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LEARNING OBJECTIVES

1. *Review changes to the HVAC recommendations provided in AAMI ST79:2017.*
2. *Discuss key changes to the quality control recommendations in AAMI ST79:2017.*

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SELF-STUDY SERIES

What's new in AAMI ST79:2017? A review

Adapted from the original article published in October 2017

by Susan Flynn, BESc, CSPDT

AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* is a go-to resource for all healthcare facilities that have steam sterilizers. The standard is as relevant and applicable to clinics with table-top sterilizers as it is to ambulatory surgery centers and acute care hospitals with larger steam sterilizers. AAMI ST79 is also referenced throughout The Joint Commission's High-Level Disinfection (HLD) and Sterilization BoosterPak.[1] Accreditation surveyors are tuned into the practice recommendations included in the document and expect to find a current copy of this evidence-based guideline accessible to front-line staff. AAMI recently published a new edition, ST79:2017,[2] and this self-study article reviews some of the new information and key changes in the revised document.

Customers sometimes call the 3M Sterilization Tech Line knowing that a particular recommendation is somewhere in ST79 but are unable to locate it to show their colleagues. The 2017 edition was designed to be more accessible to the reader, with recommendations in clear "should" statements (often bulleted) rather than buried in long paragraphs. The document explains that, "'Should' indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited." (Foreword) When you begin reading your copy of ST79:2017, remember that the verb "should" is a cue to an upcoming recommendation. Beyond the formatting changes designed to provide critical content in a consistent format, the changes in this edition of the document are rather subtle and incorporating these new guidelines into your practice should be relatively painless.

HVAC

Section 3 of AAMI ST79 provides design considerations for sterile processing areas Heating, ventilation and air conditioning (HVAC) parameters for operating rooms and sterile processing areas have been a recent source of discussion. These discussions have led to an industry consensus around the use of the American Society of Heating, Refrigeration, and Air Conditioning Engineers' (ASHRAE) Standard 170, *Ventilation of Health Care Facilities*. Eliminating specifying recommended temperature and humidity ranges altogether, the revised AAMI ST79 instead refers the reader to the HVAC parameters given in ASHRAE 170, thus harmonizing the recommendations between the two standards. This may make for easier discussions with your facility engineers. ST79:2017 recommends, "The health care organization should identify which version of ASHRAE 170 will be used based on when the HVAC system was initially installed or last upgraded." (Section 3.3.5.5) The burden of monitoring compliance with the HVAC parameters is slightly modified, with ST79 now recommending:

- "Facility engineering personnel or designated responsible personnel should establish policies and procedures for monitoring and maintaining HVAC parameters within the sterile processing areas.
- Procedures should include maintaining records of monitoring results that are retrievable either from a central system or a local log." (Section 3.3.5.5)

You may wish to initiate a discussion with your Facilities Engineering team to verify their ability and willingness to comply with these recommendations.

Guidance on response measures to any excursions from the desired operating parameters is also addressed, with ST79 recommending: "If a variance in the HVAC parameters occurs, sterile processing personnel in combination with a multidisciplinary team (e.g., facility engineer, infection preventionist, risk manager, sterile processing manager or designated personnel) should conduct a risk assessment." (Section 3.3.5.5)

Recognizing that the design temperature recommendations for decontam in ASHRAE 170 (60-73°F)[3] may cause anxiety, a new Annex Q, *Alternatives for keeping cool in the sterile processing environment*, was added to ST79:2017. The annex explains that our bodies use evaporative cooling to help regulate body temperature when a person's core temperature becomes too high. As the PPE worn in decontam can reduce the ability of sweat to evaporate, the annex provides strategies for improving employee comfort including short-

ening work periods and increasing rest periods; staying hydrated; and wearing cooling devices under PPE.

Personnel considerations

AAMI ST79:2017 continues to recommend that both Sterile Processing supervisors and personnel be qualified and competent. It is recommended that supervisors complete a sterile processing management certification exam and that other personnel "performing sterile processing activities should be certified within two years of employment." (Section 4.2)

Loaners

Expanded guidance on loaned or borrowed instrumentation is included in AAMI ST79:2017. (Section 5.2.3) This includes establishing a formal procedure with industry representatives for the receipt and use of loaned instruments and having a comprehensive facility policy. The policy should include processes to ensure that: applicable IFUs are provided before the loaner is received; the weight of loaned sets does not exceed 25 pounds; loaners are provided such that the facility has sufficient time to process them upon receipt; and records of loaner transactions are maintained. This section has a new recommendation: "Late receipt of loaned instruments should not be used to justify IUSS."

IUSS

And that takes us nicely to the next topic! ST79:2017 features a new definition and clear guidance on immediate-use steam sterilization (IUSS). IUSS of unwrapped items is no longer an option as it is recognized that rigid containers protect sterilized items from contamination. Section 10.2.3 states:

"IUSS should not be used for purposes of convenience or as a substitute for sufficient instrumentation. Instrument inventories should be sufficient to meet anticipated surgical volume and permit the time to complete all critical elements of reprocessing.

IUSS should be kept to a minimum and should be used only in urgent clinical situations.

Items processed by IUSS should:

a. be decontaminated as specified in Section 7;
b. be placed in a rigid sterilization container system that is intended for the cycle parameters to be used;
c. be used immediately and not stored for later use or held from one procedure to another; and
d. be identified as IUSS."

Loading and unloading sterilizers

The section on preparing instruments for sterilization is broadly similar in this edition. As accreditation surveyors sometimes overinterpreted the word *open* in the sentence "All jointed instruments should be in the open or unlocked position with ratchets not engaged," this statement has been simplified to read: "Ratcheted instruments should be unlatched" in the 2017 edition. (Section 8.2)

Updated figures in Section 10.1 depict the recommended loading of sterilizer carts, with rigid containers placed below absorbent materials.

What cycle should be run for Device X?
Follow the validated sterilization parameters provided in the device manufacturer's IFU.

One significant revision is the removal of the reference tables that provided typical sterilization parameters for gravity-displacement and dynamic-air-removal steam sterilization cycles. Instead, the reader is reminded to reconcile the validated cycle parameters found in the device, sterile barrier system (aka packaging) and sterilizer manufacturers' written IFUs. (Section 10.2) ST79:2017 also states, "Sterilization cycles used by the health care facility should be FDA-cleared and should incorporate sterilization monitoring accessories (e.g., CI, BI, PCD) and sterilization packaging labelled and cleared for that sterilization cycle." (Section 10.2.2.1)

ST79 continues to recommend that terminally sterilized load items be allowed to cool before being touched. A new statement reads, "The use of an infrared gun or temperature sensing device and a defined temperature (i.e., 24°C [75°F]) may be used." (Section 10.3.1)

Quality control

Cleaning Verification

One key change is the frequency at which mechanical cleaning equipment, such as automated washer-disinfectors and ultrasonic cleaning equipment, should be routinely monitored. A rationale statement explains, "Steam sterilization cannot be assured unless proper cleaning of the device and reduced bioburden and soil was achieved. Verification and documentation of automated cleaning processes through objective means is an important aspect of quality control."

It is now recommended that mechanical cleaning equipment be monitored daily.

It is now recommended that mechanical cleaning equipment be monitored daily and the results be documented. (Sections 7.6.4.5 and 13.2) ST79 states that, "Methods of verification include: a) directly testing individual instruments for residual soils (e.g., ATP, protein, hemoglobin); b) employing a test device that is a consistent and repeatable challenge to the cleaning effectiveness of the equipment; and c) monitoring critical parameters to evaluate the performance of the mechanical cleaning equipment." (Section 13.2)

Is your automated washer equipped with a printer? ST79:2017 recommends that such printers be located on the clean side of pass-through washers and that the printout be checked and initialed by operators.

With manual cleaning, it is important that cleaning agents be appropriately diluted. ST79:2017 recommends that, "When using an automated chemical delivery system/device or sink proportioner, the automated doser should be routinely verified or calibrated." (Section 7.6.3)

Sterilization monitoring

AAMI ST79 continues to recommend a steam sterilization quality assurance program which includes the use of physical monitors, internal and external chemical indicators, and biological indicators. A high-level overview of the sterilization process monitoring recommendations contained in AAMI ST79 is provided in Table 1, next page. The table includes the familiar column headers: routine load release; routine sterilizer efficacy monitoring; qualification testing; and product quality assurance testing.

Chemical indicators

When preparing sets for sterilization, have you noticed that most chemical indicators (CIs) are now labeled by 'type' rather than 'class' of CI? ANSI/AAMI/ISO 11140-1:2014 specifies the performance requirements, test methods, and labelling requirements for CI manufacturers.[4] Since this standard was released in 2014, CI manufacturers have been busy testing their products against the performance specifications and then updating the devices and labelling to reflect the new categorization term 'type'. AAMI ST79:2017 also uses this new terminology. In general, the use and application of chemical indicators did not change (see sidebar next page.) but the 'type' designation in ST79 now aligns with the labeling on the CIs actually available on your prep and pack stations.

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

Nonimplant load release

Routine load release guidance is split into two buckets: nonimplants and implants. Loads that do not contain an implant should be monitored using physical monitors (i.e., the print-out), 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 the verb *may*, rather than the verb *should*, indicates the use of a PCD is optional for nonimplant loads. The decision about whether to release a load is made after evaluating the available data.

Implant load release

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 with the PCD but the BI should still be incubated and the result documented. (Section 13.6.3) An example Exception Form for emergency load release documentation is provided in Annex K. This form continues to be a good tool to collect the reasons for emergency release. The collected data can be reviewed during quality improvement meetings so that mitigation measures can be identified and implemented.

Routine efficacy monitoring

The recommended frequency of monitoring steam sterilizers with a BI PCD did not change. AAMI ST79:2017 states: "A BI PCD should be used at least weekly and preferably daily."(Section 13.6.1). Also unchanged is the recommendation that each type of cycle used be routinely monitored.(Section 13.7.1) While smaller clinics and dental offices elect to monitor daily or weekly, many larger facilities have adopted the best practice of every load monitoring to: ensure all implant loads are monitored; ensure each cycle type is monitored; simplify staff training; and minimize the impact of a recall. A small change to the guidance on routine biological monitoring of sterilizers larger than 2 cubic feet is that this section now recommends the use of commercially available PCDs with the rationale statement explaining that, "Commercially available disposable PCDs (BI challenge test packs) provide standardization and reduce variability and potential for error."(Section 13.7.2.1)

Monitoring IUSS Cycles

Does your CSSD test the IUSS sterilizers located in the OR? AAMI ST79:2017 removed the separate section on routine biological monitoring of IUSS cycles. Other than dry time, for pre-vac cycles these sterilizers typically have the same sterilization pa-

MONITORING IUSS STERILIZERS

Previous editions of ST79 recommended end-user assembly of a representative BI PCD (typically a BI and a CI placed in an IUSS container) to monitor IUSS cycles. **This new edition recommends use of a commercially available BI PCD for sterilizers larger than 2 cubic feet, which includes IUSS sterilizers.**

Bottom line: Routine efficacy monitoring of dynamic-air-removal IUSS sterilizers should be done with a commercially available disposable BI PCD.

Testing a loaded chamber is recommended, however, as described in Table 1, for IUSS cycles, monitoring may be done in an empty chamber.

Routine efficacy monitoring of gravity **IUSS sterilizers** is done using a representative BI PCD assembled using the same type of tray that is routinely processed. (Section 13.7.4.1)

INTERNAL CHEMICAL INDICATORS

The guidance on the use of internal chemical indicators is slightly modified and now reads, "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 as these types of CIs provide the user with more information on the critical steam sterilization parameters." (Section 13.5.2.2.2)

This section goes on to state: "Internal CIs should be placed so that:

a. one CI is visible to the person opening the package;
b. CIs are in the area or areas considered least accessible to steam penetration; and
c. all applicable written IFU are followed."

Table 1—Sterilization process monitoring recommendations

Routine load release (see 13.5 and 13.6)		Routine sterilizer efficacy monitoring (see 13.7)	Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 13.8)	Periodic product quality assurance testing (see 13.9)
Nonimplants	**Implants**			
Physical monitoring of cycle External and internal CI monitoring of packages Optional monitoring of the load with a PCD containing one of the following: • a BI • a BI and a Type 5 integrating indicator • a Type 5 integrating indicator • a Type 6 emulating indicator	Physical monitoring of cycle External and internal CI monitoring of packages Monitoring of every load with a PCD containing a BI and a Type 5 integrating indicator	Physical monitoring of cycle External and internal CI monitoring of packages 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 IUSS cycles, monitoring may be done in an empty chamber. For dynamic-air- removal sanitizers, daily Bowie-Dick testing in an empty chamber, if applicable (see 13.7.6).	Physical monitoring of cycle External and internal CI monitoring of packages For sterilizers larger than 2 cubic feet and for IUSS 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 sanitizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack, if applicable (see 13.7.6).	Physical monitoring of cycle Placement of BIs and CIs within product test samples
Note: See Section 15 for general guidelines on how to assess the specific label claims of new products that become commercially available.				

rameters as those programmed on sterilizers located in the CSSD. For guidance on routine monitoring of IUSS cycles, readers should now refer to Section 13.7.2, *Routine monitoring of sterilizers larger than 2 cubic feet*. Qualification testing of dynamic-air-removal IUSS cycles is done by running a commercial BI PCD in an empty chamber in three consecutive cycles, followed by three consecutive Bowie-Dick tests.

Routine Bowie-Dick testing

For dynamic-air-removal sterilizers, AAMI ST79 continues to recommend that: "A Bowie-Dick (Type 2 CI) test should be performed each day the sterilizer is used, before the first processed load." (Section 13.7.6.1) As with BI PCDs, note that while facilities may assemble their own towel test packs, the standard now recommends the use of commercially available preassembled Bowie-Dick test packs. (Section 13.7.6.2)

Summary

All health care facilities that utilize steam sterilization should have a copy of this latest edition of ANSI/AAMI ST79 on hand and accessible to staff. The publication of this new edition provides a great opportunity to revisit your facility's policy and procedures to ensure they are aligned with current guidance. In particular, policies that may need refreshing include:

- with your facilities engineer, alignment of sterile processing area temperature and humidity operating parameters with the applicable ASHRAE 170 standard and a plan on who will monitor these parameters
- loaners
- frequency of testing mechanical cleaning equipment
- the use of internal chemical indicators
- the monitoring of pre-vacuum sterilizers used for IUSS HPN

References

1. The Joint Commission. High-Level Disinfection (HLD) and Sterilization BoosterPak. December 2015.

2. 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.

3. ANSI/ASHRAE/ASHE Addendum h to ANSI/ASHRAE/ASHE Standard 170-2013 *Ventilation of Health Care Facilities*. © 2016 ASHRAE.

*https://www.ashrae.org/File%20Library/.../StdsAddenda/170_2013_h_20160523.pdf*Accessed 8/14/2017

4. ANSI/AAMI/ISO 11140-1:2014, *Sterilization of health care products - Chemical indicators - Part 1: General requirements*. ©2014 Association for the Advancement of Medical Instrumentation, Arlington, VA.

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CONTINUING EDUCATION TEST • OCTOBER 2022

What's new in AAMI ST79:2017? A review

Circle the one correct answer:

1. **ANSI/AAMI ST79 is the go-to resource for steam sterilization in all healthcare facilities.**
   A. True B. False
2. **AAMI ST79:2017 recommends that staff performing sterile processing activities be certified within two years of employment.**
   A. True B. False
3. **AAMI ST79:2017 recommends that mechanical cleaning equipment be monitored weekly.**
   A. True B. False
4. **HVAC parameters for sterile processing areas should be based on the version of ASHRAE 170 that was applicable at the time the facility HVAC system was initially installed or last upgraded.**
   A. True B. False
5. **AAMI ST79:2017 recommends that one or more internal CIs (preferably Type 5 or Type 6) be placed within each package.**
   A. True B. False
6. **AAMI ST79:2017 recommends that all loads containing implants be monitored with a PCD that contains a BI and a Type 5 chemical indicator.**
   A. True B. False
7. **In documented emergency situations, the Type 5 integrator within the BI PCD may be used for early release of an implant.**
   A. True B. False
8. **Strategies to improve employee comfort in Decontam include staying hydrated and shortened work periods.**
   A. True B. False
9. **For automated washers equipped with a printer, the printer should be located on the clean side of pass-through washers.**
   A. True B. False
10. **Receiving loaner instruments late is a valid reason to perform IUSS.**
    A. True B. False

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