AAMI advice on Class 6 indicators

Recommendations for Class 6 emulating indicators, a new class of indicator for monitoring sterilization, have been issued for the first time by the Association for the Advancement of Medical Instrumentation (AAMI). These indicators, which entered the market a couple of years ago, use a different approach than biological indicators (BI).

BIs have a known number of microorganisms with known resistance to the sterilization process. BIs need to be incubated to verify that all of the microorganisms have been killed. Class 6 indicators, in contrast, use a chemical ink formulated to change when the indicator reaches the “stated value(s)” for that sterilization cycle, which is determined in a chemical indicator resistometer test sterilizer.

The “stated values” correspond to the critical variables the sterilizer manufacturer has defined for that sterilization process. For example, a Class 6 indicator can be set to have a stated value of 4 minutes at 270°F (132°C) in a prevacuum sterilizer.

AAMI’s new edition

AAMI provides guidance on use of the Class 6 emulating indicator in the 2010 Comprehensive Guide to steam sterilization and sterility assurance in healthcare facilities (ANSI/AAMI ST79:2010). This replaces the previous documents and includes information added after the A2:2009 amendments.

This is the most complete recommended practice for steam sterilization on the market and should be available to all ORs, sterile processing departments, and infection preventionists in facilities that process medical devices for patient use.

This is a summary of the AAMI recommendations for Class 6 emulating indicators. The AAMI recommendations should guide your policies and procedures for using these indicators for sterilization monitoring, load release, and sterilizer testing.

Definition of Class 6

The AAMI document defines Class 6 emulating indicators as: “chemical indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specified sterilization process.” AAMI’s chemical indicator standard, ANSI/AAMI/ISO 11140-1, refers to these as cycle verification indicators (definition 2.16, Section 2, and Section 10.5.2.1).

Internal chemical indicator monitoring

AAMI states that Class 6 emulating indicators may be used as internal chemical indicators inside each package, tray, or rigid sterilization container. Class 3 single-variable indicators, Class 4 multivariable, and Class 5 inte-
Grating indicators are also used as internal chemical indicators (Table 7 and Section 10.5.2.2.).

Importantly, AAMI says “Class 6 emulating indicators are cycle-specific; that is, they should be used only in the specific cycles for which they are labeled” (Section 10.5.2.2.1). For example, if the Class 6 CI (chemical indicator) is labeled for use in a 270°F/132°C, 4 minute dynamic-air-removal cycle, that is the only cycle that the Class 6 CI should be used to monitor.

You will need to purchase enough inventory to have all of the differently labeled Class 6 CI products you need for all of the different cycles in which they are used. In-service education is important to ensure the correct internal CI is used in the correct packages/cycles.

These internal chemical indicators should be placed in the locations that create the greatest challenge to air removal and steam penetration. The AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization (Recommendation IX) discuss where to place internal chemical indicators inside of packages. Place:

- a CI in the geometric center, not on the top of a wrapped pack or tray
- two CIs inside rigid containers: one in each of two opposite corners of the inside basket. Multilevel containers should have a CI placed in two opposite corners (eg, one in each of two corners of each level)
- a CI on each level of multilevel wrapped sets, such as those supplied by vendors, and that require wrapping.

**Monitoring nonimplant loads**

AAMI recommends that a Class 6 CI placed in a process challenge device (PCD) may be used to release loads without implants. (PCD is the new term for test packs.) A PCD containing a BI, a BI and a Class 5 CI, or a Class 5 CI may also be used for this optional monitoring (Table 6, Sections 10.5.4 and 10.6.2).

In this case, you will need to purchase enough inventory to have all of the different Class 6 CI PCD products you need for all cycles used, and you’ll need to educate employees to ensure the correct Class 6 CI PCD is used in the correct cycle.

In addition to the PCD, the results of physical monitors as well as external and internal chemical indicators should be used to release nonimplant loads. AAMI advises that the individual releasing the loads should be experienced, knowledgeable, and competent to make a decision on load release based on all the monitoring tool results. If any monitoring tool suggests that the process was not effective, the load should not be released for use.

**Monitoring implant loads**

Loads containing implants should be monitored with a PCD containing a BI and a Class 5 integrating indicator, and the load should be quarantined until the BI results are known (Table 7, Sections 10.5.4, 10.6.1, and 10.6.3).

Physical monitors and external and internal chemical indicators should also be used. And as with nonimplant loads, AAMI recommends that the individual releasing the loads be experienced, knowledgeable, and competent to make a decision on load release based on all the monitoring tool results. If any monitoring tool suggests that the process was not effective, the load should not be released for use.

Implants should only be released before the BI results are available in a defined emergency, AAMI states. When documented and defined medical exceptions dictate that an implant needs to be released before the BI result
is available (e.g., the need for trauma-related orthopedic screw-plate sets), the Class 5 CI results should be used to release the implant.

Class 6 CIs can be used to monitor implant loads, but the results cannot be used to release the implant in emergency situations before the BI results are available or as a replacement for the BI (Table 7).

Again, the Class 6 PCD needs to be used in the specific cycle for which it is labeled, and the results may provide additional information but cannot be used to release the load.

Early release of an implant based on the Class 5 CI results should be “documented and fully traceable to the patient,” AAMI states. Annex L has examples of an implant log and an exception form. These implant logs and exception forms should be part of an ongoing review to determine why you are releasing implants before the BI results are available. These forms should be part of a risk analysis and ongoing quality improvement process because implanting a nonsterile implant carries a serious risk to patient safety.

**Sterilizer testing**

A BI PCD, which also may contain a CI, should be used at least weekly but preferably every day the sterilizer is in use for routine sterilizer efficacy monitoring (Section 10.5.3.2). A BI PCD should also be used for sterilizer qualification testing after sterilizer installation, relocation, malfunctions, and major repairs and after sterilization process failures (Section 10.8). The CI could be a Class 3, 4, 5, or 6.

BIs are used because they are the only monitoring product that directly measures the “lethality of a sterilization cycle.” Class 5 CIs have a performance that is correlated to BIs and measure all of the critical parameters of the sterilization process. Class 6 CIs measure all of the critical parameters of the sterilization process. But neither of these CIs contains spores, and neither directly measures the lethality of the sterilization process. That is why AAMI does not recommend that either of these CIs replace use of BIs.

**Periodic product quality assurance testing of routinely processed item**

Product testing is discussed in Section 10.9 of the AAMI document. AAMI notes that this testing is done “before newly purchased or loaner sets are placed into routine use.” Product testing is also done “when major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper.”

For this testing, BIs and CIs are placed within product test samples. The CIs can be Class 3, 4, 5, or Class 6. Again, use only Class 6 CIs in the specific cycles for which they are labeled.

**In case of a sterilization process failure**

If the results of BI PCDs, Class 5 or Class 6 PCDs, or physical monitors indicate a sterilization process failure, AAMI recommends that the load be quarantined and the sterilizer removed from service while the cause of the failure is investigated (Section 10.7.5).

If the cause of the failure, usually a human error, is immediately identified, AAMI recommends correcting the cause of the failure and reprocessing the load. If the cause of the failure is not immediately identified, then the load should be quarantined, the sterilizer removed from service, and all items
processed since the last negative BI recalled. The recall should date back to the last negative BI, not to the last Class 5 or Class 6 CI PCDs that showed a pass. Use Figure 10 and Table 8 to identify reasons for the failure and test the sterilizer as required before it is placed into routine use.

Summary

Class 6 emulating indicators may be used as internal chemical indicators and in PCDs to release nonimplant loads. Class 6 CIs could be used in BI PCDs for routine sterilizer efficacy monitoring and sterilizer qualification testing and along with BIs inside products undergoing product testing. In all applications, the Class 6 CIs/CI PCDs must be labeled for the specific cycle you are monitoring.

Class 6 CIs and/or Class 6 CI PCDs are available from Getinge, Steris, SteriTec, and 3M. ↵

—Martha Young, MS, CSPDT
President, Martha L. Young, LLC, SAVVY Sterilization Solutions for Healthcare, Woodbury, Minnesota

Martha Young is an independent consultant with long experience in medical device sterilization and disinfection.

Resource

ANSI/AAMI ST79:2010, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, is available in print or electronic format. Order code: ST79 or ST79-PDF. Price $140 AAMI members/$240 nonmembers.

Visit www.aami.org or phone 877-249-8226. You may be able to purchase the document for the member price through AORN (www.AORN.org) or the International Association of Healthcare Central Service Materiel Management (www.IAHCSMM.org)

Free PDFs of future amendments may be downloaded by visiting www.aami.org/publications/standards/st79.html.

Key points on Class 6

• Class 6 emulating indicators may be used as internal chemical indicators and in process challenge devices (PCDs) to release nonimplant loads.

• Class 6 CIs may be used:
  —in biological indicator PCDs for routine sterilizer efficacy monitoring and sterilizer qualification
  —testing along with BIs inside products undergoing product testing.

• Class 6 indicators are cycle specific—that is, they should be used only in the specific cycle for which they are labeled.

• Class 6 emulating indicators measure all critical parameters of the sterilization process. But Class 6 indicators do not contain spores and do not directly measure the lethality of the sterilization process. AAMI does not recommend that the Class 6 indicators replace use of biological indicators.