

Sterile U Network

TUTORIALS

ANSI/AAMI ST79 – A2:2009 Key Changes in the 2009 Amendment

Background:

A second amendment (A2:2009) to the Association for the Advancement of Medical Instrumentation (AAMI) recommended practice, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79) was recently approved. The amendment includes 26 changes or additions and was published as part of the continuous maintenance process used to revise the standard.

The latest amendment represents a major revision to the document. Key changes included are:

- The addition of the current chemical indicator definitions, including Class 6 emulating indicators. The amendment does not, however, include recommendations for the use and application of Class 6 emulating indicators;
- Recommendations on the frequency of monitoring mechanical cleaning equipment;
- New tools, a decision tree and a checklist, to assist in taking actions and investigating when the physical monitors, chemical indicator PCD or biological indicator PCD indicate a sterilization failure;
- Easier instructions for product testing of newly purchased or loaner sets; and
- A recommendation that facilities perform an annual sterilization risk analysis.

This tutorial focuses on some of the key changes included in the 2009 amendment to ST79 and provides reprints of the new sterilization process failure investigation tools.

Instructions on how to obtain a complimentary PDF of ST79/A2:2009 from AAMI can be found in the FAQ section of this tutorial.



Key Change	Section(s)	Practical Application
<p>The definitions of chemical indicators in ST79 are updated to reflect the definitions for the six classes of chemical indicators (CIs) provided in ANSI/AAMI/ISO 11140-1: 2005, <i>Sterilization of health care products- Chemical Indicators-Part 1: General Requirements</i>. A note explains that the amendment does not include recommendations for the use and application of Class 6 emulating indicators.</p>	<p>2.16 10.5.2.1</p>	<p>Use chemical indicators that meet the performance requirements specified in ANSI/AAMI/ISO 11140-1:2005. Ask your CI supplier if the product(s) you are using meet(s) the most current ANSI/AAMI/ISO 11140-1:2005 performance requirements. Additionally, you may not be aware, but the CI standard upgraded the performance requirements for Class 5 integrating indicators, specifying that their stated values be equivalent to or exceed that of biological indicators. This ensures Class 5 CIs do not respond too quickly at lower temperatures and miss sterilization process failures.</p>
<p>The terms “product family” and “master product”, borrowed from the medical device industry, are introduced to simplify the task of product testing. A product family is defined as a “(Sterilization) group or subgroup of product that is characterized by similar attributes, such as mass, material, construction, set weight, shapes, lumens, and packaging system, and that presents a similar challenge to the sterilization process”.¹ To reduce the test burden on facilities, it is now recommended that periodic product quality assurance testing of routinely processed items be conducted on the “master product” (i.e. the most difficult to sterilize) from each product family.</p>	<p>2.74 2.102 10.9</p>	<p>Develop a policy and procedure for conducting product testing on routinely processed items and newly purchased or loaner sets using the product family concept.</p>
<p>All references to enzyme-only indicators are removed.</p>	<p>2.100, Tables 6 and 7 (previously Tables 7 and 8) 10.5.2.1, 10.5.2.2.2, 10.5.3.2, 10.5.4, 10.6.1, 10.7.1, 10.9</p>	<p>None - this category of product has not been commercially available for some time.</p>



Key Change	Section(s)	Practical Application
<p>The recommended frequency for monitoring mechanical cleaning equipment to ensure it is working properly is now provided.</p> <p>It is recommended that testing be done upon installation, weekly (preferably daily) during routine use, and after major repairs.</p>	<p>7.5.3.3</p> <p>7.5.5</p> <p>10.2</p>	<p>Develop a policy and procedure for testing the effectiveness of mechanical cleaning equipment which includes testing upon installation and after major repairs and routine efficacy testing weekly, but preferably daily.</p>
<p>A new note states, “Refer to the device manufacturer’s instructions to determine whether decontamination using microbicidal processes is required after cleaning and before terminal sterilization.”¹ If chemical disinfection is used, thoroughly rinse and dry the medical device prior to sterilization.</p>	<p>7.6.1</p> <p>7.6.2.1</p>	<p>Review device manufacturers’ reprocessing instructions to determine whether a microbicidal process is required to render a device safe to handle after cleaning.</p>
<p>When securing packs wrapped with reusable sterilization wrappers, create a tab on the indicator tape to facilitate removal.</p>	<p>8.3.3</p>	<p>If your facility uses reusable wrappers, update procedures and/or competencies as necessary to incorporate the tape tab recommendation.</p>
<p>A new note states, “Double packaging in paper–plastic pouches should not be performed without documentation from the manufacturer that the paper–plastic pouch has been validated for this use.”¹</p>	<p>8.3.4</p>	<p>Obtain documentation in writing from your paper-plastic pouch vendor on whether their product is validated for double pouching.</p>
<p>Reflecting current scientific evidence, moistening lumened devices immediately prior to sterilization is no longer recommended unless the device manufacturer specifically recommends it.</p>	<p>8.3.8</p>	<p>Consult the manufacturers of lumened devices about whether it is necessary to moisten the lumen with distilled or deionized water prior to sterilization.</p>



Key Change	Section(s)	Practical Application
<p>The recommendation to always test the open surgical tray configuration when conducting routine BI monitoring of flash sterilization cycles has been modified. The document now recommends routinely testing each type of tray configuration used.</p>	<p>10.7.4.1</p>	<p>Routinely test each type of tray configuration used for flash sterilization cycles, by placing a BI and CI in the empty tray configuration, to verify adequate air removal and steam penetration. For example, if your facility uses both rigid sterilization container systems and single-wrapped trays when flash sterilizing, both configurations should be tested.</p> <p>Ask your 3M Sales Representative for a copy of 3M's FLASH Sterilization poster that provides detailed information about appropriately monitoring flash sterilization cycles.</p>
<p>In a significant change, the section previously entitled "Positive BI results" has been renamed "Actions to take when PCDs (BI challenge test packs or CI challenge test packs) indicate failure" and now recommends quarantining the load and recalling all loads back to the last negative BI if the cause of the failure isn't immediately identified. The root cause of the sterilization failure should be investigated. The document includes two new tools, a decision tree and a checklist, to assist with this root cause investigation.</p>	<p>10.7.5</p> <p>Figure 12—Decision tree for conducting investigations of steam sterilization process failures</p> <p>Table 8—Checklist for identifying reasons for steam sterilization process failures</p> <p>Note: Figure 12 and Table 8 are reprinted at the end of this tutorial.</p>	<p>Revise your policy and procedure to reflect that anytime a physical monitor or PCD (i.e. BI or CI) indicates a sterilization failure, an investigation should be initiated and, as described in Figure 12, the load quarantined and a recall back to the last negative BI triggered if the cause of the failure isn't quickly identified.</p>
<p>Rather than specifying and illustrating the placement of BIs and CIs for evaluation of rigid sterilization container systems, the document now recommends consulting the container manufacturer "Because the areas of greatest challenge to steam penetration and air removal vary from one rigid sterilization container system to another".¹ A new note states, "The test rigid sterilization container system should contain instruments, and if the system requires filters, the filters must be in place."¹</p>	<p>10.10.3.2.2.1</p>	<p>When conducting a pre-purchase product evaluation of rigid containers, check with the manufacturer for appropriate placement of BIs and CIs.</p>



Key Change	Section(s)	Practical Application
A new Risk Analysis section has been added to Section 11, Quality process improvement. It recommends facilities perform an annual sterilization risk analysis. Components of the Risk Analysis include risk assessment, risk management, and risk communication.	11.2.2	As part of the health care facility's overall infection prevention and control risk analysis, conduct a sterilization risk analysis at least once/year and reevaluate it whenever significant changes occur.
The tables in Annex D, which discusses user verification of cleaning processes, have each been updated with an additional test method. A 2% hydrogen peroxide test for cleaned instruments was added to Table D.1 and a metal coupon with blood test soil used as a QA indicator for washer-disinfector functionality was added to Table D.2.	Tables D.1 and D.2	Consult Annex D for tests used to assess the cleanliness of medical devices and the efficacy of washer-disinfectors.

Frequently Asked Questions:

1. How can I get a copy of the amendment?

Download a free pdf at <http://marketplace.aami.org>. Enter ST79-A2 in the search field and click on the link to "Download Free Product" located in the PDF Format box. Then simply insert the amended pages into your current copy of ST79:2006, A1:2008. Buyers purchasing a new copy of ST79 will receive the consolidated text which includes amendments 1 and 2.

2. Does the amendment provide guidance on the use of Class 6 emulating indicators or Class 6 CI PCDs?

No, A2:2009 provides the definition of Class 6 emulating indicators but does not discuss the use or application of this device. Judy Veale, AAMI standards coordinator, is quoted in the July/August 2009 issue of AAMINews: "The working group has introduced the definition of Class 6 so people are aware it exists and is available...The group has not developed consensus recommendations for how people should use this type of indicator."²



3. We use a Class 5 CI PCD to release nonimplant loads. If the integrating indicator in the PCD fails to reach its endpoint, do I need to conduct a recall?

Yes, the Decision Tree provided in Table 12 is a helpful new tool to use in such a situation. If the CI result indicates a sterilization failure, and 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. Investigate the root cause of the failure, utilizing the checklist provided in Table 8. If the sterilizer requires major repairs, requalify the sterilizer before returning it to service.

Summary:

The guidelines presented in ST79 are considered “recommendations for optimum performance levels in the processing of reusable medical devices in a health care setting” to ensure safe and effective patient care. It is the responsibility of everyone involved with the sterilization process to ensure that recommended practices, policies and procedures are followed so that patient care is not adversely affected. This tutorial highlights some of the key changes introduced in the latest revision to ST79, A2:2009. All health care facilities that utilize steam sterilization should ensure they have an up-to-date copy of ST79 by purchasing a new copy of the document or downloading the latest amendment.

For more information, call the 3M Help Line: 1-800-228-3957

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1. Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST79:2006, A1:2008 and A2:2009.
 2. AAMI News. July/August 2009, Vol. 44, No. 7. Steam Sterilization Standard Undergoes Major Revision. <http://www.aami.org/publications/AAMINews/JulAug2009/st79.html>

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

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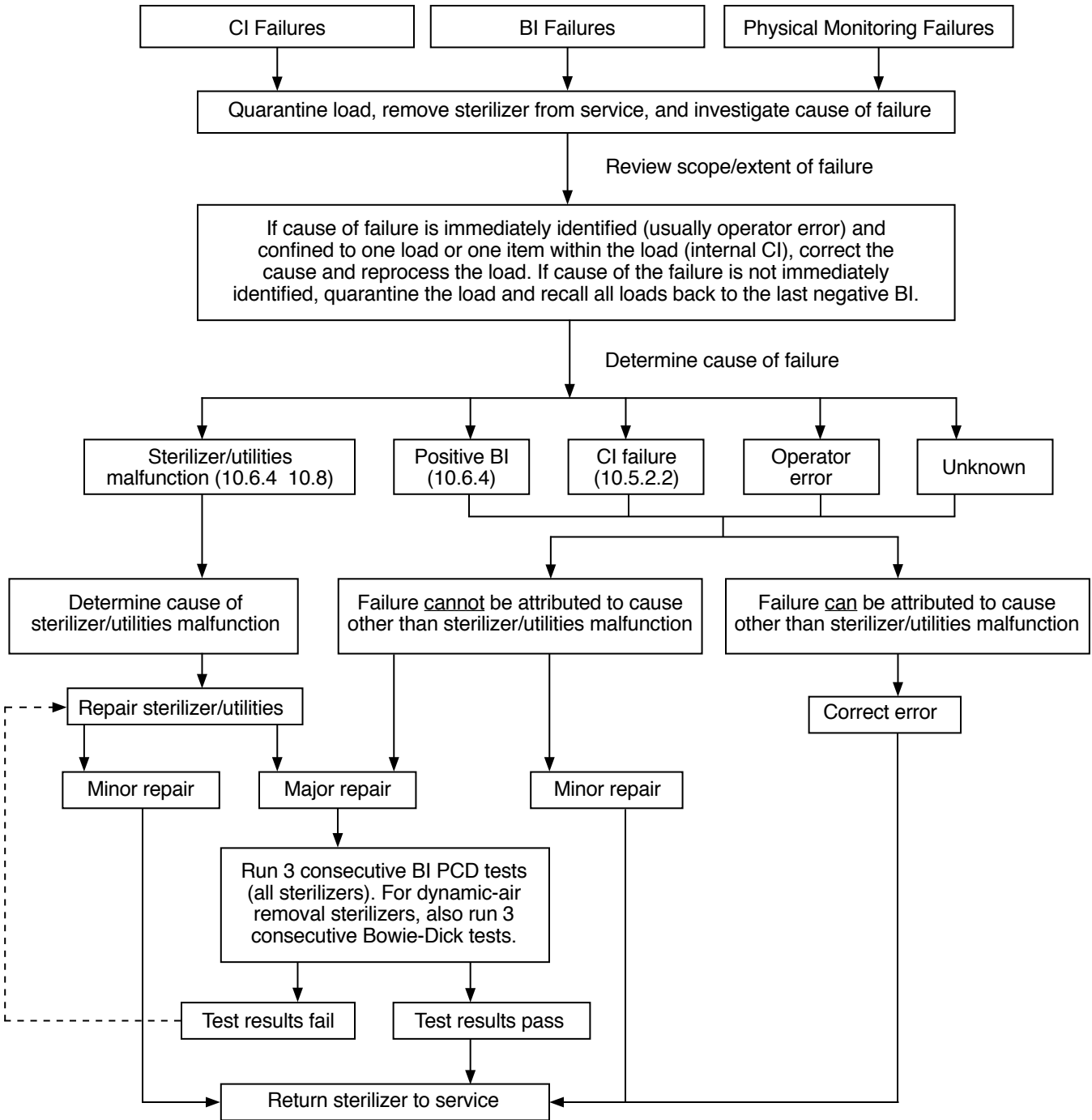


Table 8 – Checklist for identifying reasons for steam sterilization process failures

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

Incorrect loading of sterilizer

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

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Table 8 – Checklist for identifying reasons for steam sterilization process failures (cont.)

Sterilizer or Utility Malfunctions
<p>Poor steam quality or quantity</p> <ul style="list-style-type: none">• Wet steam<ul style="list-style-type: none">- 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<ul style="list-style-type: none">- 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<ul style="list-style-type: none">- 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
<p>Incomplete air removal</p> <ul style="list-style-type: none">• 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
<p>Inadequate cycle temperature</p> <ul style="list-style-type: none">• 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
<p>Insufficient time at temperature</p> <ul style="list-style-type: none">• 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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