MBA, CNOR, CRCST, CSPDT

Did you ever wish you had someone to guide you through all the necessary steps of a sterilization recall, to help you identify the reasons for the process failure, or tell you what to do if a chemical indicator did not change, or the physical monitors were incorrect? Well, your wish has come true. The Association for the Advancement of Medical Instrumentation (AAMI) has addressed these very concerns in their most current edition of the *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, ANSI/AAMI ST79:2006, A1:2008, and A2:2009 which was published this summer.[1]

As a perioperative nurse and director of a Sterile Processing Department (SPD) for the last 30 plus years, I was very pleased to see AAMI give guidance for necessary actions to take when a Biological Indicator (BI) or Chemical Indicator (CI) Process Challenge Device (PCD) indicates a sterilization process failure or the physical monitors reveal inadequate cycle parameters.

This article covers the 2009 amendments to AAMI ST79 which address the specific actions to take after a sterilization process failure, as well as other related issues. The 2009 revisions related to sterilization recalls and process failures are located in sections:

- 10.6.4 Sterilization process failures, and
- 10.7.5 Actions to take when PCDs (BI challenge test packs or CI challenge test packs) indicate failure
  - o Figure 12 - Decision tree for conducting investigations of steam sterilization process failures, and
  - o Table 8 – Checklist for identifying reasons for steam sterilization process failures.

Back to basics

Let's do a review of sterilization and monitoring before we discuss questionable loads in detail. There are four stages of reprocessing instruments and medical supplies that must be accomplished in order to have an effective sterilization process. These critically interdependent phases are:

1. Lowering and limiting bioburden before sterilization,
2. Properly preparing items for sterilization,
3. Selecting the appropriate sterilization parameters, and
4. Establishing and implementing controls to maintain sterility of sterilized items until they are used.[1]

Current recommended practices for sterilization from AAMI and the Association for periOperative Registered Nurses (AORN) declare that any healthcare facility that reprocesses medical devices must have an effective quality control program that includes the following: monitoring of steam sterilization cycles using physical monitors and chemical and biological indicators; a product recall procedure; a continuous quality improvement program; appropriate documentation; and reporting practices that enable traceability of each facility-sterilized medical device to the patient.[1, 2]

Bad item or load...now what?

If you have worked in OR, SPD, or in Infection Prevention and Control (IPC) for any length of time, you most likely have had to deal with at least one sterilization recall. Fortunately, questionable loads do not happen very often, but when they do, you must take immediate action for the sake of patient safety.

When a facility has a questionable sterilization item or load, you, as the SPD professional, will need to respond quickly. You will need to rely on knowledge, experience and critical thinking skills to help determine if a questionable load was a result of an operator error or a sterilizer or utility malfunction. Now, thanks to AAMI, you have tools to help you do just that.

A sterilization process failure can be detected by any of the sterilization process monitoring tools critical to a comprehensive quality control program: physical monitors, chemical indicators, or biological indicators.

Physical monitor process failures

Physical monitors, e.g. the sterilizer digital printout, provide a real-time assessment of

the sterilization cycle parameters and help to detect malfunction of the sterilizer as soon as possible. If the physical monitor results are not acceptable or indicate a suspicious operation, the process should not be considered complete and the load not released for patient use. The sterilizer should be taken out of service until the malfunction is corrected. The facility sterilizer maintenance personnel should be notified to help determine the root cause of the process failure, and then perform any necessary repairs. Poor steam quality, operator error, or other factors can cause a normally functioning sterilizer to have a process failure.[1]

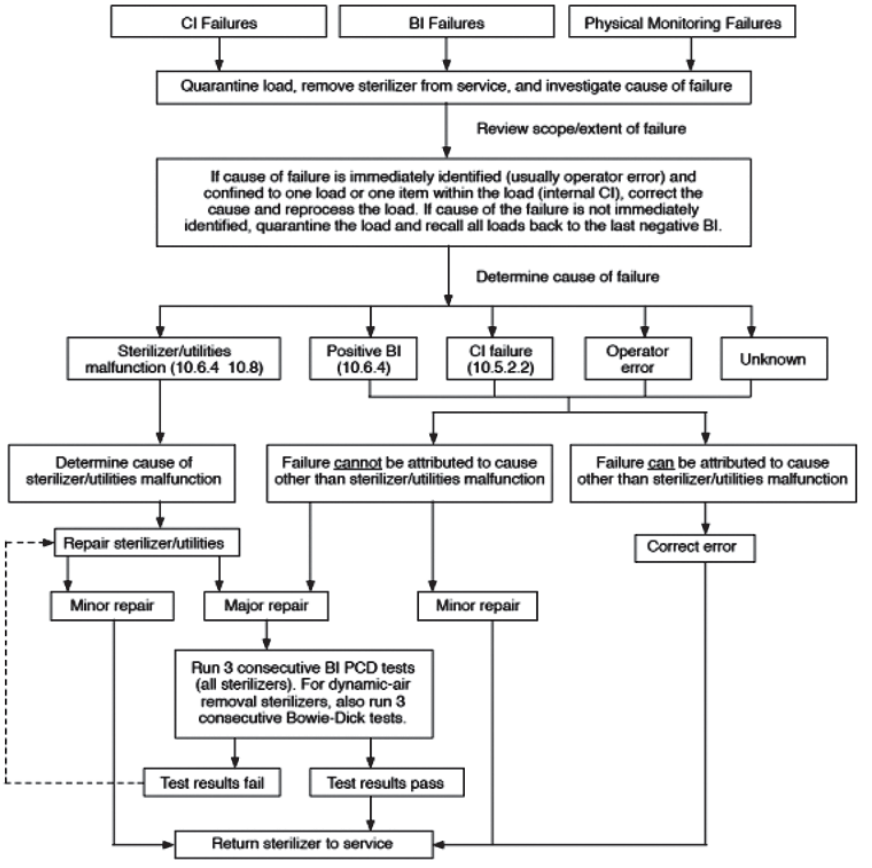
CI process failures

If an individual CI does not respond, or if the response is ambiguous, there is a possibility that the entire load is not sterile (i.e., the sterilization process failed). It is also possible that there may have been an operator error in loading or packaging which may have resulted in sterilization failures in only one, or some of the items in the load. As a result, a single nonresponsive or inconclusive CI should not be considered definitive proof that the entire load is nonsterile. Using critical thinking skills, the supervisor should exercise professional judgment in determining whether to recall the entire load. This decision should be based on all tools involved in monitoring the effectiveness of the sterilization cycle (i.e. physical monitors, CIs, and BIs).[1]

PCD process failures

A PCD containing a Class 5 Integrating Indicator may be used to monitor nonimplant steam sterilization loads. Implant loads should be monitored with a PCD containing both a BI and a Class 5 Integrating Indicator. In the newly revised AAMI ST79 under section 10.7.5 *Actions to take when PCDs (BI challenge test packs or CI challenge test packs) indicate failure,* it states: "A processed PCD with a positive BI (BI challenge test pack) or a failed Class 5 integrating CI (CI challenge test pack) is demonstrating a failure for the entire load and should be immediately reported by phone or messenger to the appropriate supervisor and to the infection prevention and control department."[1]

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



This 2009 amendment helps to clarify that unacceptable monitoring results, whether from a PCD (BI or CI) or physical monitors, constitute a failure for the entire load and should be documented and handled as such.

Investigation

The decision tree for conducting investigations of steam sterilization process failures included in the 2009 edition of AAMI ST79 will be extremely helpful the next time you encounter a sterilization process failure. This quality improvement decision making tool is intended to give guidance as you conduct the investigation of BI, CI, or physical monitoring failures. (See AAMI Figure 12)

Load quarantine

Once a failure is identified and reported to the correct supervisor, the next step should be to quarantine the load and review the extent of the failure. "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."[1]

Product recalls

Anytime there is an indication of a sterilization failure, the Infection Preventionist should be informed so that follow-up surveillance of patients can be conducted. Recall procedures should be established to expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions such as quarantine of the sterilizer, notification of physicians and affected clinical areas, and surveillance of patients.[1]

Recall report

A written report of any product recall needs to be documented and should:

- identify the circumstances that prompted the recall order,
- spell out the corrective action(s) that were taken to prevent a recurrence,
- list the products recalled,
- state the products actually located in the recall, and
- provide verification that the recalled items were reprocessed or destroyed, as appropriate.[1]

*See **SELF-STUDY** on page 24*

Self-Test Answers: 1. A, 2. A, 3. B, 4. A, 5. B, 6. A, 7. A, 8. A, 9. A, 10. B

SELF-STUDY *from page 23*

Positive BI

If the sterilization failure involved a positive BI, the microbiology laboratory should do a presumptive identification of the microorganisms present in the "failed" (positive) BI, according to the BI manufacturer's instructions.[1]

Determining the root cause of failures

Identifying what caused the sterilization failure is often the most frustrating part of the investigation. To assist with this investigation, the new AAMI document includes another useful tool: a checklist for identifying reasons for steam sterilization process failures. The checklist contains two categories of failures, operator errors and sterilizer or utility malfunctions. (See AAMI Table 8 on the last page of this PDF document.)

Operator errors

There are four main types of operator errors:

- Incorrect use and interpretation of monitoring tools,
- Selection of incorrect cycle for load contents (i.e. containment device or medical device manufacturer's instructions not followed),
- Use of inappropriate packaging materials or packaging technique, or
- Incorrect loading of sterilizer.

The AAMI checklist for identifying reasons for sterilization process failures offers more details regarding each type of operator error. This checklist will help investigate what might have gone wrong. It can also be a very valuable educational tool.

Sterilizer or utility malfunctions

The reasons for sterilization failures resulting from malfunctions of the sterilizer or utilities are grouped into four categories:

- Poor steam quality or quantity,
- Incomplete air removal,
- Inadequate cycle temperature, or
- Insufficient time at temperature.

Sterilizer and/or utility malfunctions can be very frustrating to investigate because it is often hard to pinpoint the exact cause. A defective sterilizer cannot be made operational without finding and correcting the primary problem. Extending the cycle time or increasing the cycle temperature are not appropriate solutions.[1]

The facility's sterilizer maintenance personnel should be notified; and the root cause of the sterilization process failure should be identified and corrected. Sterilization process failures can happen in a normally functioning sterilizer as a consequence of poor steam quality, operator error, or other factors.[1]

Rechallenge the sterilizer

If the cause of the failure was determined to be a sterilizer malfunction which requires a major repair, the sterilizer should be requalified with a BI PCD in three consecutive cycles. For larger sterilizers as well as flash sterilization cycles, the three consecutive BI PCD cycles should be run in an otherwise empty chamber. However, if a tabletop sterilizer exhibits a failure, the three consecutive cycles should be run in an otherwise fully loaded chamber.[1]

If the sterilizer is a dynamic-air-removal sterilizer, qualification testing also includes running a Bowie-Dick test pack in three consecutive empty-chamber cycles after the three BI PCDs have been run.[1]

Putting sterilizer back into service

If all of the test results are satisfactory (three cycles with negative BIs and, if applicable, three cycles with satisfactory color change in the Bowie-Dick indicator) and the physical monitor results are appropriate, the sterilizer should be considered in good working order and can be put back into service.

Note that if the repairs only involve parts usually replaced under preventive maintenance procedures, three BI tests and three Bowie-Dick tests are not necessary before the sterilizer is returned to service. Confirmation of the sterilizer's operation according to the sterilizer manufacturer's specifications is adequate.[1]

Summary

Ensuring patient care products are safe and effective requires a continuous quality improvement process. Using the above procedures whenever physical monitors and/or chemical or biological indicator PCDs indicate a potential sterilization failure will uncover valuable data in support of correcting the problem and recognizing possible improvements in work practices.

This article focused on only a few of the 26 revisions in the 2009 amendments of AAMI ST79. There are many other important additions/changes in ST79. The 2009 amendments may be downloaded free of charge from www.aami.org.

My final word regarding questionable failed sterilizer loads is the old adage… "When in doubt, throw it out". HPN

References

1. ANSI/AAMI ST79:2006, A1:2008 and A1:2009. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Arlington, VA; Association for the Advancement of Medical Instrumentation: 2009.

2. Recommended Practices for Sterilization in Perioperative Practice Settings. In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, Inc: 2009.

Disclosure Statement

Ms. Seavey is a consultant to 3M.

Rose Seavey *RN, BS, MBA, CNOR, CRCST, CSPDT is the President/CEO of Seavey Healthcare Consulting, Inc, and formerly the Director of the Sterile Processing Department at The Children's Hospital of Denver. Ms Seavey was elected to the Association of periOperative Registered Nurses (AORN) Board of Directors for 2008-2010. She was honored with AORN's award for Outstanding Achievement in Clinical Nurse Education in 2001. Rose served as the President of the American Society of Healthcare Central Service Professionals (ASHCSP) in 2003 and is the 2002 recipient of ASHCSP National Educator of the Year award. Rose was selected as one of the Who's Who in Infection Prevention in 2006 by Infection Control Today. Seavey is a member of several AAMI working group committees that are developing recommended practices and is currently a co-chair for the ANSI/AAMI Working Group for Hospital Steam Sterilizers performance standards. In addition she has lectured and authored many articles on various topics relating to perioperative services and sterile processing, locally, nationally and internationally.*

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Steam sterilization process failures and recalls: Taking the correct actions

Circle the one correct answer:

1. **Monitoring the sterilization process using physical monitors, chemical indicators, and biological indicators is an important part of the quality control program.**
   A. True B. False
2. **Properly preparing items for sterilization is an essential stage of instrument reprocessing.**
   A. True B. False
3. **Operator errors cannot cause steam sterilization process failures.**
   A. True B. False
4. **Nonimplant loads may be monitored with a PCD containing a Class 5 Integrating Indicator.**
   A. True B. False
5. **A single nonresponsive or inconclusive CI can be considered definitive proof that the entire load is nonsterile.**
   A. True B. False
6. **A processed Process Challenge Device (PCD) with a positive BI (BI challenge test pack) or a failed Class 5 integrating CI (CI challenge test pack) is demonstrating a failure for the entire load.**
   A. True B. False
7. **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.**
   A. True B. False
8. **The new AAMI checklist for identifying reasons for sterilization process failures can be used as an educational learning tool for staff.**
   A. True B. False
9. **If the cause of the failure was determined to be a sterilizer malfunction which requires a major repair, the sterilizer should be requalified with a BI PCD in three consecutive cycles, followed, for dynamic-air-removal sterilizers, by three consecutive Bowie-Dick tests.**
   A. True B. False
10. **If a sterilizer repair only involves parts usually replaced under preventive maintenance procedures, three BI PCD tests and three Bowie-Dick tests are still necessary before the sterilizer is returned to service.**
    A. True B. False

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

Operator Errors

Incorrect use and interpretation of monitoring tools
- Incorrect physical monitors for the load
- Incorrect use of BI or BI PCD
  - Incorrect selection of BI or BI PCD for the load
  - Incorrect placement of BI PCD in the load (e.g., another pack was placed on top of the PCD)
  - Incorrect incubation of BI
  - Misinterpretation of BI result
  - Incorrect documentation of BI result
- Incorrect use of Class 5 integrating CI PCD.
  - Incorrect selection of CI PCD for the load.
  - Incorrect placement of CI PCD in the load (e.g., another pack was placed on top of the PCD)
  - Misinterpretation of Class 5 integrating CI result
  - Incorrect documentation of Class 5 integrating CI result
- Incorrect use of internal CI
  - Incorrect selection of internal CI for the load
  - Misinterpretation of internal CI result
  - Incorrect documentation of internal CI results
- Incorrect storage of any CIs or BIs
- Failure to check physical monitors for functionality before running cycle
- Use of broken media ampoule or ampoule with missing spore strip
- Use of BI PCD or CI PCD that is missing the BI or CI
- Use of defective CI (e.g., a CI that is expired, faded, shows a partial color change because of incorrect storage, or has been previously exposed to the sterilant)

Selection of incorrect cycle for load contents
- containment device or medical device manufacturer's instructions for use not followed

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

Incorrect loading of sterilizer
- Stacking of containment devices if not recommended by manufacturer
- Stacking of perforated instrument trays
- Incorrect placement of instrument trays (i.e., not laying instrument trays flat or parallel to the shelf)
- Incorrect placement of paper–plastic pouches (e.g., placing pouches flat instead of on edge; not allowing sufficient space between pouches; not placing pouches with plastic sides facing one direction)
- Incorrect placement of basins (i.e., not placing basins on their sides so that water can drain)
- Incorrect placement of textile packs (i.e., not placing them on edge)
- Placement of packages too close together, impeding air removal and sterilant penetration in the load

Sterilizer or Utility Malfunctions

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

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

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

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