



ANSI/AAMI ST79:2010 – A1:2010

Key Changes in the 2010 Amendment

Background:

In October, 2010 the Association for the Advancement of Medical Instrumentation (AAMI) published an editorial revision to ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. An amendment to the standard, A1:2010, was published with the 2010 version. The amendment provides guidance on the use and application of Class 6 emulating indicators.

The two key changes included in ST79:2010 – A1:2010 are:

- Guidance on the use and application of Class 6 emulating indicators;
- The addition of a new Section 12, on new product evaluation.

What didn't change? AAMI ST79 continues to recommend that implant loads be monitored with a Process Challenge Device (PCD) containing a biological indicator and a Class 5 integrating indicator.

This tutorial provides details of the changes included in Amendment 1 to ST79:2010 and presents, with permission from AAMI, reprints of "Table 6 – Sterilization process monitoring recommendations" and "Table 7 – Types and applications for use of sterilization monitoring devices" which were revised to include Class 6 chemical indicators.

Key Learnings:

Sterilization Monitoring

Steam sterilization cycles are monitored using physical, chemical, and biological indicators. A variety of chemical indicators are available to health care facilities, each with different response characteristics and different monitoring applications. Tables 6 and 7 in ST79 summarize the recommended use of sterilization monitoring devices. The updated tables included in the 2010 amendment were revised to include guidance on the use and application of Class 6 emulating indicators as internal chemical

indicators and, within PCDs, to monitor sterilizer loads. There is also additional guidance provided in the text that helps to clarify the AAMI recommended use of Class 6 chemical indicators.

Class 6 CIs are cycle-specific and AAMI reminds the reader "they should be used only in the specific cycles for which they are labeled" (Section 10.5.2.2.2). When considering the use of Class 6 CI PCDs to monitor sterilizer loads, it is important to remember that a) in the case of implant loads, "a PCD containing a BI and a Class 5 integrating CI (a BI challenge test pack) should be used to monitor the load" (Section 10.5.4) and b) in the event of an unexplained sterilization process failure, all loads back to that with the last negative BI must be recalled (Section 10.7.5.1).

New Product Evaluation

The time period between the Food and Drug Administration's (FDA's) clearance of Class 6 emulating indicators and the development and publication of use and application guidelines by AAMI created some confusion for Central Sterilization Departments. A1:2010 resolves the issue for Class 6 indicators but to address this gap for future new products, the amendment features a brand new section, "Section 12 – New product evaluation".¹ The section outlines factors facilities may consider when evaluating a new product for which application guidance is not yet provided by AAMI or other professional organizations.

The new product evaluation considerations are grouped into four components as follows:

- 1) The establishment of a multidisciplinary committee;
- 2) The collection of information (FDA clearance documentation, the manufacturer's instructions for use, research articles published in peer-reviewed journals, etc.) related to the new product;
- 3) The consideration of issues such as a cost/value analysis, contribution to patient safety, ease of use of the product, etc.; and
- 4) Guidelines for conducting a product trial, if indicated.

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Frequently Asked Questions:

1. How does this amendment to ST79 change the recommended use of biological indicators (BIs)?

This amendment does NOT change the use and application of BIs. As summarized in Table 7, reprinted at the end of this tutorial, BIs continue to be recommended for:

- Routine Load Release
 - Optional monitoring, within a PCD, of non-implant loads
 - Monitoring of every implant load with a PCD containing a BI and a Class 5 integrating indicator
- Routine Sterilizer Efficacy Monitoring
- Sterilizer Qualification Testing
- Periodic Product Testing

Note that in addition to adding use and application guidance for Class 6 emulating indicators, a new, clarifying statement, “Implants should be quarantined until BI results are known, except in emergency situations” was added to both the Class 6 and BI application guidance in Table 7 to ensure this requirement is understood by the reader. As a reminder, the recommendation to quarantine implantable items until the BI result is negative comes from the CDC (Recommendation 16 g) of the Guideline for Disinfection and Sterilization in Healthcare Facilities, (2008).²

Reinforcing the importance of BIs, this amendment updates Section 10.5.3 “Using biological indicators” with the statement that Class 6 emulating indicators, like Class 5 Integrating CIs, “do not directly measure the lethality of a cycle and they are not intended to be used as the sole means of routinely verifying sterilizer efficacy or of qualifying sterilizer performance after installation, repair, or relocation”.

2. So with this new amendment, can a Class 6 CI PCD alone be used to release loads containing implants?

No. The use of Class 6 emulating indicators as a basis for early release is not recommended by AAMI.

While A1:2010 permits the use of a Class 6 CI within a PCD as part of the release criteria for implant loads, ST79 Section 10.6.1 continues to recommend that implant loads be monitored with a PCD containing a BI and a Class 5 integrating CI and that the implant be quarantined until the BI result is known, except in emergency situations. In documented emergency situations only, the Class 5 CI in the PCD may be used as a basis for early load release (ST79, Section 10.5.2.1).

3. We're thinking of using a Class 6 CI PCD to release nonimplant loads. If the chemical indicator in the PCD fails to reach its endpoint, will we need to conduct a recall?

Any indication of a sterilization process failure, including a failed CI in a PCD, needs to be investigated. And if the cause of the failure

isn't identified, then yes, a recall is indicated. Amendment 1 revises ST79 Section 10.7.5.1 a) to read:

“PCDs (BI challenge test packs and CI challenge test packs) are used to routinely test sterilizer efficacy and to release sterilized loads, and BI challenge test packs are used to routinely test sterilizer efficacy. A processed PCD with a positive BI (BI challenge test pack) or a failed Class 5 integrating CI or Class 6 emulating indicator (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.”

And 10.7.5.1 b) goes on to say:

“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.”

If the sterilizer requires major repairs, it should be re-qualified using BI PCDs and Bowie-Dick test packs (for dynamic-air-removal sterilizers) before being returned to service.

4. We run a variety of steam sterilization cycles. Is there a “universal” Class 6 emulating indicator we can use as an internal CI inside packs, trays and containers in all the different cycles we run?

Class 6 CIs are also referred to as cycle verification indicators i.e., they are cycle-specific. When used as internal chemical indicators, AAMI ST79 states “they should be used only in the specific cycles for which they are labeled” (Section 10.5.2.2.2). Facilities running multiple sterilization exposure times and using Class 6 emulating indicators as internal CIs would need to stock multiple Class 6 CIs and ensure CS staff is trained to select the correct monitoring product. At this time there are no commercially available Class 6 CIs to monitor all the different sterilization cycles used in health care facilities.

5. What is a “new product”?

Users might wonder when it is appropriate to use the guidance on evaluating new products that was added to Section 12 of ST79. To clarify this point, the definition of a “new product” was added to ST79: “A new product/technology that has been FDA approved but for which AAMI does not offer guidance for application.” (1, Section 2.79)

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

A1:2010 is included in the 2010 revision of AAMI ST79. Contact AAMI to order ANSI/AAMI ST79:2010 & A1:2010, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (Consolidated Text)

Order Code: ST79 or ST79-PDF

Price/AAMI Member Price: \$240/\$120

Call 877-249-8226 or visit <http://marketplace.aami.org>



Summary:

Health care facilities have been waiting for AAMI to provide guidance on the use and application of Class 6 emulating indicators. A new amendment to ST79:2010 addresses this issue by providing such guidance, permitting the use of Class 6 CIs as internal chemical indicators and, within PCDs, to monitor sterilizer loads. As Class 6 CIs are cycle-specific, AAMI reminds the reader “they should be used only in the specific cycles for which they are labeled”. When considering the use of Class 6 CI PCDs to monitor sterilizer loads, it is important to remember that a) in the event of an unexplained sterilization process failure, all loads back to the last load having a negative BI must be recalled (Section 10.7.5.1) and b) in the case of implant loads, “a PCD containing a BI and a Class 5 integrating CI (a BI challenge test pack) should be used to monitor the load” (Section 10.5.4).

Sterilization professionals can now refer to AAMI ST79 for guidance on the use of Class 6 CIs. A new section of the standard will be of

interest to users evaluating other new products. To address future instances of novel products cleared for use by the FDA but for which AAMI ST79 does not yet offer application guidance, the amendment includes a section entitled, “New product evaluation”. This section provides a framework for a multidisciplinary committee to assess the utility of newly introduced products in the clinical setting.

All health care facilities that utilize steam sterilization should ensure they have an up-to-date copy of ANSI/AAMI ST79:2010, which includes the 2010 amendment.

References:

1. Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST79:2010 & A1:2010 (Consolidated text).
2. Rutala, William A., Weber, David J., and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008. CDC. Available online at http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

Table 6 – Sterilization process monitoring recommendations

Routine load release (see 10.5 and 10.6)		Routine sterilizer efficacy monitoring (see 10.7)	Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 10.8)	Periodic product quality assurance testing (see 10.9)
Nonimplants	Implants			
Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle
External and internal chemical indicator monitoring of packages	External and internal chemical indicator monitoring of packages	External and internal chemical indicator monitoring of packages	External and internal chemical indicator monitoring of packages	Placement of BIs and, CIs within product test samples
Optional monitoring of the load with a PCD containing one of the following: <ul style="list-style-type: none"> • a BI • a BI and a Class 5 integrating indicator • a Class 5 integrating indicator • a Class 6 emulating indicator 	Monitoring of every load with a PCD containing a BI and a Class 5 integrating indicator	Weekly, preferably daily (each day the sterilizer is used), monitoring with a PCD containing a BI. (The PCD may also contain a CI.) For sterilizers larger than 2 cubic feet and for table-top sterilizers, monitoring is done in a fully loaded chamber. In flash sterilization cycles, monitoring is done in an empty chamber. For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber	For sterilizers larger than 2 cubic feet and for flash sterilization cycles, monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack	

NOTE 1 – See Section 12 (New product evaluation) for general guidelines on how to assess the specific label claims of new products that become commercially available.

ANSI/AAMI ST79:2010 and A1:2010, Table 6 – Sterilization process monitoring recommendations

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Table 7 – Types and applications for use of sterilization monitoring devices

Monitor	Frequency of Use	Application (release of sterilizer, package, load)
Physical monitors		
Time, temperature, and pressure recorders, displays, digital printouts, and gauges	Should be used for every load of every sterilizer.	Part of load release criteria.
Chemical indicators (CIs)		
External CIs Class 1 (process indicators)	Should be used on outside of every package unless the internal CI is visible.	Part of load and package release criteria.
Bowie-Dick-type indicators Class 2 (Bowie-Dick)	For routine sterilizer testing (dynamic-air-removal sterilizers only), should be run, within a test pack, each day in an empty sterilizer before the first processed load. For sterilizer qualification testing (dynamic-air-removal sterilizers only), should be run, within a test pack, after sterilizer installation, relocation, malfunction, and major repairs and after sterilization process failures; test should be run three times consecutively in an empty chamber after BI tests.	Test of sterilizer for efficacy of air removal and steam penetration; part of release criteria for using sterilizer for the day. Part of release criteria for placing sterilizer into service after qualification testing.
Internal CIs	Should be used inside each package. Should be used in periodic product quality assurance testing.	Part of package release criteria at use site. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging. Release criteria should include BI results.
Class 3 (single-variable indicator) Class 4 (multi-variable indicator)	May be used to meet internal CI recommendation.	Part of package release criteria at use site; NOT to be used for release of loads.
Class 5 (integrating indicator)	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor nonimplant sterilizer loads. Within a PCD, should be used to monitor each sterilizer load containing implants. The PCD should also contain a BI.	Part of package release criteria at use site. Part of load release criteria for nonimplant loads. Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known.
Class 6 (emulating indicator)	May be used to meet internal CI recommendation. Within a PCD, may be used to monitor sterilizer loads.	Part of package release criteria at use site. Part of load release criteria for nonimplant loads. Part of release criteria for loads containing implants. Implants should be quarantined until BI results are known, except in emergency situations.
Biological indicators (BIs)	Within a PCD, may be used to monitor nonimplant loads. Within a PCD, should be used in every load containing implants. The PCD should also contain a Class 5 integrating indicator. Within a PCD, should be used for weekly, preferably daily (each day the sterilizer is used), routine sterilizer efficacy testing. (The PCD may also contain a CI.) Should be run in a full load for wrapped items; for table-top sterilization, should be run in a fully loaded chamber; for flash sterilization, should be run in an empty chamber. Within a PCD, should be used for sterilizer qualification testing (after sterilizer installation, relocation, malfunction, major repairs, sterilization process failures). (The PCD may also contain a CI.) Test should be run three times consecutively in an empty chamber, except for table-top sterilizers, where the test should be run three times consecutively in a full load. Should be used for periodic product quality assurance testing.	Part of load release criteria. Part of release criteria for loads containing implants. Implants should be quarantined until BI results are known, except in emergency situations. Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known. Part of sterilizer/load release and recall criteria. Part of release criteria for placing sterilizer into service after qualification testing. Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.

NOTE 1 – See Section 12 (New product evaluation) for general guidelines on how to assess the specific label claims of new products that become commercially available.

AAMI ST79:2010 and A1:2010, Table 7 – Types and applications for use of sterilization monitoring devices

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