



Quality Assurance for Steam Sterilization

A new edition of AAMI ST79 has been published and it may therefore be time to revisit your facility's steam sterilization quality assurance policy. Healthcare accreditation organizations are paying close attention to medical device processing. To ensure the best possible patient outcomes, and successful surveys, it is important to have a robust quality assurance program in place for all sterilization modalities. Your policy should be aligned with current published standards and guidelines. To help you get started, a summary of the quality assurance recommendations included in AAMI ST79: 2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*,¹ is provided below.

Monitoring Tools

A variety of sterilization process monitoring tools are used as part of an effective steam sterilization quality assurance program. These include physical monitors and chemical and biological indicators. When monitoring steam sterilizers, biological indicators, and in some cases chemical indicators, are typically used inside a Process Challenge Device (PCD).

Physical monitors	Section 13.5.1 of AAMI ST79 states: "Physical monitors should be used to monitor sterilizer performance. These include time, temperature, and pressure monitors." The Rationale statement for this section goes on to explain, "Physical monitors and associated recording devices provide real-time assessment of the sterilization cycle conditions and a permanent record by means of charts, printouts, or digital data. Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken."
Chemical Indicators (CIs)	Chemical indicators are defined in Section 2.10 as "Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or are used in specific tests of sterilization equipment." Six 'types' of CIs are described in AAMI ST79:2017 (the new term 'type' of CI replaces the older term 'class' of CI). Guidance on using internal and external CIs is provided in Section 13.5.2.2 and on Bowie-Dick testing in Section 13.7.6.
Biological Indicators (BIs)	Biological indicators contain a known number of live microorganisms and are used to assess the adequacy of a sterilization cycle. Section 13.5.3.1 states, "Health care personnel should select BIs that consist of spores of <i>Geobacillus stearothermophilus</i> that comply with ANSI/AAMI/ISO 11138-3 and that are suitable for use in the specific sterilization cycle." The Rationale statement of this section goes on to explain, "Biological indicators are the only sterilization process monitoring device that provides a direct measure of the lethality of the process."
Process Challenge Devices (PCDs)	As explained in Section 13.5.4, "A PCD is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed." Depending on the application, the PCD may contain only a BI, only a Type 5 or Type 6 CI, or a BI and a Type 5 CI. While facility-assembled PCDs are used to monitor table-top sterilizers, ST79:2017 recommends the use of commercially available BI PCDs to monitor sterilizers larger than 2 cubic feet. (Section 13.7.2.1)

In the United States, chemical and biological indicators and commercially available, pre-assembled PCDs are medical devices regulated by the FDA.

Routine Load Release

When removing a processed load from a steam sterilizer, staff should make a decision about whether to release the load after careful evaluation of the available data. This data includes: the physical monitor (i.e. the print-out), which is checked to verify the cycle parameters were met; and the inspection of the external chemical indicators. All packages should have a Type 1 external CI, unless the internal CI is visible for inspection. Internal CIs are inspected by the person opening the set. AAMI ST79 recommends, “One or more internal chemical indicators should be placed within each package, tray, or rigid container. These indicators can be any type (Type 3, 4, 5, or 6) but preferably a Type 5 or Type 6 indicator because these types of CIs provide the user with more information on the critical steam sterilization parameters”. (Section 13.5.2.2.2)



Guidance on routine load release is split into two subcategories: nonimplant loads and implant loads.

Nonimplant loads: Loads that do not contain an implant should be monitored using physical monitors, chemical indicators, and may be monitored with a Process Challenge Device (PCD) containing: a BI; a BI and a Type 5 CI; a Type 5 CI; or a Type 6 CI. The use of a PCD is optional.

Implant Loads: As biological indicators are the only monitoring tool that demonstrate the lethality of the sterilization process, AAMI ST79:2017 continues to recommend that implant loads be monitored with a PCD containing a biological indicator and a Type 5 integrating indicator. The implant should be quarantined until the BI result is available. (Sections 13.5.3.2 and 13.6.3) In defined emergency situations, the implant can be released on the basis of the Type 5 integrator contained within the PCD but the BI should still be incubated and the result documented. (Section 13.6.3) ST79:2017 provides an example Exception Form for emergency load release documentation in Annex K.

Routine Efficacy Testing

In addition to making a release decision about each load, a robust quality assurance program includes routine efficacy testing using BI PCDs. If a sterilizer is designed to be used for multiple types of cycles, AAMI ST79 recommends testing each cycle type used. (Section 13.7.1) The recommended frequency for routine sterilizer efficacy monitoring with a BI PCD is at least weekly, but preferably every day that the sterilizer is used. (Section 13.5.3.2) Guidance on the specific BI PCD to be used is provided in three sections:

- Sterilizers larger than 2 cubic feet (Section 13.7.2)
The use of a pre-assembled, disposable BI PCD, equivalent in challenge to the AAMI 16-towel PCD, is recommended. AAMI ST79 comments that disposable PCDs “provide standardization and reduce variability and potential for error”. The PCD is placed in a loaded chamber in the area most challenging to sterilant penetration.



Note that AAMI ST79:2017 does not have a separate section on routine monitoring of IUSS cycles. As sterilizers used for IUSS have a chamber size larger than 2 cubic feet, routine testing of dynamic-air-removal IUSS cycles falls under this section i.e., they should be monitored with a pre-assembled, commercially available BI PCD. In IUSS cycles, routine testing may be done in an empty chamber. (Table 2)

- Table-top sterilizers (less than or equal to 2 cubic feet, Section 13.7.3)
To monitor table-top sterilizers, the user assembles a representative BI PCD. For example, if items are pouched for sterilization, the BI PCD is created by placing a BI, a CI and an instrument in a pouch. Routine testing is done in a fully loaded chamber.
- Gravity-displacement cycles (Section 13.7.4)
“For routine monitoring of gravity-displacement cycles, a representative of the same type of tray to be routinely processed by gravity-displacement cycles should be selected to serve as the PCD. Each type of tray configuration routinely used for gravity-displacement cycles should be tested separately.” The PCD should be placed on the bottom shelf of an otherwise empty chamber.

In each case, it is recommended that a control BI, having the same lot code as the test BI, be incubated each day a test BI is incubated. Acceptance criteria includes a negative result for the test BI and a positive result for the control BI.

Bowie-Dick Testing

For dynamic-air-removal sterilizers, routine Bowie-Dick testing is a recommended element of the quality assurance program. “A Bowie-Dick (Type 2 CI) test should be performed each day the sterilizer is used, before the first processed load. A Bowie-Dick test pack is used in conducting this test (see ANSI/AAMI/ISO 11140-5). A shortened cycle (i.e., a cycle omitting the drying phase) should be run first to heat the sterilizer. If the sterilizer is used continuously, the test may be performed at any time, but should be performed at the same time every day.” (Section 13.7.6) While facilities may assemble their own towel test packs, the standard now recommends the use of commercially available preassembled Bowie-Dick test packs. The test pack is placed in an otherwise empty preheated chamber over the drain.

Sterilization Process Failures

A sterilization process failure can be indicated by a failed physical monitor, a failed Type 5 or Type 6 CI from a PCD, or a positive result for a test BI. AAMI ST79 provides guidance on actions to take when investigating a sterilization process failure in Section 13.7.5. This section states, “If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed (see 13.7.5.2). The sterilizer in question should be taken out of service until the cause of the failure is identified and corrected.” Helpful tools in this section include Figure 10, a Decision Tree, and Table 4, which lists potential causes of sterilization failures.

Qualification Testing

AAMI ST79 states in Section 13.8.1, “Qualification testing with a BI PCD should be performed on all sterilizers after sterilizer installation, relocation, malfunctions, major repairs, sterilization process failures, or changes to the utilities (e.g., steam or water supply). If a steam sterilizer is designed to be used for multiple types of cycles, then each sterilization cycle type used should be tested.” To qualify a steam sterilizer, a BI PCD is run in three consecutive cycles, one right after the other. For pre-vacuum sterilizers, this is followed by three consecutive Bowie-Dick cycles, making a total of six cycles. Successful qualification testing verifies the sterilizer is fit to process instruments for patient use.

Traceability and Cycle Documentation

Stored items should be labeled with either an expiration statement (event related) or an expiration date. To ensure traceability of load items to the patient, AAMI ST79 recommends that each pack be labeled with a lot control identifier prior to sterilization. “The lot control identifier should identify

- a) the sterilizer identification number or code;
- b) a detailed list of the contents (e.g., identification of multiple sets and the contents of paper–plastic pouches);
- c) the person who assembled the package;
- d) the date of sterilization;
- e) the cycle number (cycle run of the sterilizer); and
- f) the patient, if applicable. Items processed for immediate use should include a patient identifier.” (Section 13.3.2)

For each sterilization cycle, the load number; specific contents of the load; exposure time and temperature; operator; results of the BI and/or CI from the PCD and Bowie-Dick test (if applicable); and reports of any failed CIs found later should be recorded.

Summary

For routine sterilizer efficacy testing, your steam sterilizer Quality Assurance Program should include the elements in the table below. To document compliance with your policy, ensure staff knows how to complete the necessary record keeping, either on paper or using an electronic software program.

Routine Efficacy Testing of Steam Sterilizers			
Monitoring Tool	Frequency	Acceptance Criteria	Record Keeping
Physical Monitor	Every load	Printout is examined to verify cycle parameters were met.	Printout is reviewed, signed, and included in cycle documentation.
Chemical Indicators (CI)	External CI (Type 1) placed on outside of each package unless internal CI is visible.	External CI examined after sterilization to verify that the package has been exposed to the steam sterilization process.	Document any reports of internal CIs which did not meet their end-point.
	Internal CI, preferably Type 5 or Type 6, used inside each package, tray, or containment device.	Internal CI retrieved and interpreted at time of use to verify it has met its end-point response.	
Bowie-Dick (Type 2 CI) Testing	Each day the sterilizer is used. Use of preassembled test pack preferred.	Test results in conformance with the test sheet manufacturer's recommended color standards.	Interpret and record the result.
Biological Indicator (BI)	Test BI, within a PCD, should be run at least weekly, but preferably every day the sterilizer is used. (AAMI ST79, Section 13.5.3.2)	Negative result from test BI.	Document test BI result and lot code.
	Implants: PCD containing a test BI and a Type 5 CI should be used to monitor every load containing implants. (AAMI ST79, Section 13.5.3.2)	Negative result from test BI. Quarantine implants until BI result is available.	Document BI result. Document premature release (i.e., release of any implant before the BI result is known).
	Control BI with matching lot code is incubated each day. (AAMI ST79, Section 13.7.2.4 g)	Positive result from control BI.	Document control BI result and lot code.

1. ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ©2017 Association for the Advancement of Medical Instrumentation, Arlington, VA.



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